FEB 14 2012
OFFICE OF HEALTH CARE ACCESS

Application Checklist

Instructions:

1. **Please check each box below, as appropriate; and**
2. **The completed checklist *must* be submitted as the first page of the CON application.**

☒ **Attached is the CON application filing fee in the form of a certified, cashier or business check made out to the "Treasurer State of Connecticut" in the amount of $500.**

For OHCA Use Only:

Docket No.: 12-31748-CON **Check No.:** 1482632
OHCA Verified by: SP **Date:** 2-14-12

☒ **Attached is evidence demonstrating that public notice has been published in a suitable newspaper that relates to the location of the proposal, 3 days in a row, at least 20 days prior to the submission of the CON application to OHCA. (*OHCA requests that the Applicant fax a courtesy copy to OHCA (860) 428-7053, at the time of the publication)***

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☒ **Attached are completed Financial Attachments I and II.**

☒ **Submission includes one (1) original and four (4) hard copies with each set placed in 3-ring binders.**

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☒ **The following have been submitted on a CD**

1. **A scanned copy of each submission in its entirety, including all attachments in Adobe (.pdf) format.**
2. **An electronic copy of the documents in MS Word and MS Excel as appropriate.**

YALE NEW HAVEN HEALTH

February 10, 2012

RECEIVED
FEB 14 2012
OFFICE OF
HEALTH CARE ACCESS

Ms. Kimberly Martone
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: Yale-New Haven Hospital and Greenwich Hospital - Establish and Operate an Elective Angioplasty Program at Greenwich Hospital

Dear Ms. Martone:

Yale-New Haven Hospital (YNHH) and Greenwich Hospital (GH) are pleased to submit an original and four copies of their CON to Establish and Operate an Elective Angioplasty Program.

The proposed program, which will augment primary angioplasty services offered as a satellite of Yale-New Haven Heart and Vascular Center, seeks to ensure undisrupted continuity of care for Greenwich Hospital's cardiac patients who prefer to be treated locally.

A notice to the public regarding the CON application was published in the Greenwich Time pursuant to Section 19a-638 of the Connecticut General Statues is enclosed for your information. Electronic copies of the document in Microsoft Word and Excel as appropriate are enclosed also.

Please forward any correspondence to:

Jean Ahn, System Director
Yale-New Haven Health Planning Office (2 Howe 3)
20 York Street
New Haven, CT 06519

Thank you for your consideration.

Sincerely,

Gayle Capozzalo
Executive Vice President
Yale New Haven Health System

Enclosures
cc: Frank Corvino
Marna Borgstrom
William Aseltyne, Esq.
Kyle L. Ballou, Esq.

Establish and Operate an Elective Angioplasty Program at Greenwich Hospital

Certificate of Need Application

February 14, 2012

YALE-NEW HAVEN HOSPITAL
GREENWICH HOSPITAL
Establish and Operate and Elective Angioplasty Program at Greenwich Hospital

Certificate of Need Application

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Public Notice Affidavit

The Greenwich Time

000007

Greenwich Time

MASON INC.
23 AMITY ROAD
BETHANY CT 06524

GREENWICH TIME
1455 East Putnam Avenue
Old Greenwich, CT 06870
Telephone: 203-330-6208
Fax: 203-384-1158
Legal.notices@scni.com

Public Notice

Pursuant to section 19a-638 of Connecticut General Statutes, Yale-New Haven Hospital will submit the following Certificate of Need application:

Applicant(s): Yale-New Haven Hospital
Greenwich Hospital
Address: 5 Perryridge Road
Town: Greenwich
Proposal: Establish and Operate an Elective Angioplasty Program at Greenwich Hospital
Estimated Total Project Cost/Expenditure: $0

GREENWICH TIME
CERTIFICATE OF PUBLICATION

I, Sara Hussey
Being duly sworn, depose and say that I am a Representative in the employ of SOUTHERN CONNECTICUT NEWSPAPERS, INC., Publisher of *The Advocate* and *Greenwich Time*, that a LEGAL NOTICE as stated below was published in the GREENWICH TIME.

Subscribed and sworn to before me on this 7.th Day of December, A.D. 2011.

Pamela E. Caluori
Pamela Caluori/Notary Public

My commission expires on January 2013

PO Number

Publication	Ad Number	Ad Caption	
Greenwich Time	0001710001-01	Public Notice	Pursuant to

Publication Schedule

12/1/2011, 12/2/2011, 12/3/2011

Filing Fee

000009

OFFICE OF HEALTH CARE ACCESS

REQUEST FOR NEW CERTIFICATE OF NEED

FILING FEE FORM

FEB 14 2012
OFFICE OF HEALTH CARE ACCESS

APPLICANT: Yale-New Haven Hospital and Greenwich Hospital PROJECT TITLE: Establish and Operate an Elective Angioplasty Program at Greenwich Hospital DATE: February 14, 2012	FOR OHCA USE ONLY: DATE / INITIAL 1. Check logged (Front desk) _____ _____ 2. Check rec'd (Clerical/Cert.) _____ _____ 3. Check correct (Superv.) _____ _____ 4. Check logged (Clerical/Cert).) _____ _____

NEW CERTIFICATE OF NEED APPLICATION	
TOTAL FEE DUE:	**$500.00**

ATTACH HERE CERTIFIED OR CASHIER'S CHECK ONLY (Payable to: Treasurer, State of Connecticut)

Bank of America

Cashier's Check

No. 1482632

Notice to Purchaser - In the event this check is lost, misplaced or stolen, a sworn statement and 90-day waiting period will be required prior to replacement. This check should be negotiated within 90 days.

Date DECEMBER 29, 2011

30-1/1140
NTX

Banking Center YALE NEW HAVEN HOSPITAL

0021178 00002 0001482632

ELECTIVE ANGIOPLASTY AT GH
Remitter (Purchased By)

Pay **FIVE HUNDRED DOLLARS AND 00 CENTS**

$ **500.00**

To The Order Of **TREASURER, STATE OF CONNECTICUT**
****

Margaret M Hulley
Authorized Signature

Bank of America, N.A.
San Antonio, Texas

VOID AFTER 90 DAYS

07-14-3774B 06-2005

⑈1482632⑈ ⑆114000019⑆ 00164100554 5⑈

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Enclosures
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Establish and Operate an Elective Angioplasty Program at Greenwich Hospital

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Pamela E. Caluori
Pamela Caluori/Notary Public

My commission expires on January 2013

PO Number

Publication	Ad Number	Ad Caption	
Greenwich Time	0001710001-01	Public Notice	Pursuant tc

Publication Schedule

12/1/2011, 12/2/2011, 12/3/2011

Filing Fee

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OFFICE OF HEALTH CARE ACCESS

REQUEST FOR NEW CERTIFICATE OF NEED

FILING FEE FORM

APPLICANT: Yale-New Haven Hospital and Greenwich Hospital PROJECT TITLE: Establish and Operate an Elective Angioplasty Program at Greenwich Hospital DATE: February 14, 2012	FOR OHCA USE ONLY: DATE INITIAL 1. Check logged (Front desk) _____ _____ 2. Check rec'd (Clerical/Cert.) _____ _____ 3. Check correct (Superv.) _____ _____ 4. Check logged (Clerical/Cert).) _____ _____

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Cashier's Check

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Date DECEMBER 29, 2011

30-1/1140
NTX

Banking Center YALE NEW HAVEN HOSPITAL

0021178 00002 0001482632

ELECTIVE ANGIOPLASTY AT GH

Remitter (Purchased By)

$ **500.00**

Pay **FIVE HUNDRED DOLLARS AND 00 CENTS**

To The Order Of **TREASURER, STATE OF CONNECTICUT**
****

Margaret M Hickey

Authorized Signature

07-14-3774B 06-2005

Bank of America, N.A.
San Antonio, Texas

VOID AFTER 90 DAYS

⑈1482632⑈ ⑆114000019⑆ 00164100554 5⑈

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Hospital Affidavits

Yale-New Haven Hospital
Greenwich Hospital

AFFIDAVIT

Applicant: **Yale-New Haven Hospital**

Project Title: **Establish and Operate an Elective Angioplasty Program at Greenwich Hospital**

I, **Marna P. Borgstrom, CEO**, of **Yale-New Haven Hospital** being duly sworn, depose and state that **Yale-New Haven Hospital's** information submitted in this Certificate of Need Application is accurate and correct to the best of my knowledge.

Marna P B
Signature

2/10/12
Date

Subscribed and sworn to before me on 2/10/12

Jacalyn D Gonzalez
Notary Public/Commissioner of Superior Court

My commission expires: 03/31/12

My Commission Expires 03/31/2

AFFIDAVIT

Applicant: Greenwich Hospital

Project Title: Establish and Operate an Elective Angioplasty Program at Greenwich Hospital

I, Frank A. Corvino, President and CEO of Greenwich Hospital being duly sworn, depose and state that information submitted in this Certificate of Need Application is accurate and correct to the best of my knowledge.

Signature

1-26-12
Date

Subscribed and sworn to before me on 1/26/12

Jacalyn D. Bryles

Notary Public/Commissioner of Superior Court

My commission expires: 3/31/16

My Commission Expires 03/31/2016

State of Connecticut
Office of Health Care Access
Certificate of Need Application

Instructions: Please complete all sections of the Certificate of Need ("CON") application. If any section or question is not relevant to your project, a response of "Not Applicable" may be deemed an acceptable answer. If there is more than one applicant, identify the name and all contact information for each applicant. OHCA will assign a Docket Number to the CON application once the application is received by OHCA.

Docket Number: TBD

Applicant(s): Yale-New Haven Hospital and Greenwich Hospital

Contact Person: Jean Ahn

Contact Person's Title: System Director, Planning & Business Development

Contact Person's Address: Yale-New Haven Hospital, Planning & Business Development
20 York Street (Howe 3), New Haven, CT 06504

Contact Person's Phone Number: 203-688-2609

Contact Person's Fax Number: 203-688-5013

Contact Person's Email Address: jean.ahn@ynhh.org

Project Town: Greenwich, CT

Project Name: Establish and Operate an Elective Angioplasty Program at Greenwich Hospital

Statute Reference: Section 19a-638, C.G.S.

Estimated Total Capital Expenditure: $0

1. Project Description: Establishment of Cardiac Services

Please provide a narrative detailing the proposal.

Greenwich Hospital and Yale-New Haven Hospital, both members of Yale New Haven Health System, propose to build upon the successful Primary Angioplasty program (PAMI) at Greenwich Hospital, which serves as a satellite of the Yale-New Haven Heart and Vascular Center, and which received permanent approval status from the Office of Health Care Access in July 2008 after completion of a three-year demonstration project. This proposal seeks to add elective angioplasty to the other cardiac services provided at Greenwich Hospital as part of the Yale-New Haven Heart and Vascular Center. The addition of elective angioplasty to a community hospital setting represents a national trend in cardiac services that has occurred over the past several years. Certain interventional cardiac services, including elective angioplasty, are no longer exclusively the province of academic medical centers and large teaching hospitals, but are being appropriately expanded to smaller community hospitals with comparable results. The addition of elective angioplasty to Greenwich Hospital's continuum of high quality cardiac services would be in keeping with similar expansions in numerous other states, and would permit the Hospital to more fully utilize and sustain its high quality infrastructure.

Angioplasty is an interventional procedure performed in the cardiac catheterization laboratory that is used to open blocked or narrowed coronary arteries due to coronary heart disease, thereby improving blood flow to the heart. In most cases, it is performed on an elective basis (and called elective angioplasty), although certain patients require a primary (emergency) angioplasty if they are experiencing a certain type of myocardial infarction. In most cases, a stent is placed in the patient's artery during the procedure in order to reduce the likelihood of future blockage in that artery. Elective angioplasty frequently relieves symptoms of coronary heart disease such as angina (chest pain) and shortness of breath. It is a relatively low-risk procedure that does not require general anesthesia and is one of the most common cardiac procedures.

Elective angioplasty services at Greenwich Hospital will complement cardiac services currently provided at the Hospital and will be a part of the integrated Yale-New Haven Heart & Vascular Center supported administratively and clinically by Yale-New Haven Hospital (YNHH). The clinical and operational infrastructure to provide a high quality full-service cardiac program already exists, and will be enhanced by the ability to offer elective angioplasties. Greenwich Hospital is already performing angioplasty on more acutely ill patients through its primary angioplasty program and the staff and physicians are well prepared to perform elective angioplasty for less acute patients. The proposed Greenwich Hospital program will be included in the existing satellite cardiology program of the Yale-New Haven Heart & Vascular Center, and as it does today with the primary angioplasty program, will follow the YNHH clinical safety and quality protocols, credentialing processes and operational policies and procedures. The Medical Director of the cardiac services program at Greenwich Hospital is appointed by the Yale University School of Medicine (YSM) Department of Cardiology and is a member of the YSM's interventional cardiology faculty. In addition, the privileged medical staff is associated with either YSM Department of Cardiology, members of which currently practice at Greenwich Hospital as part of the existing primary angioplasty program or are members

of the Greenwich Hospital medical staff with privileges in performing angioplasties. All associated physicians will utilize the lab in accordance with pre-established clinical protocols and quality standards.

2. **Clear Public Need**

   a. Explain why there is a clear public need for the proposal. Provide evidence that demonstrates this need.

   Approved Docket Number (DN) 08-30148-MDF demonstrated clear public need for emergency angioplasty services at Greenwich Hospital. The current proposal expands upon DN 08-30148-MDF to demonstrate that the same population, from which the Hospital's primary angioplasty patients originate, also have a clear need for access to their provider of choice for high quality elective angioplasty services.

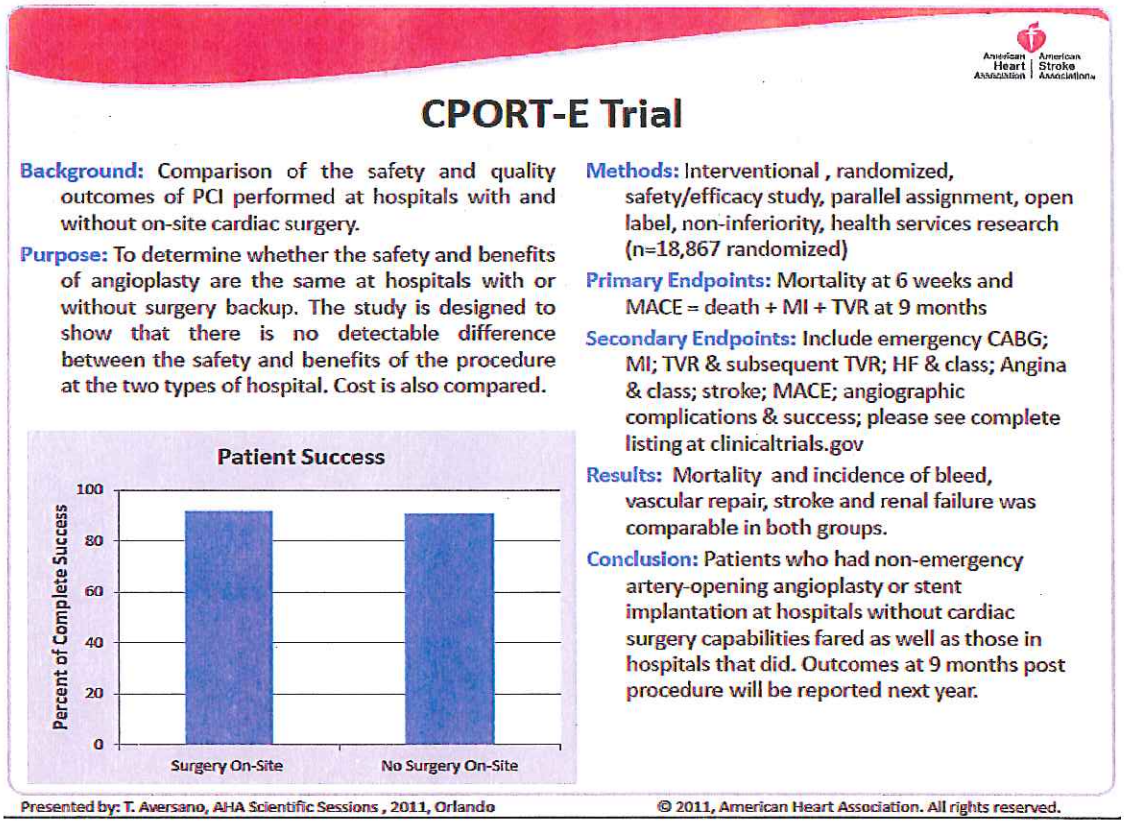
   Clear public need for the proposal is supported by the following three key factors:
   - **Local access to elective angioplasty care at Greenwich Hospital is needed and appropriate:**
   - **Greenwich Hospital must address the cost-effectiveness of angioplasty services; and**
   - **The proposed program will improve the quality of care of elective angioplasty services provided to Greenwich Hospital service area patients.**

   These factors will be described in more detail below.

   <u>Local access to elective angioplasty care at Greenwich Hospital is needed and appropriate</u> as supported by the following three key factors:
   - **Recent clinical guidelines and studies demonstrate the safety and efficacy of elective angioplasty programs without cardiac surgery back-up;**
   - **National and local trends that demonstrate improved access to elective angioplasty; and**
   - **The historical lack of access for elective angioplasty for patients who seek care at Greenwich Hospital.**

   Recent Clinical Guidelines & Studies Demonstrate the Safety and Efficacy of Elective Angioplasty without Cardiac Surgery Back-Up
   The most recent American College of Cardiology/American Heart Association/ Society for Cardiac Angiography and Intervention (ACC/AHA/SCAI) PCI guidelines released on November 7, 2011 represent a significant change in the recommendation level regarding elective angioplasty in hospitals without cardiac surgery programs. The new guidelines assign a class IIB recommendation, which means the benefit is greater than or equal to the risk, for elective angioplasty without cardiac surgery back-up.

Recent studies and publications indicate that standalone elective angioplasty can be safely performed with positive outcomes. The first major study, assessing outcomes of patients undergoing angioplasty at centers with and without surgical back-up, found comparable results at both types of facilities. Preliminary results from the CPORT-E trial led by Dr. Thomas Aversano at Johns Hopkins University were released in mid-November 2011. In this large multi-center study, nearly 14,000 patients were randomly assigned to have elective angioplasty at a hospital with onsite surgical capability, and approximately 4,500 patients were randomly assigned to have elective angioplasty at a hospital without surgical backup. The death rate after six weeks was the same for each group, and neither group of patients was more likely to need emergency cardiac surgery. A summary slide of study results presented in November 2011 at an American Heart Association conference is shown below.



An American Heart Association (AHA) news release summarizing the CPORT-E study's findings, included as Attachment I, stated that "Patients who had non-emergency artery-opening angioplasty or stent implantation at experienced hospitals without on-site heart surgery capabilities fared no worse than those in surgery-equipped hospitals" and also noted the following:

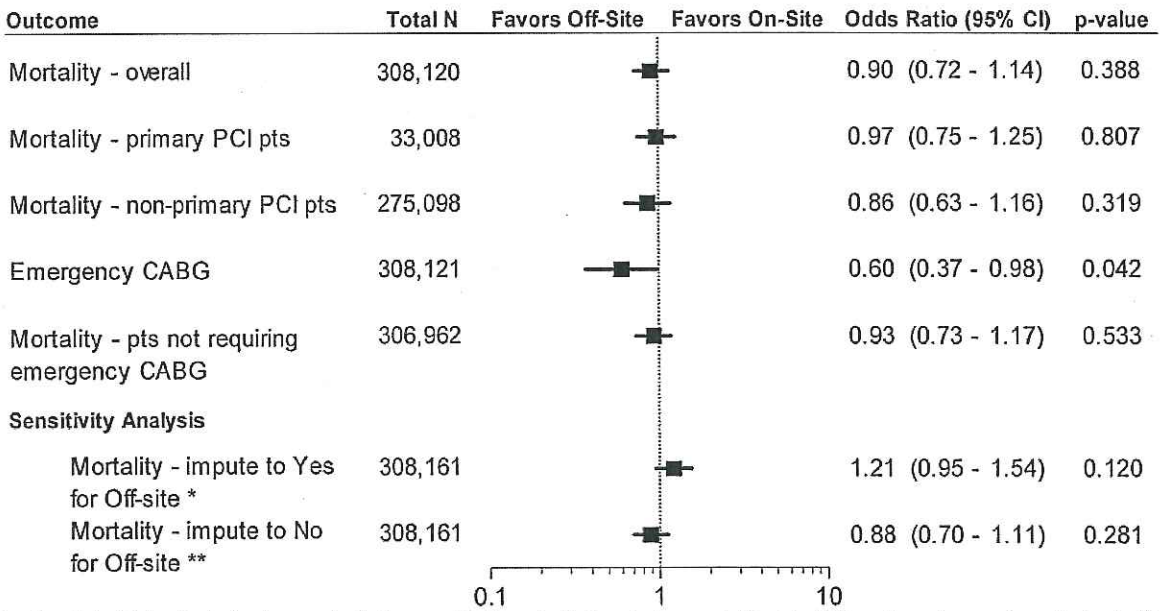
- **Patients who had non-emergency artery-opening angioplasty or stent implantation at hospitals without heart surgery capabilities fared as well as those in hospitals that did; and**
- **Both groups of patients had less than a 1 percent death rate.**

Interestingly, before results from the CPORT-E study were available, some states (such as New Jersey) that had hospitals participating in the study legislated that these hospitals that had started elective angioplasty programs on the study protocol, could continue their elective angioplasty programs even though the protocol has completed enrollment.

In a separate article, Param Puneet Singh, MD, et al (2011), published '*Outcomes of Nonemergent Percutaneous Coronary Intervention With and Without Onsite Surgical Backup: a Meta Analysis.*' The meta-analysis suggests that there is no difference in outcome with regard to risk of nonfatal myocardial infarction, need for emergency coronary artery bypass grafting, and the risk of death in patients undergoing elective angioplasty in hospitals with and without on-site cardiac surgery backup (see Attachment II).

The National Cardiovascular Data Registry (NCDR, 2009) evaluated the national experience for angioplasty without surgery onsite. The NCDR studied programs that already perform these procedures. Data from 60 hospitals and approximately 8,700 patients who had angioplasty at centers without on-site cardiac surgery ("offsite centers") were compared to 405 hospitals and approximately 300,000 patients at centers with cardiac surgery on-site ("onsite centers"). One notable finding was that after risk adjustment there were no mortality differences between off- and on-site facilities among total angioplasty patients, primary angioplasty patients, non-primary angioplasty patients, or patients who did not require emergency surgery (see chart below). In fact, there were higher risk-adjusted odds of emergency surgery in on-site angioplasty centers.

Risk-Adjusted Analysis of Outcomes



Odds ratio plot of risk-adjusted outcomes, including sensitivity analysis for missing mortality data. Odds ratio: outcomes for patients at off-site (vs. on-site) facilities, adjusting for within site correlations and potential confounding variables. *Worst case scenario: all patients with missing mortality data were considered to have died. **Best case scenario: all patients with missing mortality data were considered as alive. CABG _ coronary artery bypass graft surgery; CI = confidence interval; PCI = percutaneous coronary intervention; pts = patients.

Source: Kutcher, M, et.al, Percutaneous Coronary Interventions in Facilities Without Cardiac Surgery On Site: A Report from the National Cardiovascular Data Registry (NCDR), Journal of the American College of Cardiology, Volume 54, No. 1, June 30, 2009, pgs. 16 - 24

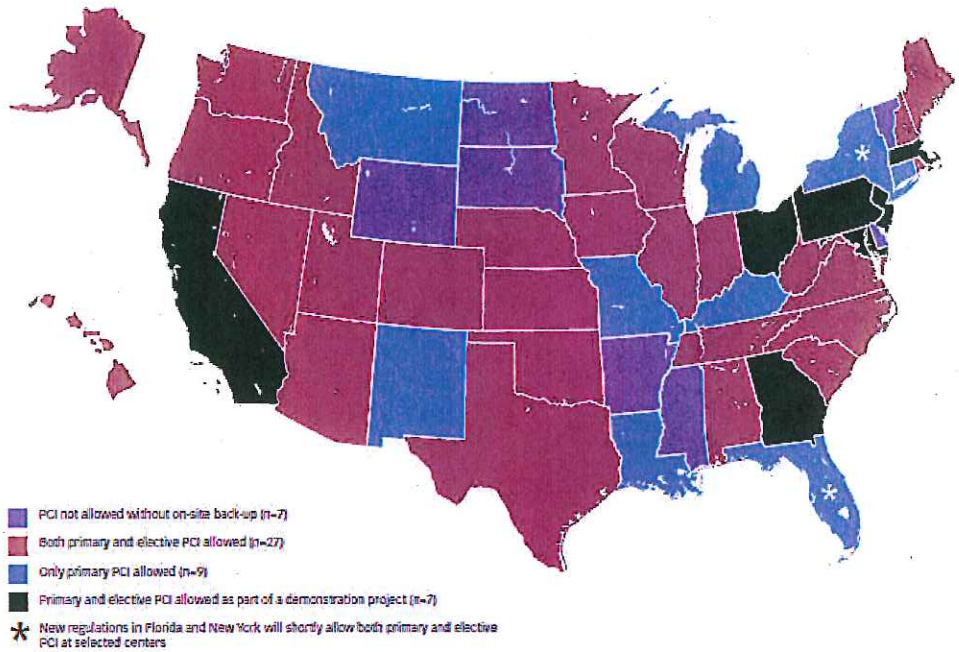
Despite lower annual angioplasty procedural volumes and more patients presenting with myocardial infarction (MI) subsets, off-site angioplasty facilities reporting to the NCDR Cath PCI Registry had similar rates of procedural success, morbidity, emergency surgery, and risk-adjusted mortality when compared with on-site angioplasty centers. Another potentially important observation is that on-site surgery did not necessarily confer an advantage for the rare patient that did require emergent surgery. In cases that required emergency surgery, off-site angioplasty centers had similar observed procedure success, morbidity, emergency cardiac surgery rates and mortality. (See Attachment III)

National and Local Trends Demonstrate Improved Access to Elective Angioplasty

In the past several years, the interventional cardiology field has experienced a significant expansion of services. Health Care Advisory Board research shows that as of 2009, 34 states allowed elective angioplasty to be performed without surgical backup, including New York, Pennsylvania, New Hampshire and Maine; seven of the 34 states allowed it as part of a demonstration project. In New York, ten hospitals have been granted approval to provide elective angioplasty without on-site cardiac surgery, including White Plains Hospital in White Plains. In January 2011, California enacted a six site "pilot" program for elective angioplasty without on-site cardiac surgery.

The map below, by the Health Care Advisory Board, shows the states that allow percutaneous coronary intervention without onsite cardiac surgical back-up as of 2009.

Figure 1: Status of Percutaneous Coronary Intervention without On-site Cardiac Surgical Back-up in the US



There are now only seven states (Arkansas, Delaware, Mississippi, North Dakota, South Dakota, Vermont, and Wyoming) where neither primary nor elective percutaneous coronary intervention (PCI) is allowed without on-site surgery. Legislation is pending in California to allow a carefully monitored demonstration project of elective PCI without on-site back-up. Primary PCI without on-site surgery is allowed in Washington, but not elective PCI. However, Washington has a liberal definition of emergency PCI such that patients with acute coronary syndromes and non-ST segment elevation myocardial infarction who have stabilized are allowed to undergo PCI at facilities without on-site surgery. Florida and New York both have rule changes pending to allow both primary and elective PCI at selected facilities without on-site surgery. Modified from Dehmer et al., 2007.[10]

Source: Dehmer, Gregory, J., Percutaneous Coronary Intervention without On-site Surgical Back-up, US Cardiology, 2009, Vol. 6 (1), pages 69-74

Since this map was published in 2009, both New York and Florida have allowed elective angioplasty without onsite surgical backup, as the footnote indicates.

Significantly, of the 34 states that allow standalone elective angioplasty, 28 require Certificate of Need regulatory approval, including New York. The majority of states permit both primary and elective angioplasty. Based on the new ACC/AHA/SCAI guidelines, the CPORT-E trial results and other recently published studies, one would expect elective angioplasty without cardiac surgery back-up to continue to expand.

An additional indication of the reduced level of risk of elective angioplasty and the routine nature of the procedure is the trend towards performing the procedure on an outpatient basis. This practice occurs throughout the country, including Connecticut. The percentage of inpatient angioplasty in Connecticut has declined each year from 98.9% in FY 2008 to 89.6% in the latest CHIME data from FY 2011.

The Historical Lack of Access for Elective Angioplasty for Patients who Seek Care at Greenwich Hospital

Since Fiscal Year 2008, 272 patients came to Greenwich Hospital and needed elective angioplasty but could not access this service. Limits placed on access to this routine cardiac procedure required these patients to be transferred to another facility, in some cases outside Connecticut. Due to existing physician referral patterns, the majority of these 246 patients were transferred to Yale-New Haven Hospital, as shown in the table below. An additional 26 patients were discharged and referred for elective angioplasty at a future time.

Number of Patients Discharged Directly from GH to Another Institution for Elective Angioplasty

Fiscal Year	Yale-New Haven Hospital	Westchester Medical Center	Cornell	Columbia	Stamford	West Haven VA	Total Transfers	Number of Patients Discharged Home and Referred for Elective Angioplasty in the Future	Total Cases
2008	44	1	0	0	0	0	45	9	54
2009	71	0	1	1	1	0	74	5	79
2010	51	0	2	0	1	0	54	10	64
2011	53	0	2	1	0	1	57	2	59
2012*	16	0	0	0	0	0	16	0	16
Totals	**235**	**1**	**5**	**2**	**2**	**1**	**246**	**26**	**272**

*Number of transfers to another institution between October 1, 2011 and December 31, 2011

Source: Greenwich Hospital Cardiology Department

Therefore, in total since FY 2008, 272 patients sought invasive cardiac care at Greenwich Hospital but could not access the necessary services in their local community. As a result of this lack of access, there are several adverse patient implications. First, the lack of access to elective angioplasty at Greenwich Hospital means that these patients received two invasive procedures instead of one since their diagnostic cardiac catheterization was performed at Greenwich Hospital and a

subsequent angioplasty was performed at a second facility. This results in increased risk for infection, delays in receiving the care required, and additional costs for a second procedure. Second, patients who were medically fragile, were subjected to transport to another facility. Third, transferring patients to another facility creates an unnecessary stressful and uncomfortable situation for patients and family. Fourth, transferring to another facility is an increased stress for the patients and their families with regard to transportation. For some, in Greenwich Hospital's greater service area, transportation outside the service area is problematic.

Greenwich Hospital Must Address the Cost-Effectiveness of Angioplasty Services
As previously described, service area residents who obtain a cardiac catheterization at Greenwich Hospital and require a subsequent angioplasty procedure must undergo two invasive procedures at two institutions. This practice increases the costs of care to patients and payers and ultimately to the health care system as a whole. Patients have to incur the additional out of pocket costs for the second procedure as well as additional transportation costs for themselves and possibly also family members. With patients receiving two procedures at two separate institutions, payers have increased expenses for the care provided to patients. Eliminating a second invasive cardiac procedure would improve the cost-effectiveness of angioplasty services for service area residents.

Primary angioplasty is a critically needed, lifesaving service that the Hospital provides to the community. Greenwich Hospital made significant investments in its primary angioplasty program in order to provide a necessary service to its service area, however, the costs of operating such a small program impede the Hospital's efforts to provide cost-effective care. An agreement is in place with the Yale School of Medicine to provide 24/7 coverage at the Hospital so that a highly skilled interventional cardiologist is always either on-site or in close proximity should a patient be in need of primary angioplasty. Greenwich Hospital is responsible for paying $1.78 million per year to the Yale School of Medicine to provide physician staffing for the primary angioplasty program. While this physician model is an essential component of the primary angioplasty program, it results in significant staffing costs to cover approximately 40 primary angioplasty cases treated at the Hospital each year. Allowing these same physicians to also perform elective angioplasty at Greenwich Hospital would be a cost-effective and efficient approach and would reduce the costs per case from the current arrangement. Since the current physician staffing covers 24/7, no additional physician expense is required to add elective angioplasty. Therefore this proposal represents a cost-effective solution to angioplasty services in Greenwich Hospital's service area.

The Proposed Program will Improve the Quality of Care of Elective Angioplasty Services Provided to Greenwich Hospital Service Area Patients
Greenwich Hospital's partnership with clinical faculty from the Yale School of Medicine and its membership in the Yale New Haven Health System will improve the quality of elective angioplasty services to Greenwich Hospital service area residents. As previously noted, service area residents who present to or desire elective angioplasty treatment at Greenwich Hospital are subjected to transfer to another Connecticut hospital and a second invasive procedure or may receive their care at a

New York hospital. The transfer process, additional procedures, and transportation out-of-state do not constitute high quality service or a positive patient experience. The term elective angioplasty is misleading as patients may have unstable, acute coronary symptoms, yet must be called elective since they do not meet the criteria for emergency angioplasty for STEMI. The proposed program will allow service area residents to remain in the local community and obtain elective angioplasty services from some of the nation's leading interventional cardiologists.

Greenwich Hospital's partnership with the clinical faculty from the Yale School of Medicine (YSM) has been a key factor in the success of its primary angioplasty program. The program is staffed by some of the nation's leading interventional cardiologists, who maintain a busy clinical practice, and many of whom perform angioplasty procedures far in excess of the minimum national standards each year. These clinicians are familiar with the Hospital's medical staff and operations. They also bring with them the procedures, clinical protocols and safety standards that are in place at Yale-New Haven Heart and Vascular Center, one of the Northeast's and nation's leading programs. In addition, the interventional cardiologists from YSM currently perform elective angioplasty procedures both at Yale-New Haven Hospital and at the West Haven VA, and are highly skilled in performing the procedure, with demonstrated outcomes that attest to their excellent quality. In fact, these same physicians are providing care to the majority of patients who currently must be transferred from Greenwich Hospital to Yale New Haven Hospital to receive elective angioplasty. Providing elective angioplasty at Greenwich Hospital will allow patients to receive the same high quality care from the same physicians without having to incur the stress of transfers and second procedures.

Greenwich Hospital has been a member of Yale New Haven Health System (YNHHS) for over twelve years. As Yale New Haven Health System has evolved, it has expanded the degree of clinical integration among its corporate members (Bridgeport Hospital, Greenwich Hospital, Yale-New Haven Hospital, and Northeast Medical Group). This clinical integration, which brings significant benefits, including consistent approaches towards clinical quality and safety practices, staffing and training, information systems, knowledge sharing and best practices, is expected to continue. Quality and outcomes will be predictable across YNHHS sites because identical care management and clinical protocols will be followed.

In addition, YNHHS is in the process of implementing the Epic common electronic medical record. This will have a major impact on YNHHS' ability to better coordinate care and services as well as easily implement and monitor best practice policies and procedures among its members, as there will be a shared medical record among all three hospitals and its clinicians. There will be a seamless flow of information within YNHHS and other providers/settings including community physicians. Providers at one site will be able to access information on a patient's visit to a different System hospital. For example, patients that are treated at both Greenwich Hospital and Yale-New Haven Hospital will share a common medical record, allowing clinicians at both sites to have 24/7 access to the most up-to-date clinical information on patients. Such integration would benefit the small number of angioplasty patients that may have to be transferred to YNHH but were also treated at Greenwich Hospital. The

implementation of Epic and the corresponding changes in System-wide processes will also facilitate the easy capture and analysis of data to support performance improvement, outcomes management, public reporting and transparency. Epic will help ensure that regulations and organizational policies and procedures regarding security, privacy and compliance are met. This will enable the Yale-New Haven Heart and Vascular Center to continue to monitor and develop all appropriate standards, protocols, policies, procedures and quality assessments which will be followed by Greenwich Hospital in providing angioplasty services to patients.

Conclusion of Public Need

Based on all of the above factors, the proposed elective angioplasty program at Greenwich Hospital, as a satellite of the Yale-New Haven Heart and Vascular Center, will be an appropriate, cost-effective, high quality program that is consistent with clinical guidelines, recent research and the approach currently being followed in many other states and at many other hospitals. Greenwich Hospital is well-prepared to embark on this project given the existing and proposed infrastructure and the program's success in treating more acutely ill patients with primary angioplasty. The program would be part of the Yale-New Haven Heart and Vascular Center, therefore it would comply with its rigorous standards and requirements, and provide patients with the ability to receive elective angioplasty locally at Greenwich Hospital, where they can benefit from high quality care and continuity, and avoid the complications and stress of transfer.

b. Provide the following regarding the proposal's location:

i. The rationale for choosing the proposed service location;

Greenwich Hospital is a progressive institution offering a wide range of medical, surgical, diagnostic and preventive programs with outstanding results. The Hospital currently provides diagnostic cardiac services including echocardiography, nuclear cardiac imaging, stress testing, cardiac CT angiography, and diagnostic cardiac catheterization. In addition, Greenwich Hospital offers interventional cardiac services to provide primary angioplasty for acute myocardial infarction (MI) patients pursuant to the Hospitals' authorization to provide primary angioplasty service under OHCA CON approval (DN 08-30148-MDF). The Hospital also has a cardiac rehabilitation program with inpatient and outpatient components for post-hospital follow-up care. A detailed list of services is below:

Ambulatory BP monitor	Arterial Doppler (PVR)
Cardiac Rehabilitation	Diagnostic Cardiac Catheterization
EKG Stress tests	Electrical Cardioversions
Peripheral angiography/intervention	Event Loop Recorder Implant
Electrophysiology Study	Holter monitor (24 and 48 hour)
Fetal Echocardiograms	Intravascular Ultrasound of Coronary/ Fractional Flow Reserve
Implantable Cardiac Defibrillator	Percutaneous Coronary Intervention in the event of an MI Alert
Nuclear Stress Tests	Permanent/Temporary Pacemakers
Pericardiocentesis	Trans-esophageal Echocardiograms (with bubbles)
Pharmacological Stress Echocardiograms (Dobutamine)	Trans-esophageal Echocardiograms (without bubbles)
Trans-thoracic Echocardiograms	Stress Echocardiograms

Greenwich Hospital is a logical location for the proposed elective angioplasty program for a multitude of reasons. The facility, physicians, staff and equipment required to provide elective angioplasty services are already in place at Greenwich Hospital. The Greenwich Hospital cardiac services program, which offers high quality diagnostic cardiac catheterization and primary angioplasty, is already a satellite under the medical direction of the Yale-New Haven Heart and Vascular Center, and employs a YSM medical director as well as YSM medical staff available 24 hours per day, 7 days per week. The Hospital is a longstanding member of Yale New Haven Health System, which will allow it to benefit from continued System-wide clinical integration, collaboration and sharing of best practices.

Patients prefer to be treated locally, close to their residence and family members. For patients in the Greenwich Hospital service area, the option to receive elective angioplasty care at their local hospital, namely Greenwich Hospital, is not available to them. Referring physicians prefer to send a patient in need of interventional cardiology to a facility that can perform both diagnostic cardiac catheterization and elective angioplasty to avoid the need for the patient to be transferred and be re-catheterized if an angioplasty is required. As a result, these patients often bypass Greenwich Hospital entirely although the Hospital is fully equipped to provide services and is an excellent local option for patients.

The lack of elective angioplasty at Greenwich Hospital results in disruptive care for patients. Under the current arrangement, Greenwich Hospital patients have to be transferred to other hospitals for elective angioplasty procedures even though experienced YSM interventional cardiologists and catheterization lab support staff are onsite and available 24 hours every day to provide the needed care at Greenwich Hospital. The vast majority of patients are transferred to Yale-New Haven Hospital, where they are treated by the same physicians from whom they would have received the same care at Greenwich Hospital if Greenwich Hospital was approved to provide elective angioplasty.

In light of these considerations, as well as the previously mentioned trends in many states to allow elective angioplasty without on-site surgery, Greenwich Hospital is an appropriate location for the proposed program.

ii. The service area towns and the basis for their selection;

The primary and secondary service area towns represent those communities which comprise 85% of Greenwich Hospital's inpatient volume. They include:

Connecticut Towns
Darien, Greenwich, New Canaan, Norwalk, Stamford, Weston, Westport and Wilton.

New York Towns
Armonk, Bedford, Bedford Hills, Harrison, Hartsdale, Katonah, Larchmont, Mamaroneck, Mount Kisco, Mount Vernon, New Rochelle, Port Chester, Pound Ridge, Purchase, Rye, Scarsdale, South Salem, West Harrison and White Plains.

The Hospital and its physicians treat many patients with heart disease who live in these service area towns and the proposed elective angioplasty program would serve to provide better access to, and coordination of, cardiac care.

iii. The population to be served, including specific evidence such as incidence, prevalence, or other demographic data that demonstrates need;

Incidence of Cardiovascular Disease
Major cardiovascular disease was the leading cause of death in Connecticut according to Department of Public Health Crude and Age-Adjusted Mortality Rate data for 2006-2008. According to the Connecticut Department of Public Health most recently published *Connecticut Resident Hospitalizations, 2009* report, diseases of the circulatory system totaled 58,853 and diseases of the heart totaled more than 40,000 discharges. There were more than 6,300 discharges for acute myocardial infarction (AMI). As shown in the Table H-5 below, diseases of the heart were the leading causes of hospitalizations for all ages combined, as well as for ages 65 and older in 2009.

Table H-5
CONNECTICUT RESIDENT HOSPITALIZATIONS, 2009
Leading Causes of Hospitalization (Numbers of Hospitalizations) by Age and Sex[a]

Sex	Rank	Age group (Years)						
		0-4	5-14	15-24	25-44	45-64	65+	All ages
Both sexes	1	Respiratory (3,053)	Mental (1,890)	Mental (4,741)	Mental (10,308)	Digestive (12,592)	Heart (27,430)	Heart (40,484)
	2	Injury/Poisoning (619)	Respiratory (1,433)	Injury/Poisoning (2,265)	Digestive (7,437)	Heart (10,902)	Respiratory (19,692)	Digestive (38,952)
	3	Endocrine[c] (503)	Digestive (1,082)	Digestive (2,244)	Injury/Poisoning (4,948)	Mental (10,649)	Digestive (15,138)	Respiratory (36,804)
	4	Digestive (459)	Injury/Poisoning (809)	Respiratory (982)	Genitourinary (3,284)	Musculoskeletal (9,630)	Injury/Poisoning (13,634)	Injury/Poisoning (30,873)
	5	Infectious (372)	Anemias/Blood (326)	Endocrine[c] (631)	Respiratory (2,964)	Respiratory (8,680)	Genitourinary (10,684)	Mental (30,160)
	6	Nervous (354)	Endocrine[c] (315)	Genitourinary (622)	Musculoskeletal (2,945)	Injury/Poisoning (8,598)	Musculoskeletal (10,660)	Musculoskeletal (23,905)
	7	Skin (290)	Nervous (311)	Anemias/Blood (586)	Endocrine[c] (2,894)	Neoplasms[b] (7,928)	Neoplasms[b] (8,371)	Genitourinary (20,495)
	8	Genitourinary (286)	Musculoskeletal (236)	Infectious (469)	Neoplasms[b] (2,483)	Genitourinary (5,401)	Infectious (8,246)	Neoplasms[b] (19,212)
	9	Anemias/Blood (208)	Genitourinary (218)	Nervous (421)	Heart (1,883)	Endocrine[c] (5,002)	Cerebrovascular (6,865)	Endocrine[c] (15,222)
	10	Neoplasms[b] (85)	Skin (211)	Musculoskeletal (391)	Infectious (1,456)	Infectious (3,566)	Endocrine[c] (5,877)	Infectious (14,312)

Source: Connecticut Department of Public Health Hospitalization Statistics:
http://www.ct.gov/dph/cwp/view.asp?a=3132&q=397512&dphNav=|46941|&dphNav_GID=1601

[a] See Appendix and Table H-1 for corresponding diagnostic groups by ICD-9 CM codes.

[b] Includes both benign and malignant neoplasms.

[c] Endocrine, nutritional, metabolic, and immunologic disorders, including diabetes mellitus and volume depletion (dehydration).

According to the Connecticut Department of Public Health Office of Health Care Access' report 'The Burden of Cardiovascular Disease in Connecticut 2010 Surveillance Report' Executive Summary (included as Attachment IV):

- **Cardiovascular diseases (CVDs) are a great public health concern. CVD account for about one-third of all Connecticut resident deaths. Coronary Heart Disease (CHD), cerebrovascular disease (stroke) and heart failure (HF) are the main types, accounting for 48%, 15% and 8% respectively of all CVD deaths.**
- **Cardiovascular disease accounted for about 33% (9,351) of all Connecticut resident deaths in 2008, as shown in the table below.**

Connecticut Resident Deaths, 2008

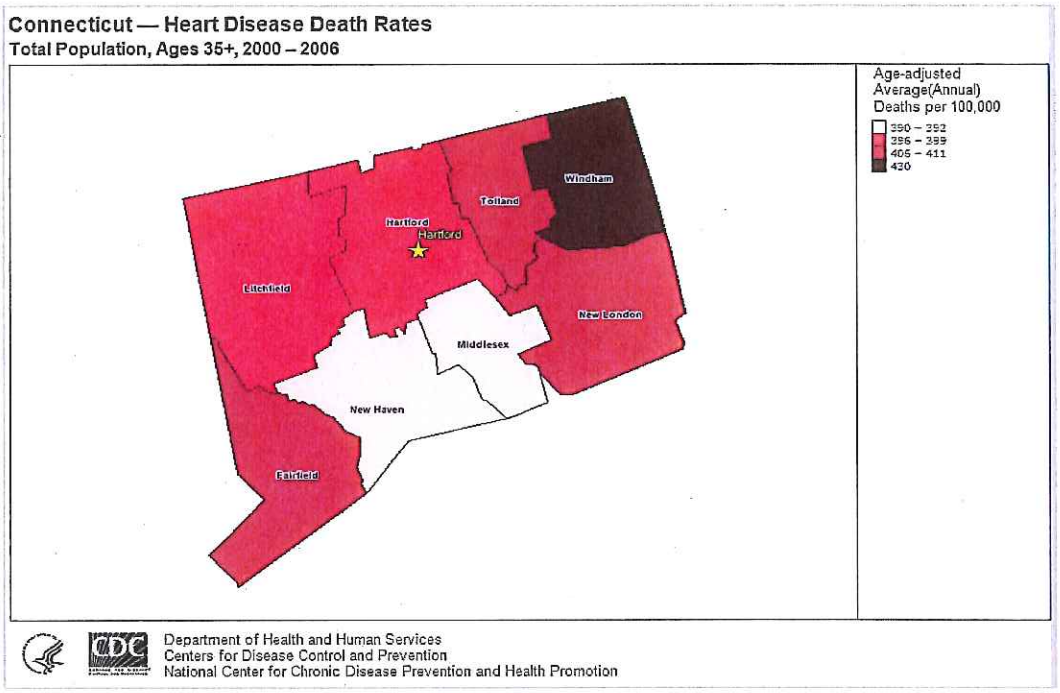
Cause of Death	Number of Deaths	Percent of Deaths
All Causes	28,749	100%
Cardiovascular Disease	9,351	33%
Cancer	6,765	24%
Chronic Liver Respiratory Disease	1,494	5%
Unintentional Injury	1,362	5%
Alzheimer's Disease	831	3%
Pneumonia and Influenza	688	2%
Diabetes	618	2%

Source: Connecticut Department of Public Health Office of Health Care Access; The Burden of Cardiovascular Disease in Connecticut 2010 Surveillance Report, March 2011

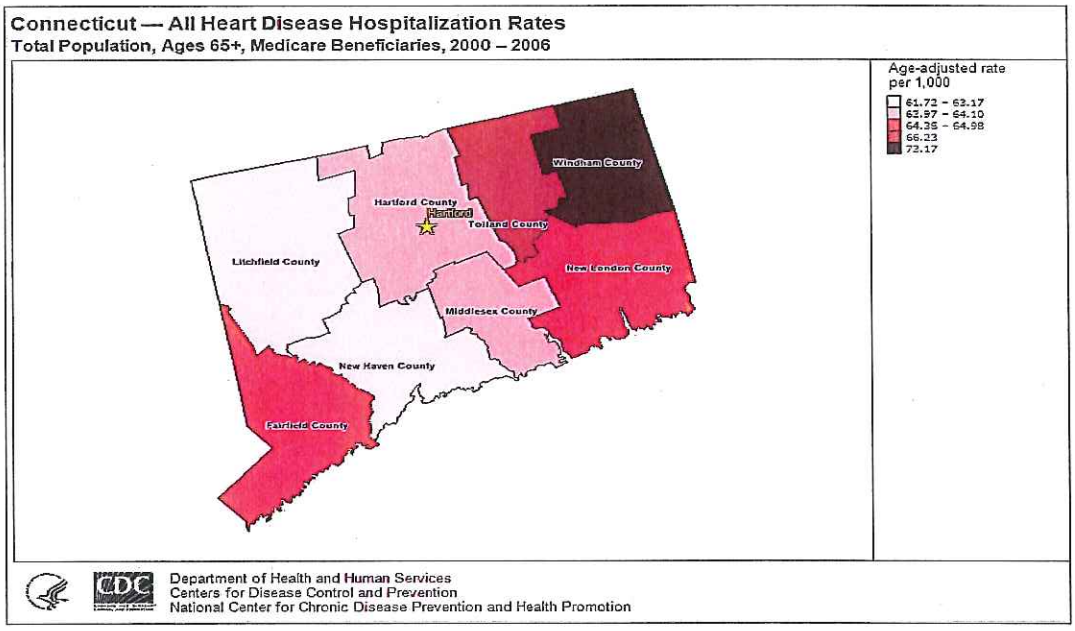
- **About $2.2 billion was billed for CVD hospitalizations in Connecticut in 2008. Approximately 34% of CVD charges are for CHD, 12% for stroke and 12% for HF. CVD also incurs enormous indirect costs.**
- **About 18% of all hospital discharges in Connecticut are due to CVD. Approximately 26% of CVD hospitalizations are due to CHD, 12% to stroke and 18% to HF (2008 data).**

The following maps show the heart disease death rate in Connecticut by county for 2000 – 2006. Fairfield County's heart disease death rate was higher than the rates in New Haven, Middlesex, Hartford and Litchfield Counties. Between 2000 and 2006, Fairfield County had the third highest 65+ heart disease hospitalization rate per 1,000 age-adjusted and spatially smoothed in Connecticut.

Heart Disease Death Rates Map



Heart Disease Hospitalization Rates Map



Service Area Demographics

The following table shows population projections for Greenwich Hospital's Connecticut and New York service area towns. The total service area will consist of over 370,000 people in Connecticut and 440,000 people in New York, of whom approximately 43% are over age 45. Because of Greenwich Hospital's location on the border of Connecticut and New York, it attracts a significant number of New York residents, who constitute a sizable proportion of the Hospital's patient population.

The proportion of Greenwich Hospital's service area patients who are over age 45 and the patients over age 65 are projected to increase between 2011 and 2016, as shown in the population table below. Both the risk and rate of heart disease increase with age, as does the corresponding need for interventional cardiology services.

Population Projections
Greenwich Hospital Service Area

Area & Age Cohort Service Area	2000	2011	2016	% Change 2000 - 2011	% Change 2011 - 2016
0-44	486,078	463,790	454,100	-4.6%	-2.1%
45-54	110,947	131,685	123,671	18.7%	-6.1%
55-64	75,351	101,043	115,399	34.1%	14.2%
65-74	56,212	60,212	72,416	7.1%	20.3%
75-84	37,209	37,304	37,086	0.3%	-0.6%
85+	14,641	18,174	19,883	24.1%	9.4%
Total	780,438	812,208	822,555	4.1%	1.3%
Ages 45+	294,360	348,418	368,455		
Ages 65+	108,062	115,690	129,385		
% 45+	37.7%	42.9%	44.8%		
% 65+	13.8%	14.2%	15.7%		

Source: Claritas

iv. How and where the proposed patient population is currently being served;

Patients from the Greenwich Hospital service area that require elective angioplasty currently go to another hospital in either Connecticut or New York to receive these services. This includes patients who receive a diagnostic cardiac catheterization at Greenwich Hospital and who subsequently require elective angioplasty as well as Greenwich Hospital primary angioplasty patients who have coronary artery disease in other vessels and require a subsequent elective angioplasty. The vast majority of these patients are transferred to Yale-New Haven Hospital and some are treated at White Plains Hospital, Columbia, Cornell and Westchester Medical Center.

Some physicians who currently utilize Greenwich Hospital services to provide care to their patients are often reluctant to direct their patients to the Greenwich Hospital cardiac catheterization lab if there is a clinical suspicion that the patient may require

angioplasty. Currently Greenwich Hospital can only address the culprit lesion for patients in need of emergency angioplasty.

As a satellite of a leading academic medical center's nationally recognized cardiac program, the Greenwich Hospital elective angioplasty program would extend the quality, safety and leading clinical advances of the Yale-New Haven Heart and Vascular Center to its patients and community. The proposed program will adhere to the same rigorous clinical, operator and institutional criteria and monitoring as the YNHH program. Consequently, the program will assure high quality outcomes, care continuity, state-of-the-art, easily accessible and high quality care.

v. All existing providers (**name, address, services provided**) of the proposed service in the towns listed above and in nearby towns;

Stamford Hospital, located at 30 Shelburne Road, Stamford CT 06904 and White Plains Hospital, located at 41 E. Post Road, White Plains, New York 10601 offer elective angioplasty in the service area.

vi. Describe existing referral patterns in the area to be served by the proposal; and

Patients are referred to Greenwich Hospital's cardiology program by their internist or cardiologist. Current referral patterns are with cardiologists within the service area and on the medical staff of Greenwich Hospital. Currently, the cardiologists (including interventional cardiologists) on the medical staff at Greenwich Hospital have practices located in Greenwich, CT (55%), Westchester County, NY (13%) and Stamford, CT (11%). The YSM physicians practicing at the Greenwich Hospital location are included in the Greenwich, CT statistics above.

vii. The effect of the proposal on existing providers, explaining how current referral patterns will be affected by the proposal.

The vast majority of patients who must be transferred from Greenwich Hospital to another hospital for elective angioplasty are sent to Yale-New Haven Hospital. Therefore, a significant proportion of the Greenwich Hospital proposed program volume will represent cases that would previously have been transferred to Yale-New Haven Hospital. This reduction in volume at Yale-New Haven Hospital has been agreed to by clinical and administrative leadership and will not negatively impact Yale-New Haven Hospital's cardiac services.

Recent discussions with the Hospital's current physician referral sources indicate that they support the provision of elective angioplasty at Greenwich Hospital, as it will allow their patients to receive their interventional cardiac care at Greenwich Hospital. Letters of support from members of the Greenwich Hospital medical staff attest to physicians' endorsement of the proposed program and are included in Attachment V.

c. Explain why the proposal will not result in an unnecessary duplication of existing or approved health care services.

The proposal will not result in unnecessary duplication of existing or approved health care services. The facility, physicians, staff and equipment required to provide elective angioplasty services are already in place at Greenwich Hospital for the primary angioplasty service.

d. The record in this docket will include, in addition to other materials, the American College of Cardiology/American Heart Association (ACC/AHA) practice guidelines. The Applicants may submit any comments in response to this evidence, which they deem appropriate.

Please see Attachment VI. Knowledge and processes related to elective angioplasty continue to evolve. As previously noted, increasing and significant evidence exists for elective angioplasty programs at facilities without on-site surgical backup. The November 7, 2011 updated ACC/AHA/SCAI angioplasty guidelines have upgraded the recommendation level for elective angioplasty programs without cardiac surgery back-up. Greenwich Hospital and Yale-New Haven Hospital adhere to these guidelines, which are incorporated into relevant policies and procedures.

e. If applicable to the proposal (e.g. establishment of cath lab without a cardiac surgical program), provide a copy of a signed agreement between the Applicant and a tertiary care facility. Identify patient selection guidelines, the process and protocols involved in the transfer of a patient requiring cardiac surgery, and joint quality assurance reviews and joint training.

A copy of the signed agreement between Greenwich Hospital and YNHH can be found in Attachment VII. The agreement addresses patient selection, emergency transfer, joint quality assurance and training.

f. Has the Applicant held any discussions with the local emergency medical service ("EMS") regarding the proposed service? Describe.

Greenwich Hospital had discussions with the Greenwich Emergency Services (GEMS) and the Emergency Medical Services companies servicing Port Chester, Rye and Harrison, New York about the proposed program, and received favorable responses from all parties.

3. Projected Volume

a. In table format, provide historical volumes (three full years and the current year-to-date) for each Applicant by service; by zip code; by inpatient/outpatient; and by unique physician identifier as applicable to the proposal.

<u>Volume by Service and Inpatient/Outpatient</u>
Historical volume for Greenwich Hospital primary angioplasties is shown in the table below.

Total Greenwich Hospital Primary Angioplasty Cases

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012*
Total Angioplasty	40	40	32	38	15
Note: All angioplasties are inpatient					

*Note: Actual Q1 volume (October – December); annualized volume would equal 60
Sources: CHIME and Greenwich Hospital Department of Cardiology

Volume by ZIP Code

Historical volume for Greenwich Hospital primary angioplasties is shown in Attachment VIII

Volume by Unique Physician Identifier

Historical volume for Greenwich Hospital primary angioplasties broken out by unique physician identifier is shown in the table below.

Total Greenwich Hospital Primary Angioplasty Cases by Unique Physician Identifier

	Angioplasty by Unique Physician Identifier				
MD	**FY 2008**	**FY 2009**	**FY 2010**	**FY 2011**	**FY 2012***
A	1	0	0	0	0
B	1	1	1	0	0
C	1	0	0	0	1
D	2	3	0	0	0
E	0	1	1	1	0
F	2	0	0	0	0
G	14	17	15	18	7
H	0	2	1	0	0
I	2	0	3	4	0
J	17	16	11	12	7
K	0	0	0	3	0
Total	**40**	**40**	**32**	**38**	**15**

*Note: Actual Q1 volume (October – December); annualized volume would equal 60
Sources: CHIME and Greenwich Hospital Department of Cardiology

b. If applicable, for the most recently completed fiscal year, identify the number of:

i. Patients with a diagnosis of ST-segment elevation acute myocardial infarction (AMI) that presented at the Hospital's emergency room

In FY 2011, there were 57 patients that presented to Greenwich Hospital's emergency department who triggered an MI Alert with a suspected diagnosis of ST-segment elevation acute myocardial infarction.

ii. Doses of thrombolytic medication, issued through its pharmacy, to patients with a diagnosis of AMI.

In FY 2011, there were zero doses of thrombolytic medication issued through the pharmacy to patients with diagnosis of AMI. In acute MI, thrombolytics are typically only used if emergency angioplasty cannot be done in a timely manner. Greenwich Hospital did not use thrombolytics for acute MI during the past year because the Hospital brought these patients to the cardiac catheterization lab in a timely fashion, which is the clinically preferred treatment for patients.

c. In table format, provide projected volumes (three full years) for each Applicant by service; by inpatient/outpatient; and by unique physician identifier as applicable to the proposal.

The tables below provides historical and three full years of projected volumes by inpatient/outpatient.

Due to the unscheduled nature of primary angioplasty cases and the scheduling rotation for the interventional cardiologists, it is difficult to project future volumes by unique physician identifier.

CON Elective Angioplasty Volume Projections

Angioplasty Volumes at Greenwich Hospital
Historical and Projected Volumes

Volumes	FY08 Actual	FY09 Actual	FY10 Actual	FY11 Actual	Year 1	Year 2	Year 3
Primary Angioplasty Cases	40	40	32	38	38	38	38
Elective Angioplasty Cases To Be Performed at GH (currently sent to other facilities)	0	0	0	0	53	53	53
Elective Angioplasty Cases Transferred or Referred to Another Facility	54	79	64	59	0	0	0
New Referred Angioplasty Cases from Physicians	NA	NA	NA	NA	105	126	151
Total	94	119	96	97	196	217	242
Variance					99	21	25

Source: CHIME database, GH Cardiology Department, YNHH statistics, telephone survey of physicians

Volumes	Year 1	Year 2	Year 3
Inpatient Angioplasties (89.6%)	176	194	217
Outpatient Angioplasties (10.4%)	20	23	25
Total	196	217	242

Source: CHIME database

d. Provide a detailed description of all assumptions used in the derivation/calculation of the projected volumes.

The angioplasty projections include primary angioplasty cases currently treated at the Hospital and elective angioplasty cases currently not treated at the Hospital.

Greenwich Hospital currently provides primary angioplasty to patients that meet the criteria for care. For the past several fiscal years, this volume has remained fairly stable. In FY11, the Hospital had 38 primary angioplasty cases. This is the same number as the four year average number of cases. This volume was projected to remain stable over the next several years. In the first quarter of FY12, the Hospital provided 15 primary angioplasties which would project to 60 annual primary angioplasties. To be conservative, projections were based on the last several fiscal years where 12 months of data was available for each year.

While the Hospital does not provide elective angioplasty at this time, there are patients who present to the Hospital each year that require elective angioplasty. These patients are either transferred or referred to another facility for care. The number of transfers or referrals for the past four fiscal years has been 54, 79, 64 and 59 respectively. Over the past four fiscal years, on average there had been 64 patients per year either transferred or referred to another facility for care. With the approval of this application, Greenwich Hospital would be able to provide elective angioplasty to the majority of these patients and thus save the patients an unnecessary transfer or referral to another facility. These patients are already part of the Greenwich Hospital physician referral patterns established at the Hospital that would continue when the Hospital is approved to provide elective angioplasty care. However, there is a small portion of patients that would need to be transferred or referred to another facility even if Greenwich Hospital was approved to provide elective angioplasty.

In the CPORT E trial, (discussed elsewhere in the CON) of patients who underwent primary angioplasty, 12% were excluded from randomization after consenting to the study, representing the subgroup who would be transferred to another facility. In reviewing the cases in FY09-11 that were either transferred or referred for care to another facility, it was felt that some of the cases would have been transferred or referred even if Greenwich Hospital was approved to provide elective angioplasty. These percentages for FY09-11 were respectively 12%, 16% and 22% for a three year average of 16.6%. For the projection of elective angioplasty at Greenwich Hospital, the conservative estimate of 16.6% was used, i.e. 83.4% of patients who had been transferred or referred to another facility in the past would be able to receive care at Greenwich Hospital. This percentage applied to the average of 64 patients per year transferred or referred to another facility yielded 53 patients in Year 1 who would be able to stay and receive their care at Greenwich Hospital. Again, to be conservative, this volume was projected to remain stable over the next several years.

Because Greenwich Hospital does not currently provide elective angioplasty services, physicians are reluctant to send their patients for cardiac catheterizations to the Hospital in case the patient will require an elective angioplasty and then have to be

transferred or referred to another facility. The Hospital conducted a telephone survey of cardiologists currently on the Hospital's medical staff. The cardiologists were asked to estimate the number of additional patients they might send to Greenwich Hospital for cardiac catheterizations if the Hospital received approval to offer elective angioplasty. In addition, some internal medicine physicians send patients directly for cardiac catheterizations to a hospital instead of to a cardiologist. The Hospital conducted a survey of the large internal medicine practices on the medical staff. These physicians were also asked to estimate the number of additional patients they might send to Greenwich Hospital.

Lastly, the cardiology practice that is part of the YNHHS cardiology program at Greenwich Hospital estimated the number of patients each year that they send directly to Yale-New Haven for cardiac catheterizations instead of to Greenwich Hospital. These patients numbered 25, 22, 21 and 25 in FY08-11 respectively for an average of 24 per year. These patients would use Greenwich Hospital if the Hospital provided elective angioplasty services. Based on the information above, 257 additional cardiac catheterizations were estimated to be sent to Greenwich Hospital for care if the Hospital provided elective angioplasty services. The surveyed physicians who indicated they would send additional cardiac catheterizations have practices located in Greenwich, Connecticut or in Westchester County, New York.

In order to estimate the number of angioplasties resulting from the additional cardiac catheterizations, the ratio of angioplasties to cardiac catheterizations was analyzed. Since primary angioplasties and elective angioplasties have the same codes, it was not possible to separate them into two categories so angioplasty volume includes both primary and elective angioplasty cases. Angioplasty volume and cardiac catheterization volume includes both inpatient and outpatient cases. New York angioplasty and cardiac catheterization outpatient historical volumes were not available from the state of New York for CY08 and for CY11 only the first five months of inpatient and outpatient data was available. Therefore, CY11 New York data was flat line projected to estimate the entire year.

The ratios of angioplasties to cardiac catheterizations were determined for Greenwich Hospital (35.4%), Yale-New Haven Hospital (45.3%), the state of Connecticut (36.3%) and the Greenwich Hospital service area (41.2%). The Greenwich Hospital average included patients transferred or referred to another facility. While the program at Greenwich Hospital will follow all of the policies, procedures and guidelines of the Yale-New Haven Heart and Vascular Center, the New Haven facility is a tertiary hospital and may see a higher rate of angioplasty/sicker patients. To be conservative, an average ratio (41.0%) of the Yale-New Haven Hospital ratio and state of Connecticut ratio was used to estimate the number of angioplasties resulting from the cardiac catheterizations. The 41.0% ratio was applied to the 256 potential angioplasties to yield an estimated 105 new referred angioplasty cases to Greenwich Hospital in Year 1 from cardiologists on the Hospital medical staff who would previously have sent the cases either to Yale-New Haven Hospital or a New York hospital. It is expected that this volume would increase 21 and 25 angioplasties respectively in Years 2 and 3 as the Greenwich Hospital program becomes established. The increases would represent less than 1 angioplasty per year from each of the

cardiologists on the medical staff of Greenwich Hospital. Since the patients will be referred by the cardiologists on the Greenwich Hospital medical staff, it is expected that the majority of patients will be from New York or Greenwich, Connecticut. The increase in volume results from several factors including the addition of New York interventional cardiologists who currently do not practice at Greenwich Hospital but have referral relationships with the cardiologists on the Hospital medical staff, increased physician comfort with elective angioplasty care at the Hospital and patient preference for the high quality care offered at Greenwich Hospital.

In FY11, inpatient angioplasties were 89.6% of total angioplasties according to the latest available data from the CHIME database. This percentage was used to estimate the distribution of angioplasties at Greenwich Hospital in Years 1, 2 and 3.

e. Provide a copy of any articles, studies, or reports that support the statements made in this application justifying need for the proposal, along with a brief explanation regarding the relevance of the selected articles.

In addition to previous studies and reports referenced, Attachment IX contains some additional supporting materials. Key points from each document are summarized below.

Document/Article	Key Points
Atlantic Cardiovascular Patient Outcomes Research Trial presentation	**"In hospitals without on-site cardiac surgery that complete a formal PCI development program, adhere to C-PORT participation requirements, and whose outcomes are monitored, non-primary PCI is safe and associated with similar rates of adverse events including mortality"**
American Heart Association /American Stroke Association CPORT-E Trial Summary	**Summarizes results of CPORT-E Trial: "Patients who had non-emergency artery-opening angioplasty or stent implantation at hospitals without cardiac surgery capabilities fared as well as those in hospitals that did."**
2011 ACC/AHA/SCAI Guideline for Percutaneous Coronary Intervention	**Provides additional explanation and documentation of the 2011 guidelines and shows classification of recommendations and levels of evidence.**
The Advisory Board Daily Briefing On-site Surgery Not Necessary to Perform Elective PCI, November 18, 2010	**Summary of Atlantic CPORT-E Trial. Conclusion "The findings ultimately may prompt regulatory changes that could effectively decouple PCI and open heart surgery, allowing more flexibility for hospitals pursuing a regionalization strategy."**

f. Please identify the number of physicians that will be providing coverage for the proposed program. Explain whether the physicians will be full time with the proposed program or also providing coverage at other hospitals.

Physician coverage for the proposed elective angioplasty program will be similar to the existing 24/7 coverage for the primary angioplasty program. Coverage will be provided by privileged medical staff associated with either YSM Department of Cardiology, members of which currently practice at Greenwich Hospital as part of the existing primary angioplasty program, or members of the Greenwich Hospital medical staff with privileges in performing angioplasties. At this time, coverage will be provided by eleven interventional cardiologists from the Yale School of Medicine. At least one physician will be full time at Greenwich Hospital weekdays and on call nights and weekends. The on call physician will be in close proximity to Greenwich Hospital for immediate response to the Hospital during nights and weekends. When on call, the physician will only be covering Greenwich Hospital. The members of the YSM Section of Interventional Cardiology also provide coverage at Yale-New Haven Hospital, the West Haven VA and Lawrence & Memorial Hospital's primary angioplasty program.

4. Quality Measures

a. Submit a list of all key professional, administrative, clinical, and direct service personnel related to the proposal. Attach a copy of their Curriculum Vitae.

Please see Attachment X for copies of Curriculum Vitae.

<u>Greenwich Hospital</u>

- **Frank Corvino, President and CEO**
- **Eugene Colucci, CFO**
- **Quinton Friesen, Executive Vice President and COO**
- **Marc Kosak, Vice President, Administration**
- **Christopher Howes, M.D., Medical Director of PAMI Program and Interventional Cardiology at Greenwich Hospital, Assistant Professor of Medicine, Yale School of Medicine**

<u>Yale-New Haven Hospital</u>

- **Marna P. Borgstrom, Chief Executive Officer**
- **Richard D'Aquila, President and Chief Operating Officer**
- **James Staten, Senior Vice President, Finance and CFO**
- **Thomas Leary, Vice President, Physician Development**
- **Michael Simons, M.D., Chief, Section of Cardiovascular Medicine**
- **Henry Cabin, M.D., Associate Section Chief of Cardiology**
- **Francine LoRusso, RN, Director, Patient Services, Heart and Vascular Center**

b. Explain how the proposal contributes to the quality of health care delivery in the region.

The current population served through Greenwich Hospital's primary angioplasty program is limited to patients that present on an emergent basis with ST segment

elevation MI or new onset left bundle branch block. This proposal would provide local access to patients requiring interventional cardiology services on an elective and urgent basis as well as the emergent patients who currently have access to these services. Patients from the Greenwich Hospital service area that require elective angioplasty are currently required to go to another hospital to receive these services, which adds additional stress for patients and their families, particularly unnecessary due to the presence of highly qualified interventional cardiologists and staff available onsite. The facility, physicians, staff and equipment required to provide elective angioplasty services are already in place at Greenwich Hospital. As discussed in the public needs section, the current practice of transferring patients who require elective angioplasty has potential negative implications to patient care quality and safety. As well, the majority of these patients are transferred to Yale-New Haven Hospital, where they are treated by the same physicians from whom they would have received the same care at Greenwich Hospital if Greenwich Hospital was approved to provide elective angioplasty.

Greater System-wide clinical integration, through the proposed closer integration of Greenwich Hospital's cardiac services with the Yale-New Haven Heart & Vascular Center and partnership with the Yale School of Medicine will have a positive impact on the quality of health care delivery in the region. The Yale-New Haven Heart & Vascular Center will provide medical and clinical direction, education, training and management and oversight to ensure the delivery of the highest quality care. In addition, the use of the Epic common electronic medical record and combining best practices at both campuses to enhance clinical quality and patient safety through standardized procedures and practices.

<u>Greenwich Hospital's High Quality Cardiac Program</u>
The most recent ACC/AHA/SCAI guidelines have and will continue to guide Greenwich Hospital in the operation of its angioplasty program. A copy of the guidelines is attached (Attachment VI).

Greenwich Hospital participates in the National Cardiovascular Data Registry NCDR – CathPCI Registry®. Launched by the American College of Cardiology (ACC) in 1995, the "ACC National Cardiovascular Data Registry: (ACC-NCDR™) is a result of the ACC's exploration of various strategies for collecting and implementing clinical data in order to improve cardiovascular care. This database includes the implanted cardiac defibrillator registry as well as a heart catheterization registry (which further breaks down to both diagnostic and interventional procedures). The information gathered from this database allows the ACC to set benchmarks that enable facilities to see where they are deficient and therefore improve upon performance. There are currently 1,380 sites that participate in the catheterization registry.

In addition, both the primary angioplasty program, which has been in place at Greenwich Hospital since 2005, and the diagnostic cardiac catheterization laboratory, have achieved outcomes that are consistent with many larger tertiary facilities. For the four quarters ending mid-2011, 100% of STEMI patients received immediate angioplasty within 90 minutes, which meets/exceeds national standards for this measure. Other strong clinical outcomes of the Greenwich Hospital primary

angioplasty program, for the four quarters ending mid-2011, are shown in the following table.

National Cardiovascular Data Registry Institutional Outcomes
Executive Summary
Greenwich Hospital
Rolling Four Quarters Ending 2011 Q2

Section II: Quality Metrics			
Metric	Greenwich Hospital	All Hospitals 50th Percentile	All Hospitals 90th Percentile
PCI Process Metrics			
Median time to immediate PCI for STEMI patients (in minutes)	67.0	63.1	50.4
Proportion of STEMI patients receiving immediate PCI within 90"	100%	91.4%	100%
Proportion of patients with aspirin prescribed at discharge	100%	98.2%	99.9%
Proportion of patients with thienopyridine prescribed at discharge	100%	99.1%	100%
Statins prescribed at discharge	100%	91.5%	97.3%
Utilization Metrics			
Median post-procedure length of stay (in days) for PCI patients with STEMI	2.0	2.7	1.7

Source: National Cardiovascular Data Registry® – CathPCI Registry® - Executive Summary – Greenwich Hospital Compared to Rolling Four Quarters for All Hospitals Ending 2011Q2. Aggregation Date: September 30, 2011 Published Date: October 19, 2011

The ACC-NCDR database has limitations on the comparative use of its angioplasty data. However, at this time the ACC-NCDR data is the only benchmarking data set available to hospitals. The ACC-NCDR reports provide comparative benchmarking for all participating programs, and do not separately benchmark programs that provide only primary angioplasty such as Greenwich Hospital. As a result, the report shows an "apples to oranges" comparison of data. Greenwich Hospital's performance is benchmarked against programs that have significantly higher volumes that include elective angioplasty cases. As well, primary angioplasty cases tend to be more medically unstable in comparison to elective angioplasty cases. Greenwich Hospital contacted NCDR but the organization was not able to provide the Hospital with data listed separately for primary versus elective angioplasty. Greenwich Hospital's most recent complete ACC-NCDR report is included as Attachment XI. A letter from Greenwich Hospital to the Office of Health Care Access dated March 9, 2011 that discusses the limitations of comparing Greenwich Hospital's primary angioplasty outcomes with larger programs that offer elective angioplasty, is included as Attachment XII.

Even given the limitations of the angioplasty data, it is clear that Greenwich Hospital is providing essential cardiac care to patients with strong results. An elective angioplasty program is a logical and cost-efficient extension of the existing diagnostic cardiac catheterization and primary angioplasty program infrastructure, and would be

performed by many of the same expert physicians and staff, and in the same dedicated laboratories, as the existing programs.

c. Identify the Standard of Practice Guidelines that will be utilized in relation to the proposal. Attach copies of relevant sections and briefly describe how the Applicant proposes to meet each of the guidelines.

American College of Cardiology - Please see Attachment VI for the 2011 ACC/AHA/SCAI Guidelines and the 2007 SCAI Expert Consensus Document.

Quality and safety standards for the elective angioplasty program are paramount. As with the primary angioplasty program, the Hospital will continue to be part of the Yale-New Haven Heart and Vascular Center and will continue to draw on the collective clinical resources and experience of the Center and comply with all standards, protocols, policies, procedures and quality assessments. Yale-New Haven Heart and Vascular Center staff will continue to provide clinical oversight, educational training and quality review services to ensure high quality outcomes. The medical direction for the program will continue to be provided by the appointed YSM interventional cardiologist. All of this ensures one standard of care across the Yale New Haven Health System and the highest possible angioplasty care provided at Greenwich Hospital. The clinical experience gained from the additional volume of the elective angioplasty program will serve to further improve the clinical competency of the program staff.

Greenwich Hospital will meet the guidelines through clinical policies and procedures, medical staff credentialing and quality assurance processes. In addition, it is important to note that the interventional cardiology clinical faculty from the Yale School of Medicine, who will perform the majority of elective angioplasty procedures at Greenwich Hospital, are highly skilled with considerable experience in this procedure. At the various sites where these physicians practice (including Yale-New Haven Hospital, Greenwich Hospital, the West Haven VA and Lawrence & Memorial Hospital), they performed more than the guideline recommended procedures in Fiscal Year 2011.

5. Organizational and Financial Information

a. Identify the Applicant's ownership type(s) (e.g. Corporation, PC, LLC, etc.).

The ownership type is Corporation.

b. Does the Applicant have non-profit status?

☒ Yes (Provide documentation) ☐ No

Please see Attachment XIII for documentation of non-profit status.

c. Provide a copy of the State of Connecticut, Department of Public Health license(s) currently

held by the Applicant and indicate any additional licensure categories being sought in relation to the proposal.

Please see Attachment XIV for copies of licenses.

d. Financial Statements

i. If the Applicant is a Connecticut hospital: Pursuant to Section 19a-644, C.G.S., each hospital licensed by the Department of Public Health is required to file with OHCA copies of the hospital's audited financial statements. If the hospital has filed its most recently completed fiscal year audited financial statements, the hospital may reference that filing for this proposal.

Copies of both YNHH's and GH's audited financial statements for FY 2010 are currently on file with OHCA.

ii. If the Applicant is not a Connecticut hospital (other health care facilities): Audited financial statements for the most recently completed fiscal year. If audited financial statements do not exist, in lieu of audited financial statements, provide other financial documentation (e.g. unaudited balance sheet, statement of operations, tax return, or other set of books.)
Not applicable.

e. Submit a final version of all capital expenditures/costs as follows:

Table 2: Proposed Capital Expenditures/Costs

Medical Equipment Purchase	**$ 0**
Imaging Equipment Purchase	
Non-Medical Equipment Purchase	
Land/Building Purchase *	
Construction/Renovation **	
Other Non-Construction (Specify)	
Total Capital Expenditure (TCE)	**$ 0**
Medical Equipment Lease (Fair Market Value) ***	
Imaging Equipment Lease (Fair Market Value) ***	
Non-Medical Equipment Lease (Fair Market Value) ***	
Fair Market Value of Space ***	
Total Capital Cost (TCC)	**$ 0**
Total Project Cost (TCE + TCC)	**$ 0**
Capitalized Financing Costs (Informational Purpose Only)	
Total Capital Expenditure with Cap. Fin. Costs	**$ 0**

* If the proposal involves a land/building purchase, attach a real estate property appraisal including the amount; the useful life of the building; and a schedule of depreciation.
** If the proposal involves construction/renovations, attach a description of the proposed building work, including the gross square feet; existing and proposed floor plans; commencement date for the construction/
*** If the proposal involves a capital or operating equipment lease and/or purchase, attach a vendor quote or invoice; schedule of depreciation; useful life of the equipment; and anticipated residual value at the end of the lease or loan term.

Not applicable. There are no capital costs associated with the proposal.

f. List all funding or financing sources for the proposal and the dollar amount of each. Provide applicable details such as interest rate; term; monthly payment; pledges and funds received to date; letter of interest or approval from a lending institution.

Not applicable. The proposal does not include any incremental capital costs; therefore, no funding or financing is required.

g. Demonstrate how this proposal will affect the financial strength of the state's health care system.

This proposal will result in lower costs resulting from a decrease in patient transfers and a second procedure for some patients. Through the fuller use of its existing angioplasty infrastructure at Greenwich Hospital, including physicians and staff, more efficient care and enhanced patient quality and safety will result. The facility, physicians, staff and equipment required to provide elective angioplasty services are already in place at Greenwich Hospital.

6. Patient Population Mix: Current and Projected

a. Provide the current and projected patient population mix (based on the number of patients, not based on revenue) with the CON proposal for the proposed program.

Table 3: Patient Population Mix

	Current** FY ***	Year 1 FY ***	Year 2 FY ***	Year 3 FY ***
Medicare*	40.5%	40.5%	40.5%	40.5%
Medicaid*	5.4%	5.4%	5.4%	5.4%
CHAMPUS & TriCare				
Total Government	**45.9%**	**45.9%**	**45.9%**	**45.9%**
Commercial Insurers*	48.7%	48.7%	48.7%	48.7%
Uninsured	5.4%	5.4%	5.4%	5.4%
Workers Compensation				
Total Non-Government	**54.1%**	**54.1%**	**54.1%**	**54.1%**
Total Payer Mix	**100.0%**	**100.0%**	**100.0%**	**100.0%**

* Includes managed care activity.
** New programs may leave the "current" column blank.
*** Fill in years. Ensure the period covered by this table corresponds to the period covered in the projections provided.

b. Provide the basis for/assumptions used to project the patient population mix.

The current population mix for the current cases performed at the hospital was utilized in the projections.

7. Financial Attachments I & II

a. Provide a summary of revenue, expense, and volume statistics, without the CON project, incremental to the CON project, and with the CON project. **Complete Financial Attachment I.** (Note that the actual results for the fiscal year reported in the first column must agree with the Applicant's audited financial statements.) The projections must include the first three full fiscal years of the project.

Please see Attachment XV.

b. Provide a three year projection of incremental revenue, expense, and volume statistics attributable to the proposal by payer. **Complete Financial Attachment II.** The projections must include the first three full fiscal years of the project.

Please see Attachment XVI.

c. Provide the assumptions utilized in developing **both Financial Attachments I and II** (e.g., full-time equivalents, volume statistics, other expenses, revenue and expense % increases, project commencement of operation date, etc.).

Please see Attachment XVII.

d. Provide documentation or the basis to support the proposed rates for each of the FYs as reported in Financial Attachment II. Provide a copy of the rate schedule for the proposed service(s).

Rates for the proposed service will be approximately the same as the current service.

e. Provide the minimum number of units required to show an incremental gain from operations for each fiscal year.

Each additional incremental case produces an incremental gain.

f. Explain any projected incremental losses from operations contained in the financial projections that result from the implementation and operation of the CON proposal.

No incremental losses from operations are anticipated.

g. Describe how this proposal is cost effective.

The proposed elective angioplasty program maximizes use of the existing high-cost infrastructure of the primary angioplasty program and permits existing and available highly qualified expert physicians and staff to perform both primary and elective angioplasties for which they have been trained and are qualified to perform. In addition, as noted above, through System-wide integration, coordination of care practices and standardization, more cost effectiveness and evidence-based care will be provided.

ATTACHMENTS

ATTACHMENT I

American Heart Association (AHA)
Late-Breaking News Trial Report
November 14, 2011

American Heart Association.
Learn and Live

Elective angioplasty patients can fare well in experienced hospitals with no heart surgery capabilities

American Heart Association Late-Breaking Clinical Trial Report - Abstract: 18558 - EMBARGOED UNTIL 8AM ET November 14, 2011

Study Highlights:

- Patients who had non-emergency artery-opening angioplasty or stent implantation at hospitals without heart surgery capabilities fared as well as those in hospitals that did.
- Both groups of patients had less than a 1 percent death rate.

ORLANDO, FLA., Nov. 14, 2011 — Patients who had non-emergency artery-opening angioplasty or stent implantation at experienced hospitals without on-site heart surgery capabilities fared no worse than those in surgery-equipped hospitals, according to late-breaking research presented at the American Heart Association's Scientific Sessions 2011.

In a study from the Cardiovascular Patient Outcomes Research Team (CPORT), researchers randomly assigned 13,995 patients to have their procedure done at a hospital with cardiac surgery capabilities and 4,523 patients at hospitals without.

The death rate after six weeks was almost the same for each group — just under 1 percent, researchers said. Furthermore, neither group were more likely to need emergency heart bypass surgery.

If emergency surgery was required at a hospital without on-site surgery, the patient was transferred urgently.

The American College of Cardiology Foundation/American Heart Association guidelines have recommended that elective angioplasty and stent implantation be done at hospitals with cardiac surgery facilities in the same building in case emergency surgery is needed.

In this study, emergency surgery was needed for 20 of the 13,995 patients undergoing procedures at hospitals without on-site surgery and 10 of the 4,523 patients treated at hospitals with surgery available.

However, the need for emergency surgery during these procedures has plummeted over the last few decades, said Thomas Aversano, M.D., the study's lead researcher and associate professor of medicine at Johns Hopkins Medical Institutions in Baltimore, Md.

"In the 1980s, the need for cardiac surgery was high; 5 percent to 7 percent of these cases could require emergency open heart or bypass surgery," Aversano said. "The cardiac operating room was kept open in the event a complication requiring surgery occurred. Now it's one in 500 or one in 1,000. It's very uncommon."

In this carefully structured study, the 60 hospitals without cardiac surgery capabilities had to be able to annually perform at least 200 angioplasties or stent implantations, also called percutaneous coronary interventions or PCI. The physicians doing the procedures were required to be performing more than 75 PCI cases annually. All centers underwent a formally developed PCI program.

Some states restrict hospitals from performing these procedures without on-site surgery, except for an emergency, Aversano said.

"We do not support the spread of angioplasty to every hospital in the United States," he said. "However, it can be burdensome and costly for all medical centers to have cardiac surgery capabilities. And it doesn't make sense to create more surgical programs just to support the angioplasty programs."

He said regional healthcare planners can use the data from the study to make informed decisions about which hospitals should have PCI capability, with the aim of improving quality, improving access and lowering costs.

The study provides only short-term results, but early next year, researchers will have data revealing how patients fared nine months after the procedure. They said this will be important in assessing the overall effect of these two systems of care on ultimate patient outcomes.

Co-authors are the C-PORT investigators.
Disclosures are here: http://newsroom.heart.org/pr/aha/document/Disclosures_for_LBCT.xlsx.
The participating medical centers funded the study.

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Statements and conclusions of study authors that are presented at American Heart Association scientific meetings are solely those of the study authors and do not necessarily reflect association policy or position. The association makes no representation or warranty as to their accuracy or reliability. The association receives funding primarily from individuals; foundations and corporations (including pharmaceutical, device manufacturers and other companies) also make donations and fund specific association programs and events. The association has strict policies to prevent these relationships from influencing the science content. Revenues from pharmaceutical and device corporations are available at www.heart.org/corporatefunding.

CONTACT:
AHA News Media in Dallas: (214) 706-1396
AHA News Media Office, Nov. 12-16, at the
Orange County Convention Center: (407) 685-5410
For public inquiries: (800) AHA-USA1 (242-8721)

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ATTACHMENT II

American Journal of Therapeutics
Outcomes of Nonemergent Percutaneous Coronary Intervention With and Without On-site Surgical Backup: A Meta-Analysis

American Journal of Therapeutics 18, e22–e28 (2011)

Outcomes of Nonemergent Percutaneous Coronary Intervention With and Without On-site Surgical Backup: A Meta-Analysis

Param Puneet Singh, MD,* Mukesh Singh, MD, Updesh Singh Bedi, MD, Sasikanth Adigopula, MD, Sarabjeet Singh, MD, Vamsi Kodumuri, MD, Janos Molnar, MD, Aziz Ahmed, MD, Rohit Arora, MD, and Sandeep Khosla, MD

Despite major advances in percutaneous coronary intervention (PCI) techniques, the current guidelines recommend against elective PCI at hospitals without on-site cardiac surgery backup. Nonetheless, an increasing number of hospitals without on-site cardiac surgery in the United States have developed programs for elective PCI. Studies evaluating outcome in this setting have yielded mixed results, leaving the question unanswered. Hence, a meta-analysis comparing outcomes of nonemergent PCI in hospitals with and without on-site surgical backup was performed. A systematic review of literature identified four studies involving 6817 patients. Three clinical end points were extracted from each study and included in-hospital death, myocardial infarction, and the need for emergency coronary artery bypass grafting. The studies were homogenous for each outcome studied. Therefore, the combined relative risks (RRs) across all the studies and the 95% confidence intervals (CIs) were computed using the Mantel-Haenszel fixed-effect model. A two-sided alpha error less than 0.05 was considered to be statistically significant. Compared with facilities with on-site surgical backup, the risk of in-hospital death (RR, 2.7; CI, 0.6–12.9; $P = 0.18$), nonfatal myocardial infarction (RR, 1.3; CI, 0.7– 2.2; $P = 0.29$), and need of emergent coronary artery bypass grafting (RR, 0.46; CI, 0.06– 3.1; $P = 0.43$) was similar in those lacking on-site surgical backup. The present meta-analysis suggests that there is no difference in the outcome with regard to risk of nonfatal myocardial infarction, need for emergency coronary artery bypass grafting, and the risk of death in patients undergoing elective PCI in hospitals with and without on-site cardiac surgery backup.

Keywords: onsite backup surgery, percutaneous coronary intervention

INTRODUCTION

Percutaneous coronary interventions (PCI) were introduced for the first time in 1977 by Andreas Gruntzig.[1] Since then, many technologic and pharmacologic advances in PCI have been made. Steerable guidewires, coronary artery stents,[2] and new antiplatelet therapies have improved the success rate of PCI procedures and significantly reduced the risk of per-procedural complications needing urgent cardiac surgery. Recent studies have shown that the need for emergency cardiac surgery is now as low as 0.3% to 0.6%.[2,3] As a result, the number of procedures has increased worldwide,[4] and an increasing proportion of procedures are performed at centers without surgical backup.[5,6] Despite major advances in PCI technique, the current American College of Cardiology/American Heart Association/-Society of Cardiovascular Angiography and Intervention 2005 guidelines[7] for PCI recommend against elective PCI at hospitals without on-site cardiac surgery (Class III indication). Acknowledging this trend, the Society for Cardiovascular Angiography and Interventions recently issued an expert consensus statement that provides practice standards for elective PCI at hospitals

Department of Cardiology, Chicago Medical School, Rosalind Franklin University of Medicine & Science, North Chicago, IL.
**Address for correspondence: Department of Cardiology, Chicago Medical School, Rosalind Franklin University of Medicine & Science, North Chicago, IL 60064. E-mail: drparamsingh@gmail.com*

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without on-site cardiac surgery.[8] Because of the conflicting literature on this subject, the question about safety of elective PCI at centers without surgical backup remains unanswered. Hence, a meta-analysis comparing outcomes of nonemergent or elective PCI in hospitals with and without on-site surgical backup was performed.

METHODS

We performed this review in accordance with the Quality of Reporting of Meta-analysis statement and the Consolidated Standards of Reporting Trials Group recommendations.[9]

Literature search

A systematic review of the medical literature was performed to identify studies evaluating the efficacy or adverse outcomes of combination therapy in patients with congestive heart failure, acute myocardial infarction, or high-risk diabetes mellitus. Eligible studies were identified by searching MEDLINE (January 1966–December 2008), EMBASE (January 1980–December 2006), the Cochrane Library (Controlled Trials Register and Database of Systematic Reviews, all years), the National Institute of Health Clinical Trials (http://www.clinicaltrials.gov), and the U.S. Food and Drug Administration web sites (http://www.FDA.gov) and relevant bibliographies.

Study selection

There was a written protocol with explicit inclusion and exclusion criteria, which was followed for all articles that were screened. All titles and abstracts from the results of our computerized search were reviewed by the authors for potential inclusion in our study. We also searched for relevant review articles and their bibliographies for articles. In addition to our computerized search, we manually reviewed the reference list of all retrieved articles to complete our search for randomized, controlled trials comparing outcome of PCI with and without surgical backup. Study selection process is outlined in Figure 1.

Studies were excluded if they did not meet the inclusion criteria. Those studies that were not done in human subjects, not randomized, published in nonpeer-reviewed journals, or with inadequate follow up were excluded from our analysis.

End points and definitions

Three clinical end points were extracted from each study and included: in-hospital death, nonfatal myocardial infarction (MI), and need for emergency coronary artery bypass surgery (CABG). End point definitions were those used in the individual trials. Death was defined as in-hospital mortality from any cause. MI was defined as enzymatic and electrocardiographic changes consistent with MI. Emergency CABG surgery was defined as unplanned surgical revascularization within 48 hours of PCI. All end points were assessed at the end of follow up of the trial.

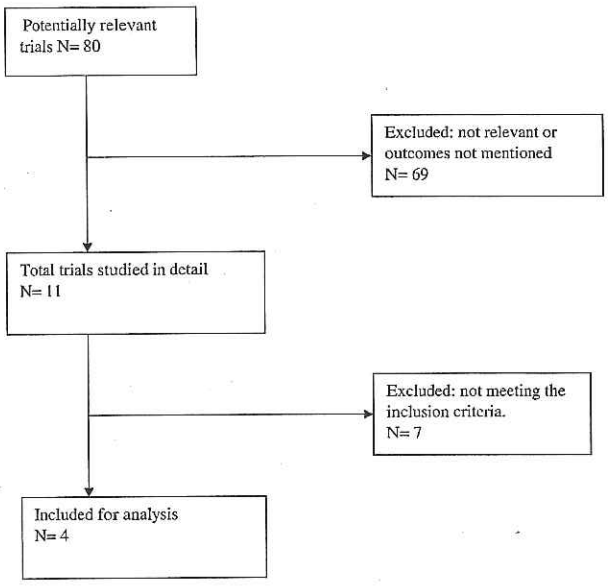

FIGURE 1. Trial selection and inclusion flow diagram.

Data extraction

The two authors (PS, MS) independently screened the titles and abstracts for eligibility. Full articles were retrieved for all titles for which abstracts were not available and for all abstracts that appeared to potentially fulfill the inclusion and exclusion criteria. It was decided that if there was a conflict between the two authors, then the study in question would be brought to the panel of all authors where the decision would be made for its inclusion. Data extraction was done independently by two authors. Each author tabulated important trial characteristics and assessed methodological quality (jaded score), including patient demographics such as age, study population, sample size diabetes, hypertension, and angiographic characteristics.

Statistical analysis

The statistical analysis was performed with the Comprehensive Meta-Analysis software package (Version CM 2.2; Biostat, Englewood, NJ). We calculated odds ratio for each study outcome to allow for pooling of similar outcomes. All the results are reported as the pooled odds ratio with 95% confidence interval (CI). Chi square test

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Table 1. Results of heterogeneity analysis.

End Point	Q-value	df (Q)	*P* Value	I-squared	Result
In-hospital death	3.4	1	0.067	70.2	Homogenous
Nonfatal myocardial infarction	1.4	3	0.707	0.0	Homogenous
Emergency coronary artery bypass graft	2.0	1	0.155	50.7	Homogenous

was used to assess heterogeneity. The studies were homogenous for each outcome studied (Table 1). Therefore, the combined relative risks (RRs) across all the studies and the 95% CIs were computed using the Mantel-Haenszel fixed-effect model. A two-sided alpha error less than 0.05 was considered to be statistically significant.

Role of funding source

The funding source had no role in the design, conduct, or reporting of the study or in the decision to submit the manuscript for publication.

RESULTS

Data synthesis and study characteristics

Figure 1 represents the trial selection and inclusion flow diagram. After the initial search based as described previously, a total of 80 articles was considered as potentially relevant. After the title and abstract review, 69 of the 80 were excluded because they were not randomized, non-English trials, or did not meet our inclusion criteria. From the remaining 11, seven were excluded after full text review because there was inadequate follow up, the outcomes measured were different, or the study characteristics did not meet our inclusion criteria. Our search of abstracts from conference proceedings of the American College of Cardiology, American Heart Association, European Society of Cardiology, and Heart Failure Society of America did not reveal any additional studies that satisfied our inclusion and exclusion criteria. Our meta-analysis included the remaining four randomized, controlled trials involving 6817 patients.[10–13]

Baseline characteristics

Table 2 summarizes the study population characteristics of all the studies included for the analysis. All four studies were large randomized, controlled trials with adequate follow up. Mean duration of follow up was 31 months. Mean age of patients enrolled was 64 years. Allocation sequence generation and concealment were adequately described in all four studies. All the studies had two arms comparing the outcome of patients undergoing elective PCI at two centers with and without on-site cardiac surgery backup. In-hospital death and need for emergency surgery as outcomes were reported in two studies,[12,13] whereas non-fatal MI was reported in all four studies included in this meta-analysis.[10–13]

Clinical outcomes

Angiographic characteristics of patients in the included studies are given in Table 3. The outcomes measured in our analysis were in-hospital death, nonfatal MI, and need for emergent CABG.

In-Hospital Death

Compared with hospitals with surgical capability, there was no difference in the risk of in-hospital death in patients undergoing elective PCI at centers without surgical back up (RR, 2.7; CI, 0.6–12.9; $P = 0.18$) (Fig. 2).

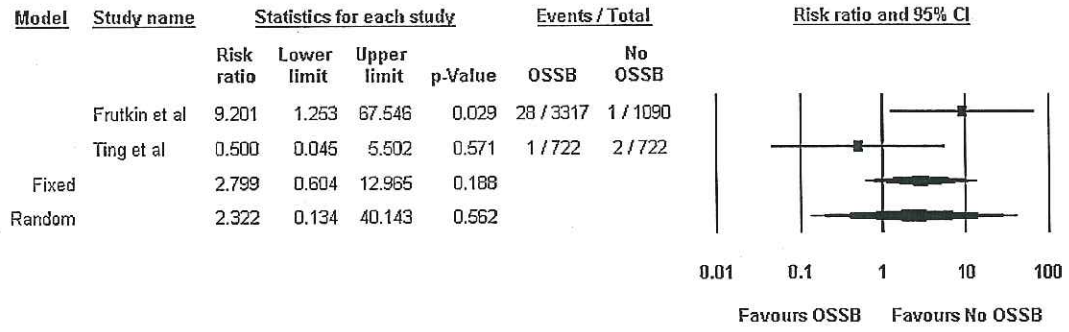

FIGURE 2. Risk of in-hospital death with on-site surgical backup versus no backup.

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Table 2. General characteristics of the patient population in studies included in meta-analysis.

Characteristics		Dellavalle, 1995	Melberg, 2006	Frutkin, 2008	Ting, 2006
N	SB	154	304	3317	722
	NSB	174	305	1090	722
Age	SB	55 ± 12	58 ± 10	66 ± 13	64.9 ± 12.5
	NSB	64 ± 18	59 ± 10	66 ± 12	64.9 ± 12.7
Females	SB	37 (24%)	61 (20%)	1129 (34%)	246 (34%)
	NSB	33 (19%)	64 (21%)	300 (27.5%)	218 (30%)
Prior MI	SB	72 (47%)	39	1320 (40%)	273 (39%)
	NSB	108 (62%)	39	319 (29%)	248 (34%)
Prior PCI	SB	15 (9.1%)	9	1583 (48%)	245 (34%)
	NSB	30 (17.2%)	6	477 (44%)	244 (34%)
Prior stroke/TIA	SB	—	—	603 (18%)	80 (11%)
	NSB	—	—	163 (15%)	69 (10%)
Prior CABG	SB	1 (0.6%)	6	728 (22%)	84 (12%)
	NSB	5 (2.7%)	5	220 (20%)	74 (10%)
PVD	SB	—	—	421 (13%)	72 (10%)
	NSB	—	—	125 (11%)	86 (12%)
DM	SB	—	5	110 (34%)	170 (24%)
	NSB	—	9	310 (28%)	176 (24%)
HTN	SB	—	25	2527 (76%)	480 (69%)
	NSB	—	24	820 (75%)	496 (69%)
CKD	SB	—	—	193 (6%)	18 (2%)
	NSB	—	—	29 (3%)	18 (3%)
CHF	SB	—	—	346 (10%)	38 (5%)
	NSB	—	—	65 (6%)	39 (5%)
LVEF less than 40%	SB	—	—	374 (19%)	92 (13%)
	NSB	—	—	59 (9%)	74 (10%)

MI, myocardial infarction; PCI, percutaneous coronary intervention; TIA, transient ischemic attack; CABG, coronary artery bypass grafting; PVD, peripheral vascular disease; DM, diabetes mellitus; HTN, hypertension; CKD, chronic kidney disease; CHF, congestive heart failure; LVEF, left ventricular ejection fraction; SB, on-site surgical backup group; NSB, no on-site surgical backup group.

Nonfatal Myocardial Infarction

The risk of nonfatal MI was similar in both groups of patients without any significant difference (RR, 1.3; CI, 0.7–2.2; $P = 0.29$) (Fig. 3).

Need for Emergent Coronary Artery Bypass Grafting

The risk for need for emergent CABG did not differ between the patients undergoing PCI at centers with and without surgical backup (RR, 0.46; CI, 0.06–3.1; $P = 0.43$) (Fig. 4).

DISCUSSION

Our meta-analysis shows that there is no difference in the incidence of in-hospital mortality, nonfatal MI, and

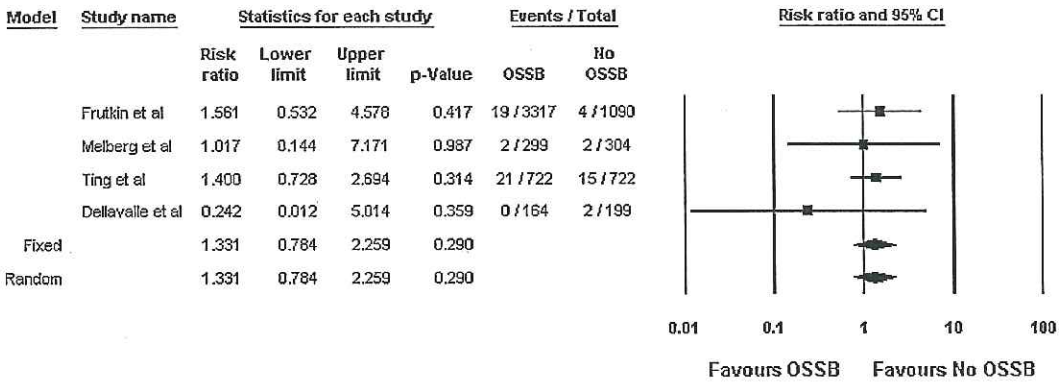

FIGURE 3. Risk of nonfatal myocardial infarction with on-site surgical backup versus no backup.

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Table 3. Angiographic characteristics of patients in studies included in the meta-analysis.

Characteristics	Dellavalle		Melberg, 2006		Frutkin		Ting, 2006	
	SB	NSB	SB	NSB	SB	NSB	SB	NSB
Extent of disease								
SVD	98 (60%)	139 (70%)	39	39	999 (30%)	299 (27%)	—	—
DVD	56 (34%)	44 (22%)	35	37	1079 (33%)	356 (33%)	423 (62%)	429 (61%)
TVD	10 (6%)	16 (8%)	26	24	1231 (37%)	434 (40%)		
Type of PCI								
SV	131 (80%)	179 (90%)	—	—	2244 (68%)	773 (71%)	646 (90%)	636 (88%)
MV	33 (20%)	20 (10%)	—	—	852	282 (26%)	75 (10%)	86 (12%)
LM	3 (2%)	0	—	—	27 (0.8%)	4 (0.4%)	—	—
VG	1 (0.5%)	4 (2%)	—	—	263 (8%)	60 (6%)	22 (3%)	24 (3%)
No. of stents placed	—	—	—	—	1.7 ± 1.3	1.8 ± 1.1	1.3 ± 0.9	1.5 ± 1.0

SB, on-site surgical backup group; NSB, no on-site surgical backup group; SVD, single-vessel disease; DVD, double-vessel disease; TVD, triple-vessel disease; SV, single vessel; MV, multiple vessel; LM, left main; VG, venous graft.

the need for emergency CABG in patients undergoing PCI at centers with and without surgical backup (Fig. 5). Overall, of 6817 patients in all four studies, total in-hospital deaths were 32 (0.47%). In the group with no surgical backup, in-hospital mortality was 0.13% (three of 2315 patients died), whereas in the group with on-site surgical backup, the in-hospital mortality rate was 0.6% (29 of 4502 patients died).

The purpose of cardiac surgical backup for PCI is to provide emergent hemodynamic support and revascularization to salvage complications that cannot be addressed by catheter-based techniques. PCI can be complicated by life-threatening hemodynamic and ischemic emergencies that can be addressed only by the availability of emergency cardiac surgery. The role of on-site cardiac surgical backup is twofold: on-site cardiac surgical backup provides prompt availability of cardiac surgical support in the event of a hemodynamic or ischemic emergency and on-site cardiac surgical backup is a surrogate for an institution's overall capability to provide a highly experienced and promptly available team to respond to a catheterization laboratory emergency.[14] Technical improvements in PCI instruments and techniques have led to the concept that the requirement for emergency cardiac surgery is sufficiently rare that PCI can be performed safely without on-site surgery. This has led to the development of elective angioplasty programs without on-site surgical coverage.

Cardiac surgical backup for PCI has evolved from a formal surgical standby in the 1980s to an informal arrangement of first-available operating room and, in some cases, off-site surgical backup.[15–21] With the advent of intracoronary stenting, there has been a decrease in the need for emergency CABG ranging between 0.4% and 2%.[2,3,21–28] Not surprisingly, emergency CABG surgery for a patient with an occluded or dissected coronary artery is associated with a higher mortality than elective surgery.[21,29–34] Emergency procedures are also associated with high rates of perioperative infarction and less frequent use of

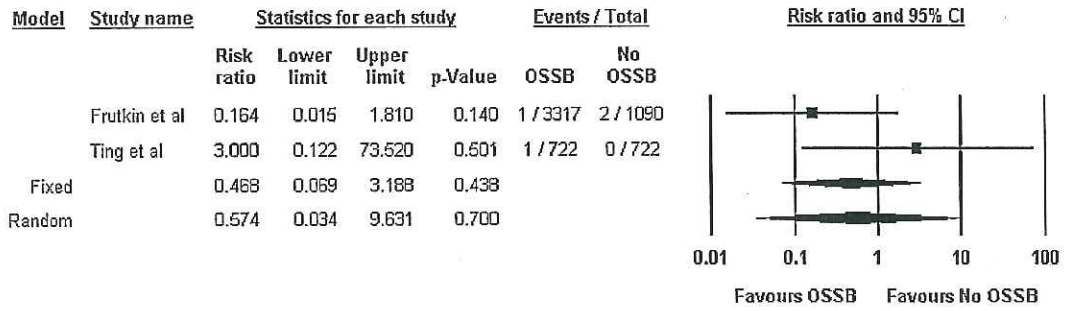

FIGURE 4. Risk of emergency coronary artery bypass graft with on-site surgical backup versus no backup.

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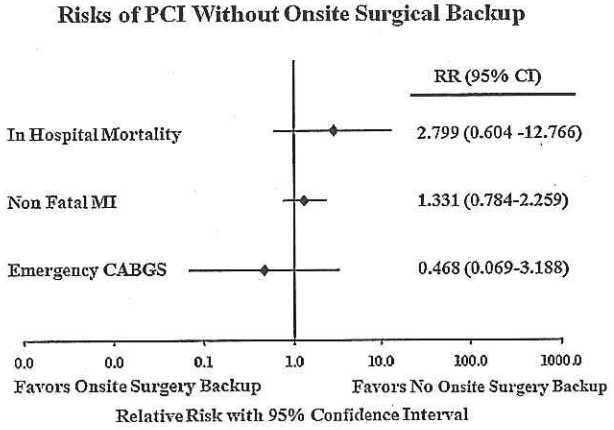

FIGURE 5. Summary figure.

arterial conduits. Complex coronary artery disease intervention, hemodynamic instability, and prolonged time to reperfusion are contributing factors to the increased risk of emergency bypass surgery.

A recently published report from analysis of National Cardiovascular Data Registry showed findings similar to our meta-analysis. This National Cardiovascular Data Registry data analysis showed that off-site PCI centers had similar observed procedure success, morbidity, emergency cardiac surgery rates, and mortality in cases that required emergency surgery. The risk-adjusted mortality rates in off-site PCI facilities were comparable to those of PCI centers that had cardiac surgery on-site regardless of whether PCI was performed as primary therapy for ST-elevation MI or in a nonprimary setting.[35]

Like with any meta-analysis, our analysis has limitations inherent to such analysis. Meta-analyses have inherent methodological limitations in that summary data are pooled from studies of different designs. The study population used in all the trials, although being somewhat similar, is not exactly the same. Although we detected no significant heterogeneity, a meta-analysis cannot replace large, well-conducted randomized trials as evidence for and against an intervention.

Our meta-analysis adds to the current body of literature on PCI by considering between study heterogeneity, bias, consistency of outcomes among studies and inclusion of large recent studies. This meta-analysis shows that there is no difference in the outcome with regard to risk of nonfatal MI, need for emergency CABG, and the risk of death in patients undergoing elective PCI in hospitals with and without on-site cardiac surgery backup.

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ATTACHMENT III

Journal of the American College of Cardiology
News from the NCDR – Percutaneous Coronary Interventions in Facilities without Cardiac Surgery On Site: A Report from the National Cardiovascular Data Registry (NCDR)

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News from the NCDR

NCDR™ National Cardiovascular Data Registry

Percutaneous Coronary Interventions in Facilities Without Cardiac Surgery On Site: A Report From the National Cardiovascular Data Registry (NCDR)

Michael A. Kutcher, MD,* Lloyd W. Klein, MD,† Fang-Shu Ou, MS,‡ Thomas P. Wharton, JR, MD,§ Gregory J. Dehmer, MD,‖ Mandeep Singh, MD, MPH,¶ H. Vernon Anderson, MD,# John S. Rumsfeld, MD, PHD,** William S. Weintraub, MD,†† Richard E. Shaw, PHD,‡‡ Matthew T. Sacrinty, MPH,* Albert Woodward, PHD, MBA,§§ Eric D. Peterson, MD, MPH,‡ Ralph G. Brindis, MD, MPH,‖‖ on behalf of the National Cardiovascular Data Registry (NCDR)

Since the introduction of percutaneous coronary intervention (PCI) in 1977 by Andreas Gruntzig (1), the presence of cardiac surgery backup on site has been a recommended practice to treat the potential of life-threatening complications. As a result of major improvements in technology and pharmacology, the need for emergency cardiac surgery is now infrequent (0.3% to 0.6%) (2,3). Moreover, primary PCI has been accepted as superior to fibrinolytic therapy for ST-segment elevation myocardial infarction (STEMI) (4). These developments have provided the justification for some hospitals without cardiac surgery to develop PCI programs based on a strategy to provide more rapid care for STEMI (5,6) and to increase the availability of PCI to patients in geographically underserved areas.

Favorable outcomes for primary PCI performed in facilities without cardiac surgery backup on site have been reported (7–9). In addition, smaller observational studies have extended this concept to both primary and elective PCI (10–14), and even PCI limited to elective cases (15). However, there are few large studies that have directly compared the procedural outcomes of both primary and elective PCI at facilities without cardiac surgery on site with those that have traditional surgery on site (16–18). Because of the conflicting literature on this subject, the American College of Cardiology (ACC), American Heart Association (AHA), and Society for Cardiovascular Angiography and Interventions (SCAI) 2005 PCI guidelines continue to designate primary PCI a Class IIb indication (may be considered), and elective PCI a Class III indication (not recommended) when performed at facilities without surgical backup on site (19). The 2007 PCI guideline focused update did not address or change these designations (20). Despite

From the *Wake Forest University School of Medicine, Winston-Salem, North Carolina; †Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois; ‡Duke Clinical Research Institute, Durham, North Carolina; §Exeter Hospital, Exeter, New Hampshire; ‖Texas A&M University College of Medicine, Scott & White HealthCare, Temple, Texas; ¶Mayo Clinic, Rochester, Minnesota; #University of Texas Health Science Center, Houston, Texas; **Denver VA Medical Center, Denver, Colorado; ††Christiana Health Care System, Newark, Delaware; ‡‡Sutter Pacific Heart Centers, San Francisco, California; §§National Cardiovascular Data Registry, Washington, DC; and ‖‖Northern California Kaiser Permanente, San Francisco, California. Data analysis was performed by the Duke Clinical Research Institute with funding from the National Cardiovascular Data Registry. Drs. Kutcher and Klein perform percutaneous coronary intervention (PCI) at facilities that have on-site cardiac surgery. Dr. Wharton is a consultant to Corazon, The Heart and Vascular Experts, and performs PCI at a facility that does not have on-site cardiac surgery. Dr. Dehmer is Chief, Division of Cardiology, Texas A&M College of Medicine, Scott & White HealthCare, which includes facilities that have on-site cardiac surgery and facilities that do not. Dr. Singh performs PCI at Mayo Clinic facilities that have on-site cardiac surgery and facilities that do not. Dr. Anderson performs PCI at a facility that has on-site cardiac surgery.

these classifications, the number of PCI programs in the U.S. without surgery on site has increased significantly over the past several years (21). Recently, a SCAI expert panel outlined practical consensus principles for PCI performed at facilities without surgery on site, while not specifically encouraging or endorsing this practice (22).

The National Cardiovascular Data Registry (NCDR) was established by the ACC to proactively monitor and assess the clinical practice of cardiology in the U.S. (23). The NCDR CathPCI Registry, cosponsored by the ACC and SCAI, offers its participant institutions data field definitions, uniform data entry, secure transmission requirements, a data quality program, and risk-adjustment algorithms (24–26). Therefore, this registry provides an excellent resource of comparative data, in a relative contemporary clinical setting, to address the controversy over PCI at facilities without surgical backup on site.

Abbreviations and Acronyms

ACC = American College of Cardiology
AHA = American Heart Association
CABG = coronary artery bypass graft surgery
IABP = intra-aortic balloon pump
MI = myocardial infarction
NSTEMI = non–ST-segment myocardial infarction
PCI = percutaneous coronary intervention
SCAI = Society for Cardiovascular Angiography and Interventions
STEMI = ST-segment elevation myocardial infarction

Methods

Study population. Clinical characteristics and in-hospital outcomes were assessed in consecutive PCI cases reported to the NCDR CathPCI Registry from January 1, 2004, to March 30, 2006. Standardized NCDR version 3.04 definitions and data fields were used by all participating sites (27). The analysis cohort consisted of 308,161 patients from 465 PCI-capable facilities. Of these, 8,736 patients had PCI performed at 60 institutions in which it was verified there was no surgical backup on site within the buildings or campus that constituted the facility (off-site facility). The remaining 299,425 patients underwent PCI at 405 facilities that had cardiac surgery on site (on-site facility). Off-site PCI facilities comprised 13% of sites and 3% of patients in the NCDR CathPCI Registry during the study period.

Definitions. The primary outcomes for analysis were the incidence of emergency surgery and in-hospital death from all causes after PCI. Emergency surgery was defined as coronary artery bypass graft (CABG) surgery performed after PCI in which there was evidence of active ischemia or mechanical dysfunction (emergency), or if the patient required cardiopulmonary resuscitation en route to the operating room or before anesthesia (emergent/salvage). Secondary outcomes included procedure success, total complications (any general, bleeding, or vascular complications), and reperfusion time in cases of primary PCI for STEMI.

Off-site data clarification. During initial analysis, variations in 2 data fields unique to off-site PCI programs were noted. The field "CABG during this admission" permitted entry of only 1 category. In off-site centers, there was a disproportionately low incidence of "emergency" surgery, but a proportionately large number of patients "transferred for CABG" entered in this field. In addition, "transfer" patients could be counted as "alive" in the data field "discharge status" from an off-site center, but this opened the potential that a subsequent death after emergency surgery at the outside surgical center may not have been captured.

To resolve these issues, we conducted a data clarification project. Off-site centers with specific data points in question were queried to clarify whether a "transfer for CABG" data point was for elective or emergency surgery, and to verify the eventual survival at the off-site surgical center. This effort also provided an opportunity to gather additional information by a Capabilities Survey to reaffirm a true off-site status and to assess organization, staffing, and logistics. All of the off-site programs were invited to fill out the survey form, even those sites in which data clarification was not necessary.

Of the 8,736 patients undergoing PCI in off-site centers, 172 (2%) patients from 43 sites required data clarification regarding transfer surgery or mortality status. Of these 43 sites, 38 (88%) sites were able to clarify CABG status and/or mortality information for 154 of the 172 (90%) patients. For the 18 patients (0.2% of 8,736) whose transfer or mortality data were not clarified, if CABG status was uncertain, the original record entry was used for the CABG status-related analysis. If the subsequent mortality at the receiving surgery center could not be clarified, these patients were not included in the analysis of observed or risk-adjusted mortality.

Statistical analysis. Data analysis was performed by the Duke Clinical Research Institute. For descriptive analyses, institutional comparisons between off- and on-site PCI centers were made based on hospital characteristics. Comparisons between patients were made based on clinical characteristics, treatment profiles, procedural details, and clinical outcomes. These aggregates were further divided and analysis performed in patients who underwent primary PCI as first-line therapy for reperfusion in the presence of STEMI, and to the remainder of patients who underwent PCI in a nonprimary setting. Continuous variables are presented as mean with SD or as frequencies with percentages in each pre-specified category. Categorical variables are expressed as frequencies with percentages. To test for independence of patients' baseline characteristics, in-hospital care patterns and outcomes with respect to off-site versus on-site centers, the Wilcoxon rank-sum test was used for continuous variables, and the Pearson chi-square test was used for categorical variables.

A multivariable logistic regression model was then used to estimate the risk-adjusted association between on-site versus off-site PCI center surgical status and primary outcomes. Variables adjusted to mortality in-

cluded age, sex, insulin-treated diabetes mellitus, hypercholesterolemia, hypertension, dialysis, cerebrovascular disease, chronic lung disease, peripheral vascular disease, congestive heart failure, prior CABG, prior PCI, prior myocardial infarction (MI), cardiogenic shock at presentation, MI status (STEMI, non–ST-segment myocardial infarction [NSTEMI], and no MI), pre-operative intra-aortic balloon pump (IABP), PCI status (rescue, emergent, urgent, and elective), subacute thrombosis in a major artery, any treated lesion in left main artery, any treated lesion with pre-procedure stenosis 100%, any treated lesion with pre-procedure Thrombolysis In Myocardial Infarction (TIMI) flow grade 0, any treated lesion with high/C risk characteristics (see definition, bottom legend, Table 1), and total number of lesions treated. Variables adjusted to emergency CABG included cardiogenic shock, MI status (STEMI, NSTEMI, and no MI), pre-operative IABP, PCI status (rescue, emergent, urgent, and elective), and any treated left main artery lesion.

The Generalized Estimate Equation method (28) was applied to account for within-hospital clustering, considering patients at the same hospital are more likely to have similar responses relative to patients in other hospitals (i.e., within-center correlation for response). This method produces estimates comparable to those from ordinary logistic regression, but estimated variances are adjusted for the correlation of outcomes within each hospital.

Because not all off-site PCI center patient mortality data could be clarified, a sensitivity analysis was performed. This analysis utilized the same multivariable logistic regression model but imputed data to either of the following: patients with missing mortality data were considered either as all had died (worst scenario) or as all were alive (best scenario) on discharge.

Results

Institutional characteristics. Institutional characteristics are shown in Table 2. Compared with on-site centers, off-site PCI facilities had smaller bed capacity, were more likely to be located in nonurban areas, and had lower annual total PCI and primary PCI volume ($p < 0.001$). Overall, 43 (72%) of the off-site programs performed <200 total PCIs per year, and only 3 sites (5%) had >400 cases, suggesting that it was unlikely the outcomes were preferentially influenced by a few large-volume centers. The recommended volume standard of 36 or more primary PCIs per year (19) was achieved by 42% of the off-site programs compared with 80% of the on-site centers ($p < 0.001$).

Off-site capabilities survey. The survey (Table 3) was completed by 53 of the 60 off-site PCI facilities (88%). Approximately one-quarter of the centers had travel distances >40 miles and transit times (estimated driving or flight) >30 min. This information also reaffirmed that these were true off-site programs and did not have surgery back-up nearby in the next building. Full 24-h, 7-day coverage for PCI was provided by 92% of the sites. Both primary and elective PCI were performed in 79% of the centers, and none of the programs performed only elective PCI. Descriptive demographics regarding the organization of technical staff, interventional cardiologists, and transpor-

Table 1 Clinical Characteristics by PCI Status

	All PCI Patients			Primary PCI Patients			Nonprimary PCI Patients		
Characteristic	Off-Site (n = 8,736)	On-Site (n = 299,425)	p Value	Off-Site (n = 1,934)	On-Site (n = 31,099)	p Value	Off-Site (n = 6,802)	On-Site (n = 268,312)*	p Value
Age, yrs, mean ± SD	63.5 ± 12	64.1 ± 12	<0.001	61.2 ± 13	60.6 ± 13	0.194	64.2 ± 12	64.4 ± 12	0.062
Male	5,817 (67)	198,656 (66)	0.639	1,384 (72)	21,958 (71)	0.371	4,433 (65)	176,688 (66)	0.243
Previous MI >7 days	2,285 (26)	87,521 (29)	<0.001	327 (17)	5,440 (17)	0.509	1,958 (29)	82,077 (31)	0.001
Previous CHF	839 (9.6)	30,953 (10.3)	0.026	80 (4)	1,442 (5)	0.308	759 (11)	29,510 (11)	0.675
Diabetes	2,534 (29)	95,160 (32)	<0.001	361 (19)	6,514 (21)	0.016	2,173 (32)	88,642 (33)	0.058
Previous renal failure	367 (4)	15,868 (5)	<0.001	56 (3)	1,033 (3)	0.308	311 (4.6)	14,835 (5.5)	<0.001
Cerebrovascular disease	817 (9)	33,865 (11)	<0.001	105 (5)	2,165 (7)	0.010	712 (10)	31,700 (12)	<0.001
Peripheral vascular disease	895 (10)	35,519 (12)	<0.001	123 (6)	2,019 (6)	0.818	772 (11)	33,500 (12)	0.005
Hypertension	6,226 (71)	225,404 (75)	<0.001	1,069 (55)	18,275 (59)	0.002	5,157 (76)	207,120 (77)	0.007
Dyslipidemia	5,827 (67)	220,220 (74)	<0.001	974 (50)	17,432 (56)	<0.001	4,853 (71)	202,780 (76)	<0.001
Previous PCI	2,711 (31)	105,133 (35)	<0.001	321 (17)	5,254 (17)	0.735	2,390 (35)	99,875 (37)	<0.001
Previous CABG	1,068 (12)	56,815 (19)	<0.001	99 (5)	1,810 (6)	0.199	969 (14)	55,000 (21)	<0.001
Lesion characteristics									
≥2 lesions in laboratory visit	2,503 (29)	99,309 (33)	<0.001	478 (25)	8,463 (27)	0.048	2,025 (30)	90,843 (34)	<0.001
Segment in SVG	396 (5)	20,644 (7)	<0.001	55 (3)	989 (3)	0.657	341 (5)	19,675 (7)	<0.001
High-risk C lesion†	3,426 (39)	123,207 (41)	<0.001	1,106 (57)	18,933 (61)	0.001	2,320 (34)	104,270 (39)	<0.001

Data are n (%) unless otherwise indicated. *14 patients not included due to missing value for variable "Acute PCI." †High risk C lesion includes any of the following: diffuse (length >20 mm), excessive tortuosity of proximal segment, extremely angulated segments >90 degrees, total occlusions >3 months old and/or bridging collaterals, inability to protect major side branches, and degenerated vein grafts with friable lesions.

CABG = coronary artery bypass grafting; CHF = congestive heart failure; MI = myocardial infarction; PCI = percutaneous coronary intervention; SVG = saphenous vein graft.

tation modalities are further outlined in Table 3. Of note, 81% of the off-site programs reported that their interventional operators also rotated and performed PCI at on-site facilities.

Clinical characteristics. Clinical characteristics are shown in Table 1. In aggregate, on-site PCI centers generally treated patients with more risk factors and performed a greater percentage of PCI in multiple-lesion (33% vs. 29%, $p < 0.001$), saphenous vein graft (7% vs. 5%, $p < 0.001$), and higher lesion-risk cases (41% vs. 39%, $p = 0.001$). This difference was more pronounced in patients who underwent nonprimary PCI. In contrast, off-site facilities had a greater incidence of patients who had a clinical presentation of STEMI or NSTEMI (41% vs. 29%, $p < 0.001$) (Fig. 1).

Observed unadjusted procedural outcomes. Observed unadjusted procedural outcomes are shown in Table 4. Off-site facilities had slightly higher aggregate procedural success (94% vs. 93%, $p = 0.010$), predominantly due to higher success rates in nonprimary PCI cases. Aggregate total complications were similar in both off- and on-site facilities (6.5% vs. 6.3%), but off-site programs tended to have more bleeding events, and on-site more vascular complications. Off-site programs had fewer total complications in primary PCI (11.6% vs. 13.4%, $p = 0.029$) and had lower general (2.6% vs. 3.3%, $p = 0.001$) and vascular (0.8% vs. 1.1%, $p = 0.017$) complication rates in nonprimary PCI patients compared with on-site facilities.

In the overall PCI cohort, there was no significant difference in the incidence of emergency CABG surgery (0.3% vs. 0.4%, $p = 0.271$) or mortality with emergency CABG (13.6% vs. 12.8%, $p = 0.907$) between off- and on-site facilities, respectively. There was no difference in either of these variables when the analysis was stratified into primary PCI and nonprimary PCI patients. Although the unadjusted aggregate mortality rate was higher in off-site facilities (1.7% vs. 1.2%, $p < 0.001$) and appeared to be confined to patients who did not require emergency surgery, this difference did not persist when stratified by primary or nonprimary PCI. This increased unadjusted aggregate mortality was most likely due to a higher proportion of primary PCI patients (22% vs. 10%, $p < 0.001$) and STEMI and NSTEMI presentations (41% vs. 29%, $p < 0.001$) in off-site compared with on-site programs, respectively.

Primary PCI reperfusion times in nontransferred patients were significantly shorter in off-site PCI centers (mean 2.1 ± 5.1 h, median 1.4 h) compared with on-site (mean 2.6 ± 8.4 h, median 1.5 h, $p < 0.001$). These "reperfusion times" were defined as the time of arrival at the facility to the time of first treatment device deployment (27). Although both groups followed the same definition, these data were collected before there were major national quality

Table 2 Institutional Characteristics

Variable	Off-Site (n = 60)	On-Site (n = 405)	p Value
Number of CMS-certified beds			
Median	198	371	<0.001
Mean ± SD	212 ± 109	403 ± 188	
<200	31 (52%)	40 (10%)	<0.001
≥200 and <400	27 (45%)	178 (44%)	
≥400	2 (3%)	185 (46%)	
Location/community type			
Rural	21 (35%)	67 (17%)	<0.001
Suburban	24 (40%)	115 (28%)	
Urban	15 (25%)	223 (55%)	
Average annual PCI volume			
Median	134	612	<0.001
Mean ± SD	166 ± 138	745 ± 551	
<200	43 (72%)	23 (6%)	<0.001
≥200 and <400	14 (23%)	98 (24%)	
≥400	3 (5%)	284 (70%)	
Average annual primary PCI volume			
Median	32	66	<0.001
Mean ± SD	35 ± 22	78 ± 52	
≥36	25 (42%)	324 (80%)	<0.001

Two sites had missing Centers for Medicare and Medicaid Services (CMS) bed data. Primary percutaneous coronary intervention (PCI) indicates PCI performed as first-line therapy for reperfusion in the presence of ST-segment elevation myocardial infarction (STEMI), and does not include rescue or facilitated PCI or PCI for non-STEMI.

Table 3 Off-Site Capabilities Survey

Characteristic	Off-Site (n = 53)
Average travel distance to surgical facility, miles	
Mean ± SD	36 ± 59
<10	11 (21%)
≥10 and <20	18 (34%)
≥20 and <40	11 (21%)
≥40	13 (25%)
Average transit time to surgical facility, min	
Mean ± SD	25 ± 17
<10	4 (8%)
≥10 and <20	16 (30%)
≥20 and <30	19 (36%)
≥30	14 (26%)
Predominant transportation mechanism	
Ground ambulance	28 (53%)
Helicopter	11 (21%)
Fixed wing aircraft	1 (2%)
Combination of ground or air	13 (25%)
Dedicated staff and facilities for PCI	
24 h, 7 days a week	49 (92%)
Daytime during weekdays only	3 (6%)
Variable time frames	1 (2%)
Type of PCI provided	
Only primary PCI for acute MI	11 (21%)
Both primary PCI and elective PCI	42 (79%)
Only elective PCI	0 (0%)
Catheterization laboratory staff experience*	
Work only at off-site PCI center	41 (77%)
Rotate between off- and on-site PCI centers	11 (21%)
Interventional operators at facility	
Mean ± SD	5 ± 4
1	5 (9%)
2 to 3	18 (34%)
4 to 5	11 (21%)
6 or more	19 (36%)
Interventional operators' experience*	
Work only at off-site PCI center	9 (17%)
Rotate between off- and on-site PCI centers	43 (81%)

*One site did not respond.
Abbreviations as in Table 1.

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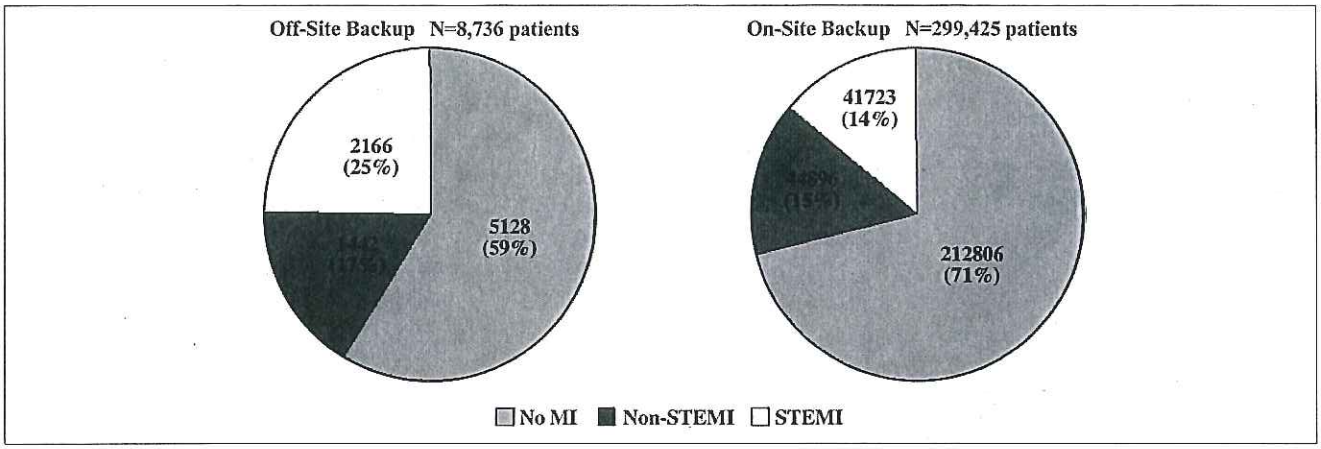
Figure 1 MI Presentation Status

Pie charts showing the relative distribution of myocardial infarction (MI) presentation within centers with on- or off-site surgical backup. **Blue areas** indicate no MI; **purple areas** indicate non–ST-segment elevation myocardial infarction (non-STEMI); **yellow areas** indicate STEMI. $p < 0.001$.



improvement initiatives and attention to the detailed measurements of true "door-to-balloon" times. Therefore, these times do not reflect the current door-to-balloon standards.

Risk-adjusted outcomes. After risk adjustment, there were no mortality differences between off- and on-site facilities among total PCI patients, primary PCI patients, nonprimary PCI patients, or patients who did not require emergency surgery (Fig. 2). There was a higher risk-adjusted odds of emergency surgery in on-site PCI centers (odds ratio: 0.60 [95% confidence interval: 0.37 to 0.98], $p = 0.042$).

A sensitivity analysis was performed comprising models that imputed missing mortality from off-site centers to 2 potential scenarios. Although the point estimate changed from 0.88 to 1.21, the confidence intervals surrounding these estimates were not statistically significant between off- and on-site facilities under either of these extreme assumptions.

Discussion

This study represents the largest and most comprehensive clinical comparison of PCI centers in the U.S. with and without cardiac surgery support on site. Despite lower annual PCI procedural volumes and more patients presenting with MI subsets, off-site PCI facilities reporting to the NCDR CathPCI Registry had similar rates of procedural success, morbidity, emergency surgery, and risk-adjusted mortality when compared with on-site PCI centers. These results persisted whether PCI was performed as primary therapy for STEMI or in a less urgent nonprimary PCI setting. In addition, the off-site Capabilities Survey in this study provided more descriptive information than has been previously reported in the literature regarding the organization and logistics of established off-site PCI programs.

It is important to contrast this study with the few large comparative reports in the literature. Wennberg et al. (16) found no difference in risk-adjusted mortality for primary PCI at facilities without surgery backup on site, but an increase in mortality for nonprimary/rescue PCI, particularly at very low-volume programs (<50 Medicare PCIs per year). Although their study had more hospitals without surgery on site (n = 178) and similar patient volumes (n = 8,168), the time period was from 1999 to 2001, and the data were derived from coded admission/discharge billing diagnoses confined to the Medicare population. In contrast, our study was based on well-defined contemporary clinical parameters and included clarification of ambiguous transfer data from the off-site PCI programs. We found no significant difference for risk-adjusted mortality between centers with and without surgery on site, in either primary or nonprimary PCI patients.

Ting et al. (17) previously reported comparable acute and long-term outcomes for both primary and elective PCI in a propensity score analysis of 1,007 cases from a PCI center without surgery on site matched to the same number of patients from a center with surgery on site. Of note, these Mayo Clinic facilities did not participate in the NCDR, and thus their patients were not included in our analysis.

Finally, in a recent report based on SCAAR (Swedish Coronary Angiography and Angioplasty Registry), Carlsson et al. (18) compared 8,838 PCI procedures from 14 PCI facilities that did not have cardiac surgery on site to 25,525 procedures from 10 PCI centers that did have surgery on site. Their analysis was adjusted for baseline variables, and demonstrated comparable 30-day and 1-year mortality and morbidity outcomes for both primary PCI and nonacute PCI. Although different variables were used in our risk-

Table 4 Observed Unadjusted Procedural Outcomes

Outcome	All PCI Patients			Primary PCI Patients			Nonprimary PCI Patients		
	Off-Site (n = 8,736)	On-Site (n = 299,425)	p Value	Off-Site (n = 1,934)	On-Site (n = 31,099)	p Value	Off-Site (n = 6,802)	On-Site (n = 268,312)*	p Value
PCI procedure success	8,194 (94)	278,844 (93)	0.010	1,756 (92)	27,909 (91)	0.139	6,438 (95)	250,923 (94)	<0.001
Total complications	567 (6.5)	18,796 (6.3)	0.399	222 (11.6)	4,104 (13.4)	0.029	345 (5.1)	14,692 (5.5)	0.150
General complications	320 (3.7)	11,629 (3.9)	0.304	144 (7.5)	2,792 (9.1)	0.021	176 (2.6)	8,837 (3.3)	0.001
Bleeding complications	261 (3.0)	7,036 (2.4)	<0.001	104 (5.4)	1,620 (5.3)	0.749	157 (2.3)	5,416 (2.0)	0.093
Vascular complications	66 (0.8)	3,198 (1.1)	0.005	14 (0.7)	344 (1.1)	0.115	52 (0.8)	2,854 (1.1)	0.017
Overall mortality	151 (1.7)	3,632 (1.2)	<0.001	97 (5.1)	1,607 (5.2)	0.869	54 (0.8)	2,025 (0.8)	0.700
Emergency CABG	26 (0.3)	1,110 (0.4)	0.271	14 (0.7)	357 (1.2)	0.091	12 (0.2)	753 (0.3)	0.107
Mortality									
Emergency CABG	3/22† (13.6)	142/1,110† (12.8)	0.907	2/12† (16.7)	59/357† (16.5)	0.990	1/10† (10.0)	83/753† (11.0)	0.918
No emergency CABG	148/8,669† (1.7)	3,488/298,293† (1.2)	<0.001	95/1,894† (5.0)	1,547/30,741† (5.0)	0.975	53/6,775† (0.8)	1,941/267,538† (0.7)	0.587
Reperfusion times (h), nontransfer patients				(n = 1,678)	(n = 19,708)				
Mean ± SD				2.1 ± 5.1	2.6 ± 8.4	<0.001			
Median				1.4	1.5				

Procedure success was defined as residual stenosis <50% with Thrombolysis In Myocardial Infarction flow grade 3 and minimal decrease in stenosis ≤20% in all lesions attempted. Total complications was defined as any of the following complications: general complications: periprocedural MI, cardiogenic shock, congestive heart failure, cerebrovascular accident, tamponade, thrombocytopenia, contrast reaction, renal failure; bleeding complications: bleeding at the access site, retroperitoneal, gastrointestinal, genitourinary, or other; vascular complications: access site occlusion, peripheral embolization, arterial dissection, arterial pseudoaneurysm, or arterio-venous fistula. Primary PCI was defined as PCI performed as first-line therapy for reperfusion in the presence of STEMI; does not include rescue or facilitated PCI or PCI for non-STEMI. Reperfusion time indicates time of arrival to facility to time of first intracoronary treatment device deployment. *14 patients not included due to missing value for variable "Acute PCI." †Clarified data.

Abbreviations as in Tables 1 and 2.

adjusted model, the in-hospital mortality/morbidity results are similar to these 2 studies.

The nonprimary PCI patient cohort in our study is not a reflection of purely elective PCI, as this group includes some patients who presented with acute coronary syndromes, NSTEMI, or after STEMI. However, the consideration of this group as "nonurgent" and a reasonable surrogate for elective PCI is consistent with the analyses done in the literature cited in the preceding text. In our study, the differentiation of patients in off-site versus on-site PCI centers into primary PCI and nonprimary PCI permitted a more comprehensive assessment and risk-adjustment analysis of the major clinical end points.

Within our study cohort, the aggregate incidence of emergency surgery was comparably low at off- and on-site PCI facilities (0.3% to 0.4%, respectively) and consistent with contemporary studies (2,3). When emergency surgery was necessary, the mortality rate was similarly high between off- (13.6%) and on-site (12.8%) facilities, and comparable to that reported in prior literature (2,3).

There have been concerns that off-site PCI facilities may tend to keep some borderline stable patients with suboptimal procedural results rather than initiate the logistics of emergency transfer to an outside surgical center. These patients may have adverse outcomes, as seems to be suggested by the aggregate unadjusted mortality rate in our study. However, in the risk-adjusted analyses, there was comparable in-hospital mortality for those off-site patients who were not transferred for emergency surgery.

Conversely, the 1.5-fold higher risk-adjusted incidence of emergency surgery at on-site PCI centers could reflect a lower threshold to opt for emergency surgery if there is any doubt about a suboptimal result, as surgery is available without the added logistics of transfer. An alternative explanation could be that on-site centers perform higher risk elective cases, as is suggested by the clinical and lesion characteristics profiles in this study. In addition, it is possible that patients may have had initial angiography at off-site facilities, found to have complex coronary anatomy and/or high-risk MI subsets with a higher predisposition to emergency surgery, then deferred and transferred to an on-site center for PCI. These complicated potential scenarios and the detailed reasons for case selection were beyond the scope of the NCDR database elements. Regardless, the increased risk-adjusted incidence of emergency surgery at on-site PCI programs did not translate into an increase in mortality.

Data from the Capabilities Survey revealed a mean transit time of 25 ± 17 min from off-site facilities. The British Cardiovascular Interventional Society has recommended a 90 min to emergency surgery standard (29).

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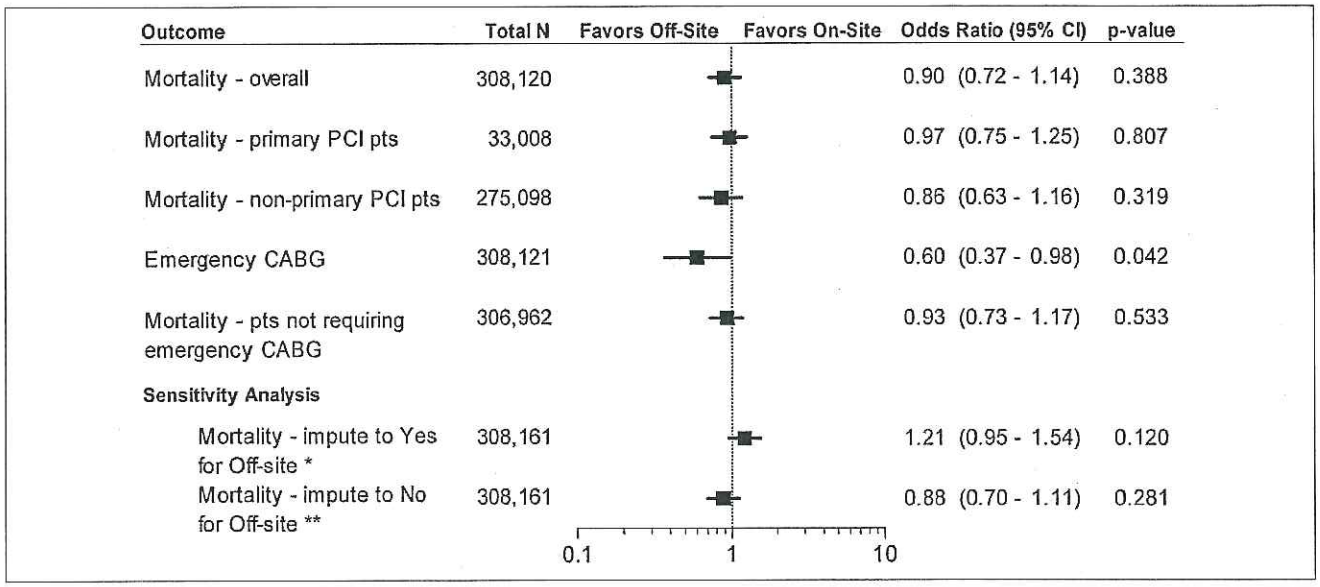
Figure 2 Risk-Adjusted Analysis of Outcomes

Odds ratio plot of risk-adjusted outcomes, including sensitivity analysis for missing mortality data. Odds ratio: outcomes for patients at off-site (vs. on-site) facilities, adjusting for within site correlations and potential confounding variables. *Worst case scenario: all patients with missing mortality data were considered to have died. **Best case scenario: all patients with missing mortality data were considered as alive. CABG = coronary artery bypass graft surgery; CI = confidence interval; PCI = percutaneous coronary intervention; pts = patients.



This includes not only the transit time, but also the total time from the initial decision to transport (including call time, transfer of patient from catheterization laboratory to vehicle, vehicle to operating suite), to the actual time of initiating cardiopulmonary bypass at the receiving surgical center. The transit time in the NCDR survey was an estimate of basic travel time and did not include the above additional time elements. However, based on the transit time, most off-site PCI programs in our study may be able to meet this global standard of 90 min by having a clear decision process and heightened logistical coordination with ambulance services and the receiving surgical center.

The demographics of the off-site centers in our study suggests these facilities conform to the stated goals of lowering geographic barriers and facilitating access to PCI, particularly for those patients presenting with STEMI (5,6). The Capabilities Survey also indicates these programs are well staffed and organized with good logistical plans. The fact that 81% of the off-site center operators rotated to an on-site PCI center suggests that most of the off-site facilities were hub-and-spoke centers staffed by large group practices. Overall, the information suggests that the off-site PCI programs in this study have demonstrated a strong commitment to the classic Donabedian triad of structure, process, and outcomes measurements (30).

Study limitations. First, this study is subject to the usual concerns regarding observational registry data. There may be an inherent bias in off-site PCI programs that are either mandated by regulatory agencies or choose on their own to participate in the NCDR. Participants in any registry may be prone to "game" the system, particularly if score carding and public disclosure is an issue.

Second, this study includes outcomes up to the time of hospital discharge. Data regarding long-term outcomes are not currently captured in the NCDR CathPCI Registry. In addition, outcomes are assessed and analyzed on an institutional level, not on an individual operator level.

Third, specific in-depth details regarding clinical presentation, case selection, procedural complications, morbidity, and mortality were sometimes beyond the purview of the basic datasets. However, a special data clarification effort was utilized to resolve the 172 of 8,736 off-site patients (2%) for whom mortality or transfer data were questioned, resulting in clarification of 154 of these patients (90%), leaving 18 of 8,736 (0.2%) not clarified. A sensitivity analysis confirmed that the unclarified data would not have affected the risk-adjusted mortality analysis results.

Fourth, although this NCDR study indicates that nonprimary PCI can be done safely at off-site facilities, the efficacy of truly elective PCI at off-site facilities can perhaps be best addressed by a large randomized prospective trial such as the C-PORT (Cardiovascular Patient Outcome Research Team) Elective Angioplasty Study, which is under way. However, such studies are difficult to conduct, and results may not be forthcoming for some time. In the interim, a comprehensive large database such as the NCDR CathPCI Registry offers a realistic and

relative contemporary quality assurance standard to monitor these issues. Based on the experiences gained with this current study, the NCDR plans to sponsor a proactive comprehensive working group of off-site PCI centers to further communicate and track outcomes. This effort will coincide with the upcoming transition to the next CathPCI database version 4.0.

Finally, a participation bias cannot be excluded. The total number of PCI centers in the U.S. that do not have surgery on site is not definitively known (22) but may number ≈250. Of these, it is estimated that one-third submit data to another peer-reviewed registry, a spoke and hub partner database, or a multicenter trial. Thus, the 60 off-site PCI facilities in this NCDR study may represent a minority of such programs in the nation and are probably in the upper tier of quality. With this perspective, the results reported here may not be applicable to all PCI centers without surgical backup on site, particularly those that do not participate in any formal data registry or clinical trial.

Conclusions

Compared with on-site PCI centers, off-site PCI programs in the NCDR were predominantly located in nonurban areas, had lower annual PCI volume, treated a higher percentage of patients who presented with subsets of MI, and had better reperfusion times in primary PCI. Off-site PCI centers had similar observed procedure success, morbidity, emergency cardiac surgery rates, and mortality in cases that required emergency surgery. The risk-adjusted mortality rates in off-site PCI facilities were comparable to those of PCI centers that had cardiac surgery on site, regardless of whether PCI was performed as primary therapy for STEMI or in a nonprimary setting.

These findings should not be extrapolated to encourage the widespread proliferation of more PCI programs without surgery on site to fulfill a political or an economic agenda. Rather, our study does confirm the safety of an off-site strategy at PCI centers where rigorous clinical, operator, and institutional criteria are in place and where data are submitted and reviewed in a comprehensive multicenter registry such as the NCDR.

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Reprint requests and correspondence: Dr. Michael A. Kutcher, Professor of Internal Medicine (Cardiology), Wake Forest University School of Medicine, Medical Center Boulevard, Winston-Salem, North Carolina 27157-1045. E-mail: mkutcher@wfubmc.edu.

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Key Words: percutaneous coronary intervention ■ cardiac surgery ■ outcomes analysis.

APPENDIX

For supplemental NCDR information, please see the online version of this article.

ATTACHMENT IV

The Burden of Cardiovascular Diseases in Connecticut –
2010 Surveillance Report
March 2011

The Burden of Cardiovascular Diseases in Connecticut

2010 Surveillance Report

March 2011

State of Connecticut
Department of Public Health
410 Capitol Avenue
P.O. Box 340308
Hartford, CT 06134-0308

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Prepared by
Stephanie M. Poulin, MPH, MT(ASCP) and Margaret M. Hynes, PhD, MPH
Connecticut Department of Public Health
Health Information Systems and Reporting Section
Surveillance and Reporting Unit

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EXECUTIVE SUMMARY

- Cardiovascular diseases (CVD) are a great public health concern. CVD account for about one-third of all Connecticut resident deaths. Coronary heart disease (CHD), cerebrovascular disease (stroke) and heart failure (HF) are the main types, accounting for 48%, 15%, and 8% respectively of all CVD deaths.

- The CVD, CHD, and stroke age-adjusted mortality rates of Connecticut residents decreased significantly between 1999 and 2008.

- Approximately 55% of all Connecticut resident CVD deaths are among females. However, males have significantly higher age-adjusted CVD mortality rates (2006-2008 data).

- Black Connecticut residents have the highest age-adjusted CVD mortality rate as well as higher age-adjusted CVD, CHD, and stroke premature mortality rates compared with White and Hispanic residents (2006-2008 data).

- Hispanic Connecticut residents have significantly lower age-adjusted CVD and CHD mortality rates than White residents (2006-2008 data).

- About 18% of all hospital discharges in Connecticut are due to CVD. Approximately 26% of CVD hospitalizations are due to CHD, 12% to stroke, and 18% to HF (2008 data).

- Connecticut male residents have higher age-adjusted rates of hospitalizations for CVD, CHD, stroke, and HF than female residents. Black Connecticut residents have higher rates of hospitalizations for CVD, stroke, and HF than White and Hispanic residents (2008 data).

- About $2.2 billion was billed for CVD hospitalizations in Connecticut in 2008. Approximately 34% of CVD charges are for CHD, 12% for stroke, and 12% for HF. CVD also incur enormous indirect costs.

- Risk factors for CVD may be modifiable or non-modifiable. Key modifiable risk factors are high blood pressure, high blood cholesterol, smoking, diabetes, obesity, and physical inactivity. Non-modifiable risk factors include increasing age and family history of heart disease and stroke.

- High blood pressure (HBP) is a major risk factor for heart attack and stroke. About 27% of Connecticut adults have HBP. Connecticut males are more likely than females to have HBP. About 25% of White, 36% of Black, and 22% of Hispanic adults in Connecticut have HBP. Also, Connecticut adults with lower annual household incomes are more likely to have HBP compared to adults with higher annual household incomes (2007-2009 data).

- High blood cholesterol (HBC) is a major risk factor for CHD. About 38% of Connecticut adults have HBC. Connecticut males are more likely than females to have HBC. The prevalence of HBC increases with age. Black and Hispanic Connecticut adults are less likely than White adults to have had their blood cholesterol tested. Connecticut adults with lower annual household incomes are less likely than adults with higher annual household incomes to have had their blood cholesterol tested (2007-2009 data).

- Cigarette smoking increases the risk of heart attack, stroke, and death from CHD. About 16% of Connecticut adults are current smokers. Current adult smokers are more likely to be younger, have lower annual household incomes, and be less educated. Among adults, smoking rates do not vary significantly by gender or race and ethnicity (2007-2009 data). According the 2009 Connecticut School Health Survey, 15.3% of high school students are current smokers. White high school students are more likely than Black and Hispanic students to be current smokers.

- Diabetes has been recognized as a major risk factor for CVD. An estimated 6.9% of Connecticut adults have diagnosed diabetes. Connecticut males are more likely to have diabetes than females. Also, high rates of diabetes are associated with older age, lower socioeconomic position, and racial and ethnic minority status. About 5.6% of White, 14.9% of Black, and 10.5% of Hispanic adults in Connecticut have diabetes (2007-2009 data).

- Obesity is an independent risk factor for CVD. An estimated 10.4% of high school students in Connecticut are obese. High school males are more likely to be obese than females and Hispanic students are more likely to be obese than White and Black students (2009 data). Approximately 21% of Connecticut adults are obese. Older adults are more likely to be obese than younger adults; males are more likely to be obese than females; and those with lower annual household incomes are more likely to be obese than those with higher annual household incomes. Also, Black and Hispanic adults are more likely to be obese than White adults (2007-2009 data).

- Physical inactivity is associated with an increased risk of a number of chronic health conditions including CHD, high blood pressure, and obesity. Approximately 47% of Connecticut adults participate in less than the recommended amount of physical activity. Older adults, females, and adults with lower annual household incomes have higher rates of physical inactivity. About 44.5% of White, 59.7% of Black, and 54.2% of Hispanic Connecticut adults are physically inactive (2007-2009 data).

- The co-prevalence of risk factors places an individual at elevated risk for CHD and stroke. About 42% of Connecticut adults have two or more modifiable risk factors for CVD (2007-2009 data).

- Early recognition of the signs and symptoms of heart attack and stroke increase the likelihood of immediate emergency transport to the hospital and timely medical care. Only 13.6% of Connecticut adults can identify all the proper heart attack signs and only 22.6% can identify all the proper stroke signs. Women tend to be more knowledgeable than men about the signs and symptoms of heart attack and stroke (2007-2009 data).

- Access to health care is crucial to the prevention, treatment, and management of CVD. About 9% of adults in Connecticut do not have health insurance. Approximately 6% of White, 21% of Black, and 30% of Hispanic adults in Connecticut do not have health insurance (2007-2009).

- Targeted public health interventions are warranted for all Connecticut residents with multiple risk factors. Special emphasis should be placed on evidence-based interventions that address risk factor reduction among Black, Hispanic, and lower-income Connecticut adults.

THE BURDEN OF CARDIOVASCULAR DISEASES IN CONNECTICUT

INTRODUCTION

Cardiovascular disease refers to a wide variety of heart and blood vessel diseases. The most common forms of cardiovascular disease are coronary heart disease (CHD) and cerebrovascular disease. Essential hypertension, heart failure (HF), and atherosclerosis are other common cardiovascular diseases (CVD).[1] CVD are of great public health concern because more than one-third of all deaths in Connecticut are due to CVD and because prevention efforts have shown great potential in reducing the morbidity, mortality, and disability of CVD.[2, 3]

MORTALITY

CVD accounted for 9,351 Connecticut resident deaths in 2008, or about 33% of all deaths for the period. In contrast, cancer deaths accounted for 24%; chronic lower respiratory disease, 5%; unintentional injuries, 5%; and diabetes, 2% of all Connecticut resident deaths (Table 1).[3]

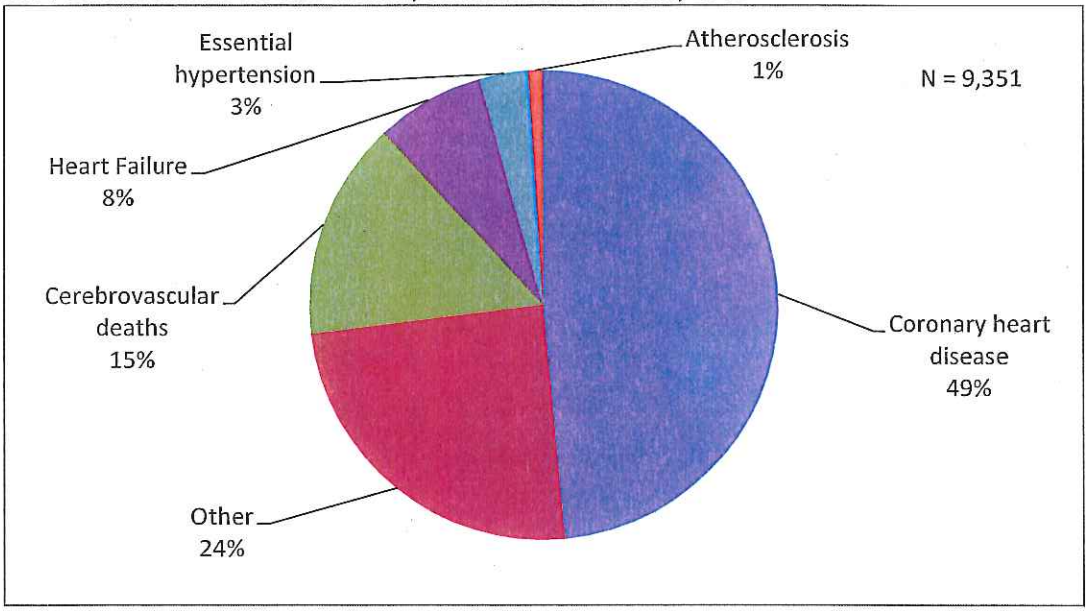
Table 1. Connecticut Resident Deaths, 2008

Cause of Death	Number of Deaths	Percent of Deaths
All Causes	28,749	100%
Cardiovascular Disease	9,351	33%
Cancer	6,765	24%
Chronic Lower Respiratory Disease	1,494	5%
Unintentional Injury	1,362	5%
Alzheimer's Disease	831	3%
Pneumonia and Influenza	688	2%
Diabetes	618	2%

Source: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

The major CVD are CHD and cerebrovascular disease or "stroke". Stroke is the most severe clinical manifestation of cerebrovascular disease, and the terms are used interchangeably in this report.[4] CHD accounts for 49% of all CVD deaths and includes hypertensive heart disease and ischemic heart disease (2008 data). Stroke is responsible for about 15% of CVD deaths in Connecticut, and includes two major types - ischemic stroke and hemorrhagic stroke. HF accounts for 8% of all CVD deaths, while essential hypertension and atherosclerosis account for 4% of all CVD deaths in Connecticut (Figure 1).[3]

Figure 1. Cardiovascular Disease Deaths, Connecticut Residents, 2008

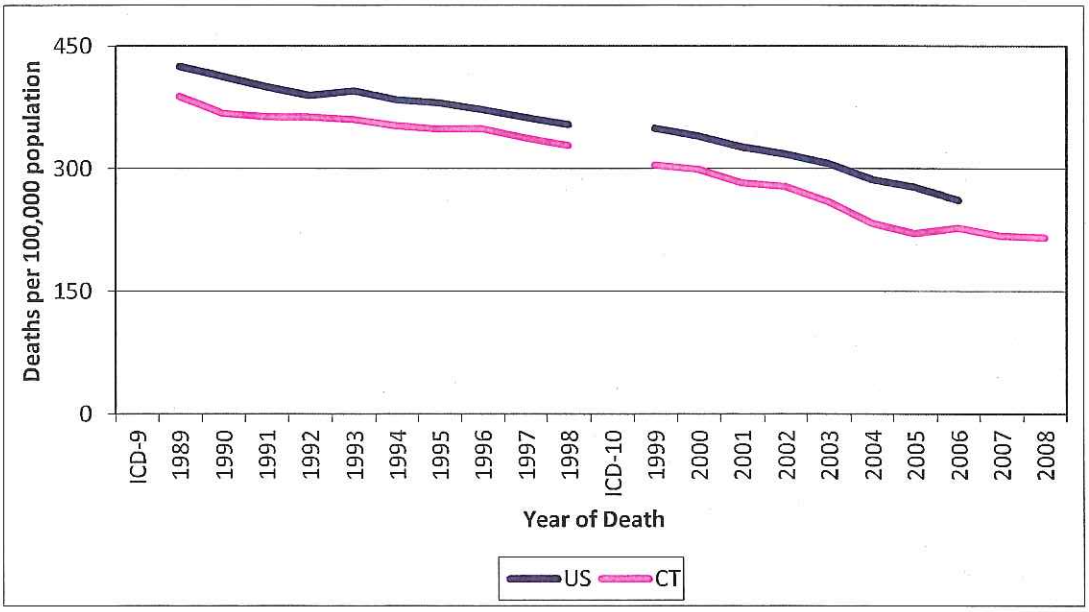


Sources: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

Trends in Age-adjusted Mortality

Since the 1990s, CVD and CHD mortality rates* have decreased significantly for all Connecticut residents.[5, 6] This continuing decrease in Connecticut CVD and CHD mortality rates mirrors a similar decline in CVD and CHD mortality rates nationwide.[7] CVD and CHD mortality rates for Connecticut residents have been consistently lower than those for the United States population (Figure 2 and Figure 3).[3, 7] Since 2001, the Connecticut resident CHD mortality rate has been below the *Healthy People 2010* target of 166 per 100,000 population (Figure 3). There is no *Healthy People 2010* target for CVD.[8]

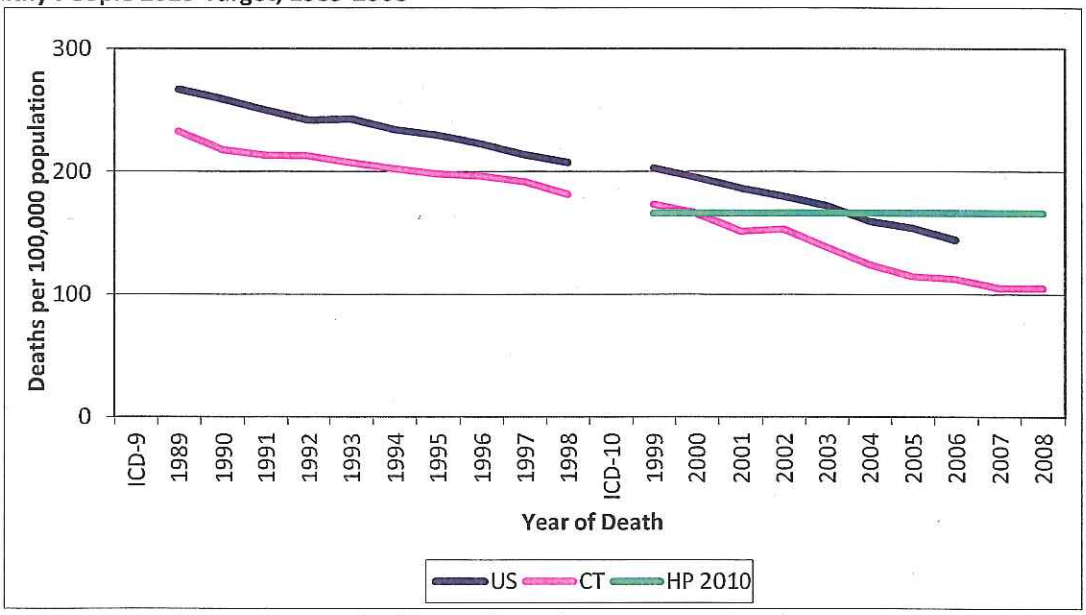
Figure 2. Age-adjusted Mortality Rates for Cardiovascular Disease, Connecticut & United States, 1989-2008



Sources: Connecticut Department of Public Health, Vital Statistics Mortality Files, 2010. Centers for Disease Control and Prevention, 2010. Note: Rates are adjusted to the 2000 US standard population. Classification includes deaths with ICD-9 codes: 390-459.9 (1989 to 1998); ICD-10 codes: I00-I78.9 (1999 to 2008).

* The mortality rates presented in this report are age-adjusted mortality rates (AAMR). The AAMRs were computed by the direct method using the 2000 U.S. standard million population. The AAMRs were calculated using the death records of Connecticut residents.

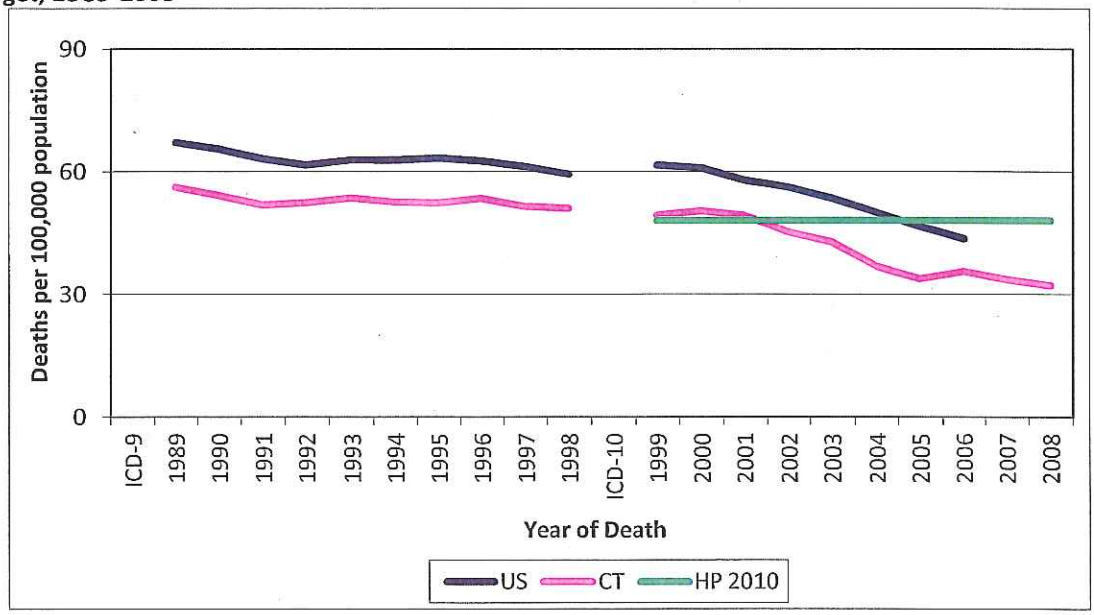
Figure 3. Age-adjusted Mortality rates for Coronary Heart Disease, Connecticut, United States, & Healthy People 2010 Target, 1989-2008



Source: Connecticut Department of Public Health, Vital Statistics Mortality Files, 2010. Centers for Disease Control and Prevention, 2010. Note: Rates are adjusted to the 2000 US standard population. Classification includes deaths with ICD-9 codes: 402,410-414, 429.2 (1989 to 1998); ICD-10 codes: I11, I20-25 (1999 to 2008).

Stroke mortality rates of Connecticut residents did not change significantly in the 1990s.[5] However, decreasing trends have been observed since 1999.[6] Connecticut resident mortality rates from stroke have been consistently lower than those of the U.S.[7] Since 2002, the Connecticut resident stroke mortality rate has been below the *Healthy People 2010* target of 48 per 100,000 population (Figure 4).[3, 8]

Figure 4. Age-adjusted Mortality Rates for Stroke, Connecticut, United States, & Healthy People 2010 Target, 1989-2008

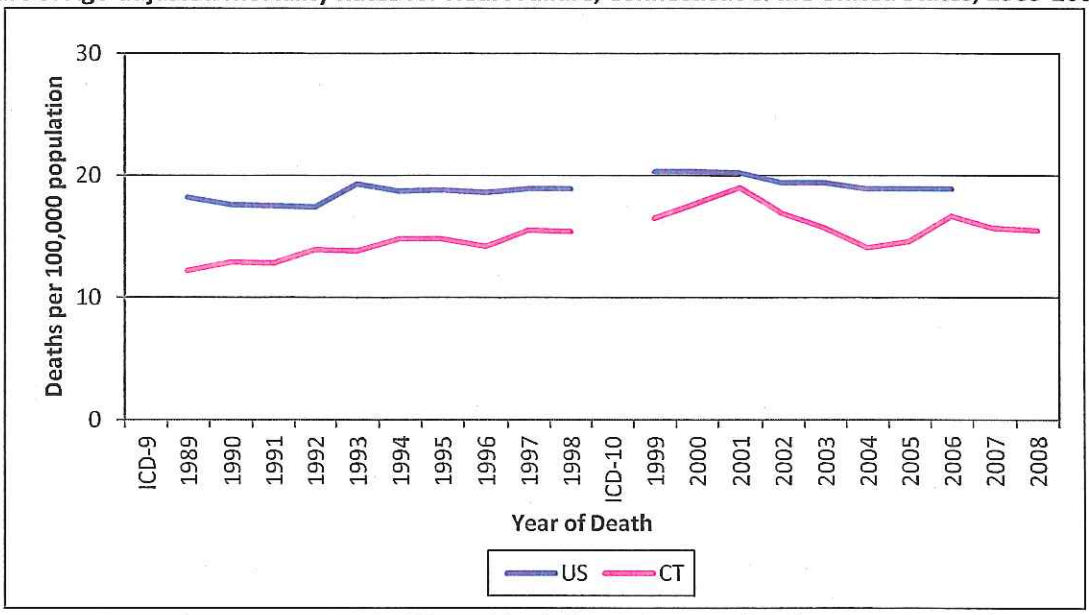


Sources: Connecticut Department of Public Health, Vital Statistics Mortality Files, 2010. Centers for Disease Control and Prevention, 2010. Note: Rates are adjusted to the 2000 US standard population. Classification includes deaths with ICD-9 codes: 430-438 (1989 to 1998); ICD-10 codes: I60-69 (1999 to 2008).

During the 1990s, the Connecticut resident HF mortality rates increased significantly.[5] The increase in the HF mortality rates throughout the 1990s has been attributed to more people surviving heart attacks experienced earlier in life and to the aging population.[1] Approximately 60% of all HF deaths in Connecticut occur in persons aged 85 or older. In contrast, 45% of all CHD deaths and 49% of all cerebrovascular disease deaths occur in persons 85 and older.[7] The 2006-2008 Connecticut resident HF mortality rate was significantly lower than the 1999-2001 rate [data not shown]; however, linear trend analyses of HF mortality rates did not show a statistically significant change ($p \leq 0.05$) for the period 1999-2008.[3,6]

Connecticut HF mortality rates have been consistently lower than those of the U.S.[3,7] There is no *Healthy People 2010* target for HF (Figure 5).[8]

Figure 5. Age-adjusted Mortality Rates for Heart Failure, Connecticut & the United States, 1989-2008



Sources: Connecticut Department of Public Health, Vital Statistics Mortality Files, 2010. Centers for Disease Control and Prevention, 2010. Note: Rates are adjusted to the 2000 US standard population. Classification includes deaths with ICD-9 code: 428.0 (1989 to 1998); ICD-10 code: 150.0 (1999 to 2008).

Mortality by Gender

Approximately 55% of all Connecticut resident CVD deaths are among females (2006-2008 data). While more females than males die from CVD in Connecticut, males have higher CVD mortality rates (Table 2). Connecticut males have a 45% higher mortality rate due to CVD compared with females, a 71% higher mortality rate due to CHD, and a 30% higher mortality rate due to HF ($p<0.001$ for all comparisons). The stroke mortality rates of Connecticut males and females do not differ significantly.[3]

Table 2. Cardiovascular Diseases Deaths and Age-adjusted Mortality Rates (AAMR) per 100,000 Population, Connecticut Residents, 2006-2008

Cause of Death	All		Male		Female	
	Deaths	AAMR	Deaths	AAMR	Deaths	AAMR
All Cardiovascular Diseases	28,369	219.7	12,889	266.8	15,480	184.4
Coronary Heart Disease	13,840	107.4	6,874	141.3	6,966	82.7
Stroke	4,385	33.8	1,646	34.5	2,739	32.6
Heart failure	2,139	16.0	863	18.6	1,276	14.4

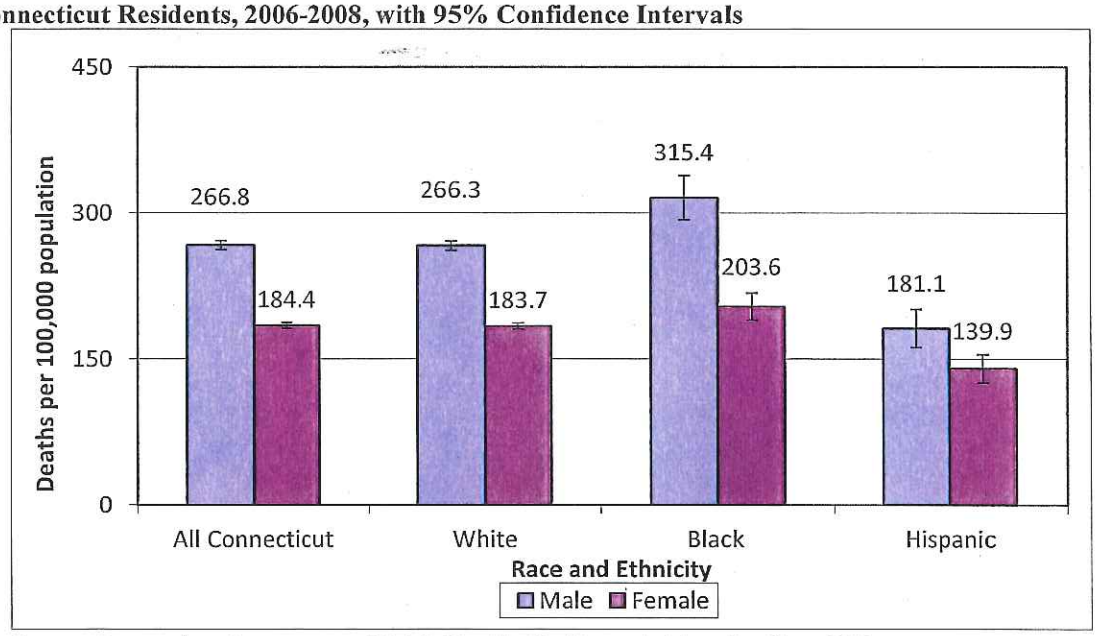
Source: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

Mortality by Gender, Race and Ethnicity

Cardiovascular Disease

The Connecticut resident CVD mortality rates differ by gender, race and ethnicity[†] with Black Connecticut residents having the highest CVD mortality rates (2006-2008 data). The CVD mortality rates of Black males and females are significantly higher than those of White males ($p<0.001$) and females ($p<0.05$), respectively. Black males and females also have significantly higher CVD mortality rates compared with Hispanic males and females ($p<0.001$ for both comparisons).[3] Conversely, Hispanic males and females have significantly lower mortality rates due to CVD than White males and females ($p<0.001$ for both comparisons) [Figure 6].[3] CVD mortality rates declined significantly for all subpopulation groups between 1999-2001 and 2006-2008 ($p<0.001$ for White and Black males and females; $p<0.005$ for Hispanic males; $p<0.01$ for Hispanic females) [data not shown].[3]

Figure 6. Age-adjusted Mortality Rates for Cardiovascular Disease by Gender, Race and Ethnicity, Connecticut Residents, 2006-2008, with 95% Confidence Intervals



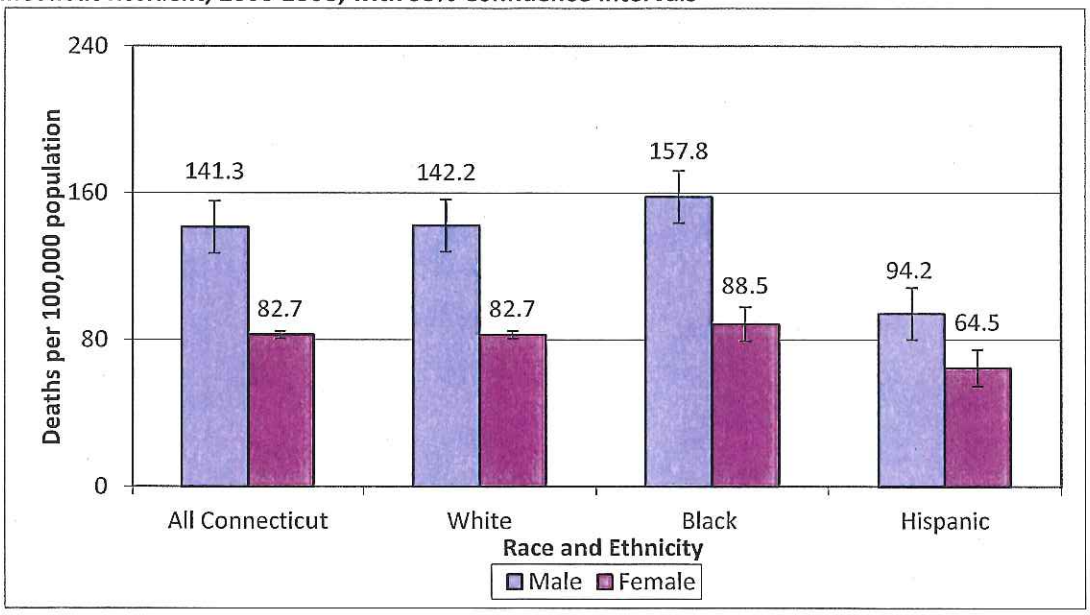
Source: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

[†] Throughout this report racial groupings (e.g., "Black", "White") exclude persons of Hispanic ethnicity. A Hispanic ethnicity category is included in figures and tables reflecting data separate from race categories. Therefore, the modifier "non-Hispanic" is assumed.

Coronary Heart Disease

The CHD mortality rates differ somewhat by gender, race and ethnicity (2006-2008 data). Hispanic males and females have significantly lower CHD mortality rates than White males and females as well as Black males and females ($p < 0.001$ for males; $p<0.005$ for females) [Figure 7].[3] The CHD mortality rates of White males and females do not differ significantly from the rates of Black males and females (Figure 7).[3] CHD mortality rates declined significantly for all subpopulation groups in Connecticut between 1999-2001 and 2006-2008 ($p<0.01$ for Hispanic females; $p<0.001$ for other comparisons) [data not shown].[3]

Figure 7. Age-adjusted Mortality Rates for Coronary Heart Disease by Gender, Race and Ethnicity, Connecticut Resident, 2006-2008, with 95% Confidence Intervals

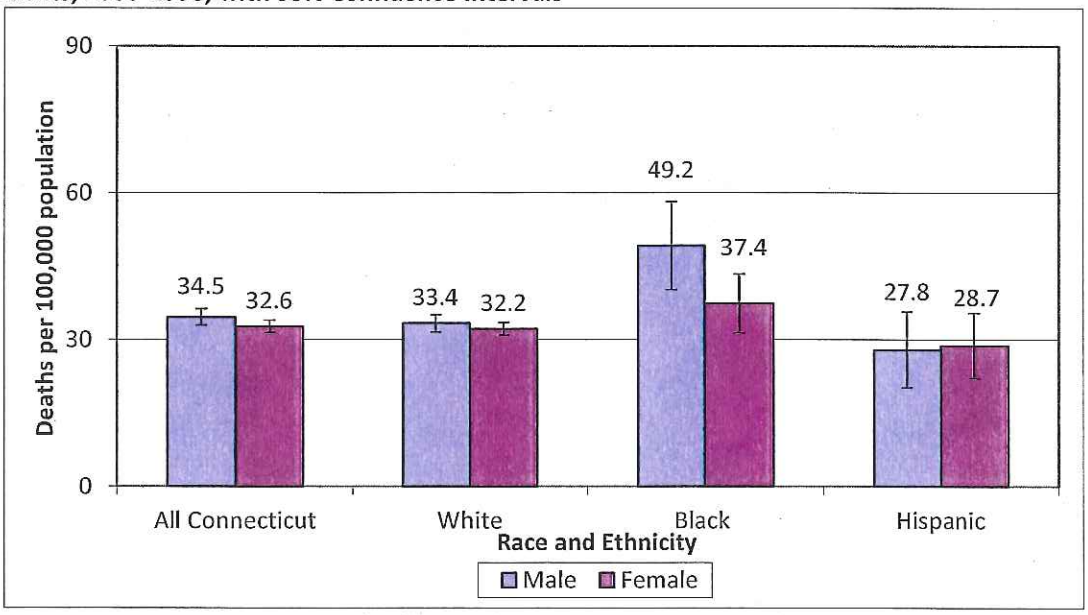


Source: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

Stroke

Stroke mortality rates differ somewhat by gender, race and ethnicity (2006-2008). Black males have a significantly higher stroke mortality rate than White ($p<0.005$) and Hispanic males ($p<0.05$) [Figure 8].[3] However, the stroke mortality rates for Hispanic and White males do not differ significantly.[3] Likewise, the stroke mortality rates for White, Black, and Hispanic females do not differ significantly (Figure 8).[3] Stroke mortality rates declined significantly for White males ($p<0.001$), White females ($p<0.001$) and Black females ($p<0.005$) between 1999-2001 and 2006-2008 [data not shown].[3]

Figure 8. Age-adjusted Mortality Rates for Stroke by Gender, Race and Ethnicity, Connecticut Residents, 2006-2008, with 95% Confidence Intervals

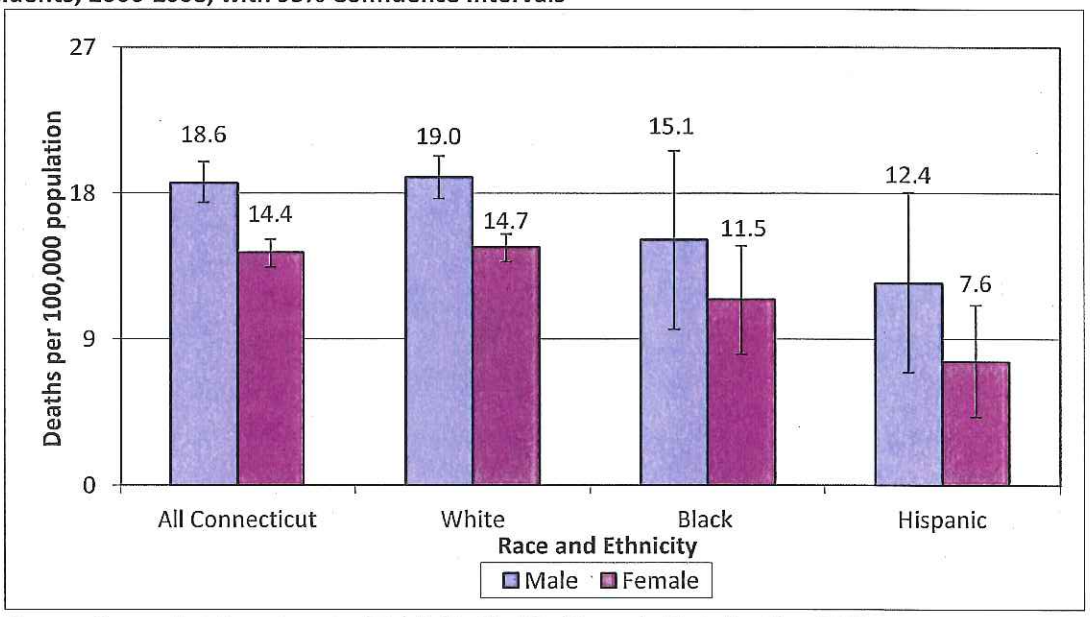


Source: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

Heart failure

HF mortality rates vary little by gender, race and ethnicity (2006-2008 data). While the HF mortality rate of White females is significantly higher than the rate of Hispanic females ($p<0.005$), the HF mortality rate of White and Black females does not differ significantly [Figure 9].[3] The difference in the mortality rates of Black and Hispanic females does not reach statistical significance.[3] Also, the HF mortality rates of White, Black, and Hispanic males do not differ significantly [Figure 9].[3] White females and the overall Black Connecticut population experienced a statistically significant decline in the HF mortality rate between 1999-2001 and 2006-2008 ($p<0.05$ for both comparisons) [data not shown].[3]

Figure 9. Age-adjusted Mortality Rates for Heart Failure by Gender, Race and Ethnicity, Connecticut Residents, 2006-2008, with 95% Confidence Intervals



Source: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

Premature Mortality by Gender, Race and Ethnicity

Premature mortality[‡], defined as the "years of potential life lost before age 75," focuses on deaths that occur at younger ages. For example, a person who dies at age 45 is considered to have lost 30 years of life, and a person who dies at 70 is considered to have lost 5 years of life.[9] Premature mortality is important because it emphasizes the years of productive life that are lost to society.

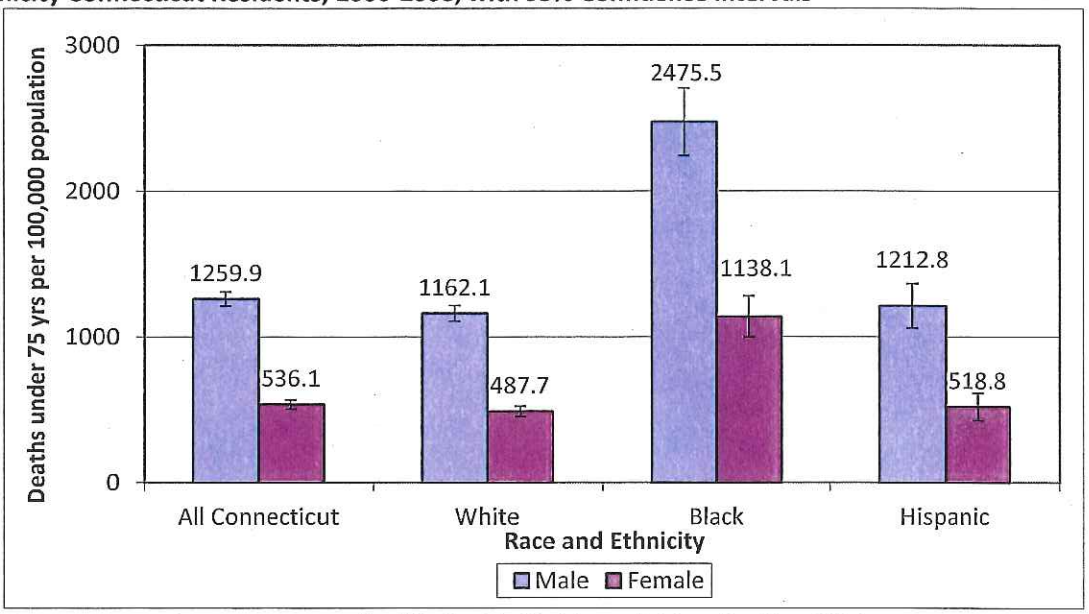
Cardiovascular Disease

CVD premature mortality rates differ by race and ethnicity as well as gender (2006-2008 data). Black males and females have significantly higher CVD premature mortality rates compared with White and Hispanic males and females ($p < 0.001$ for all comparisons) [Figure 10].[3] However, the CVD premature mortality rates of White males and females do not differ significantly from the rates of Hispanic males and females.[3] Also, males have significantly higher CVD premature mortality rates than females ($p<0.001$) (Figure 10).[3]

The CVD premature mortality rate declined significantly for the overall Connecticut population between 1999-2001 and 2006-2008 ($p<0.001$) [data not shown]. Similarly, CVD premature mortality rates declined significantly for White males ($p<0.001$), White females ($p<0.001$), Black females ($p<0.001$), Hispanic males ($p<0.05$), and Hispanic females ($p<0.05$) [data not shown]. CVD premature mortality rates for Black males did not change significantly from 1999-2001 to 2006-2008 [data not shown].[3]

[‡] The premature mortality rates presented in this report are age-adjusted "Years of Potential Life Lost (YPLL) under 75 years". Age-adjusted rates were computed by the direct method using the 2000 U.S. standard million population and Connecticut resident death records.

Figure 10. Age-adjusted Premature Mortality Rates for Cardiovascular Disease by Gender, Race and Ethnicity Connecticut Residents, 2006-2008, with 95% Confidence Intervals



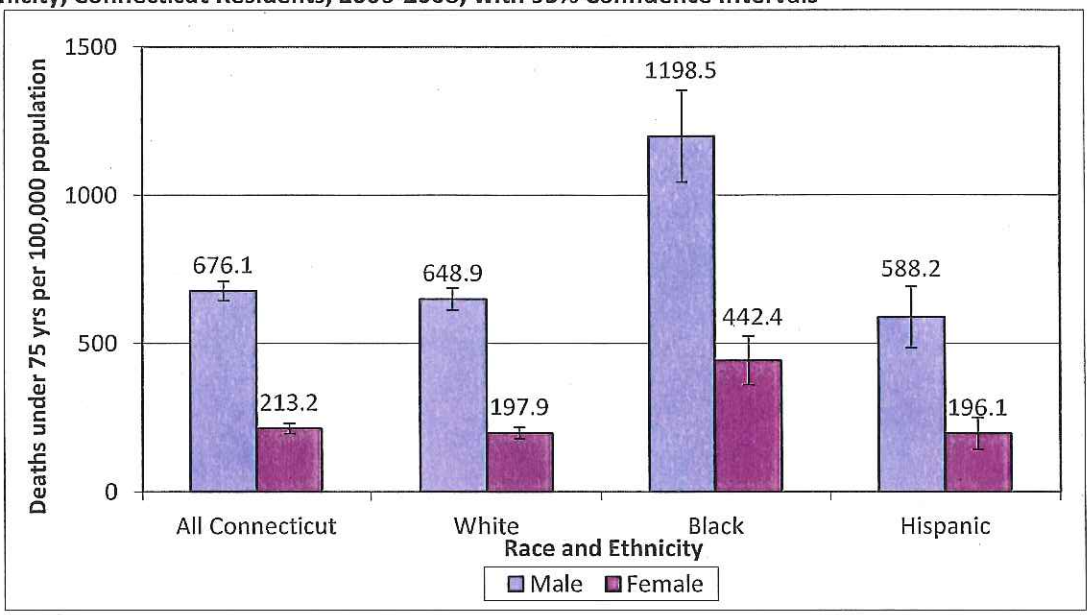
Source: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

Coronary Heart Disease

CHD premature mortality rates differ by race, ethnicity, and gender (2006-2008 data). The CHD premature mortality rates of Black males and females are significantly higher than those of White and Hispanic males and females ($p<0.001$ for all comparisons) [Figure 11].[3] However, the CHD premature mortality rates of White and Hispanic residents do not differ significantly.[3] Also, males have a significantly higher CHD premature mortality rate than females ($p<0.001$) [Figure 11].[3]

The CHD premature mortality rate declined significantly for the overall Connecticut population between 1999-2001 and 2006-2008 ($p<0.001$) [data not shown]. Similarly, CHD premature mortality rates declined significantly for all subpopulation groups (White males, $p<0.001$; White females $p<0.001$; Black males, $p<0.05$; Black females, $p<0.001$; Hispanic males, $p<0.005$; and Hispanic females, $p<0.05$) [data not shown].[3]

Figure 11. Age-adjusted Premature Mortality Rates for Coronary Heart Disease by Gender, Race and Ethnicity, Connecticut Residents, 2006-2008, with 95% Confidence Intervals



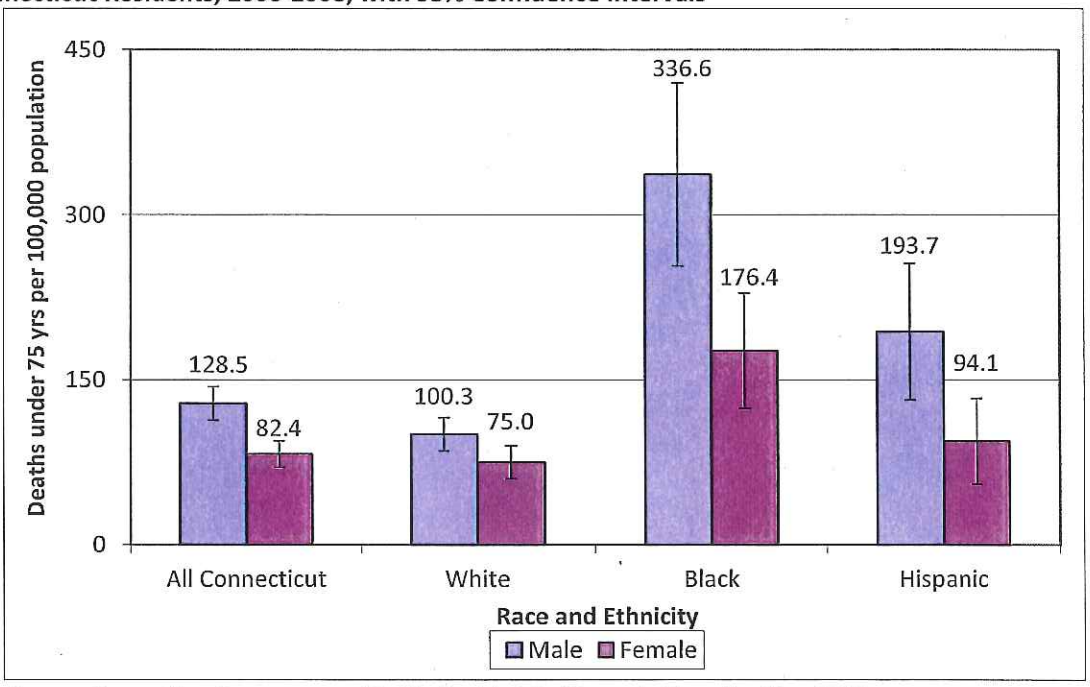
Source: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

Stroke

Stroke premature mortality rates vary by gender, race and ethnicity (2006-2008 data). Overall, males have a significantly higher stroke premature mortality rate than females ($p<0.005$) [Figure 12].[3] The stroke premature mortality rates of Black and Hispanic males are significantly higher than that of White males ($p<0.001$ for Black and White male comparison; $p<0.05$ for Hispanic and White male comparison) [Figure 12].[3] However, the stroke premature mortality rates of Hispanic and Black males do not differ significantly.[3] While Black females have a significantly higher stroke premature mortality rate than White females ($p<0.005$), the stroke premature mortality rates of Hispanic and White females are not statistically different [Figure 12].[3] Also, the stroke premature mortality rates of Black and Hispanic females do not differ significantly.[3]

The stroke premature mortality rate declined significantly for the overall Connecticut population ($p<0.005$), White males ($p<0.05$), and White females ($p<0.05$) between 1999-2001 and 2006-2008 ($p<0.005$) [data not shown]. The decline in the stroke premature mortality rates for Black and Hispanic males and females do not reach statistical significance (data not shown).[3]

Figure 12. Age-adjusted Premature Mortality Rates for Stroke by Gender, Race and Ethnicity, Connecticut Residents, 2006-2008, with 95% Confidence Intervals

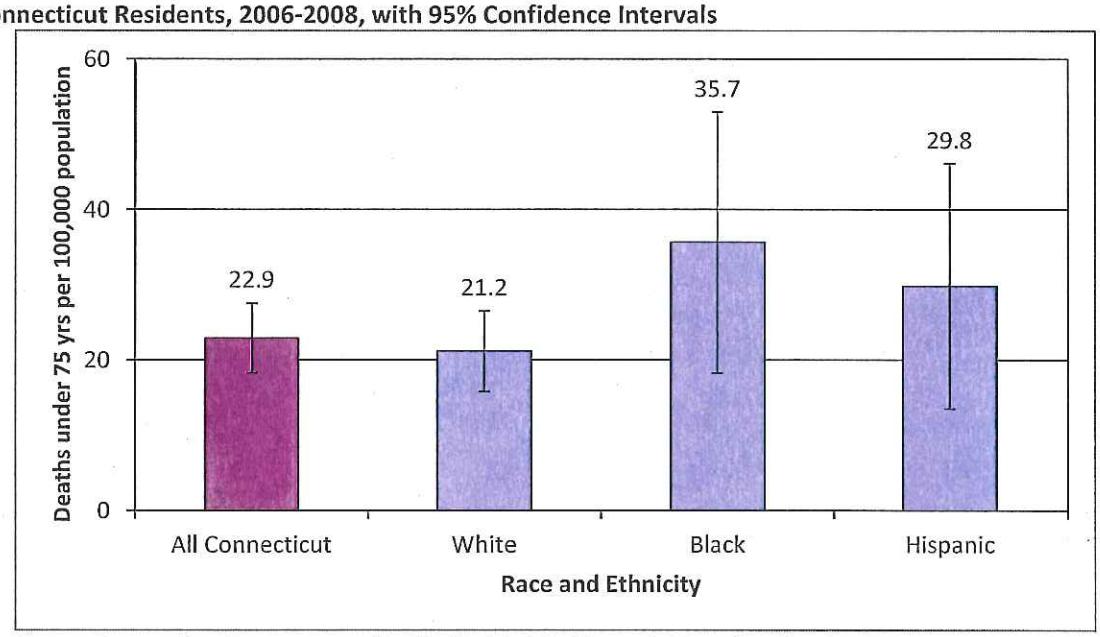


Source: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

Heart failure

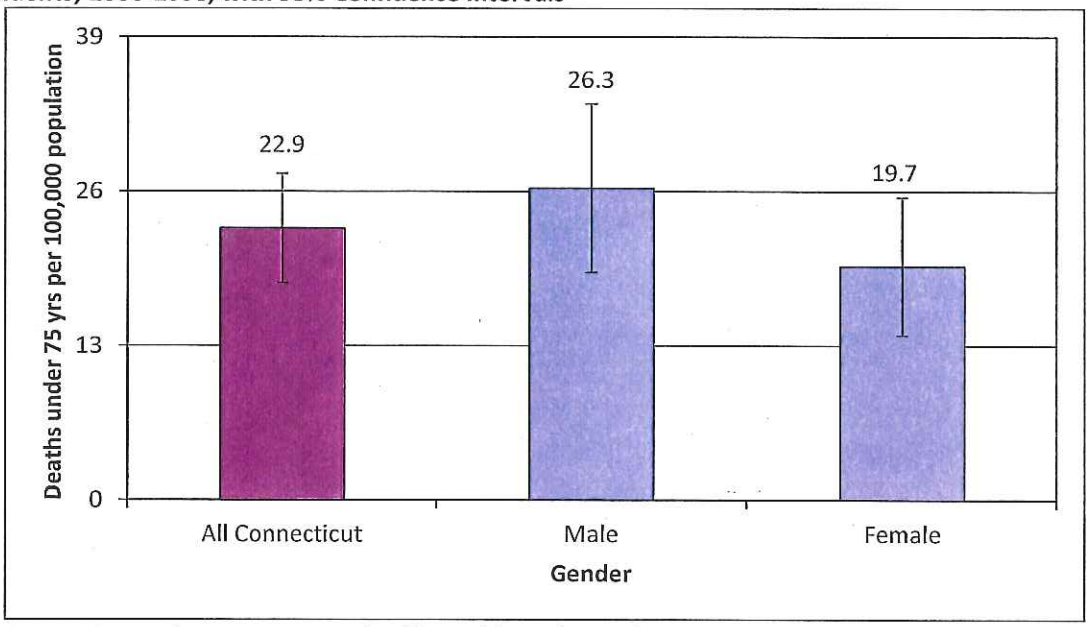
The Connecticut resident HF premature mortality rate does not differ significantly by gender or race and ethnicity (Figure 13 and Figure 14) [2006-2008 data].[3] HF premature mortality rates did not decline significantly between 1999-2001 and 2006-2008 [data not shown].[3]

Figure 13. Age-adjusted Premature Mortality Rates for Heart Failure by Gender, Race and Ethnicity, Connecticut Residents, 2006-2008, with 95% Confidence Intervals



Source: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

Figure 14. Age-adjusted Premature Mortality Rates for Heart Failure by Gender, Connecticut Residents, 2006-2008, with 95% Confidence Intervals



Source: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

MORBIDITY

There were 59,664 Connecticut resident discharges from Connecticut hospitals for all CVD in 2008. This represents 18% of all hospital discharges (excluding pregnancy and childbirth related discharges) and 23% of all hospital billing charges in the state.[10] Approximately 26% of all CVD discharges are due to CHD, 12% are for stroke, and 18% are for HF. The median length of stay for CHD, stroke, and HF is two, three, and four days, respectively. The median length of stay for all hospital discharges in Connecticut is three days.[10]

Hospitalizations by Gender

Hospitalization rates[§] vary by gender (2008 data). Males have significantly higher rates of hospitalizations for all CVD, CHD, stroke, and HF compared with females ($p < 0.001$). More females than males, however, are hospitalized for stroke and HF [Table 3].[10]

Table 3. Hospitalizations and Age-adjusted Hospitalization Rates (AAHR) for Cardiovascular Diseases per 100,000 Population, Connecticut Residents by Gender, 2008

Diagnostic Group	All		Male		Female	
	Discharges	AAHR	Discharges	AAHR	Discharges	AAHR
All Cardiovascular Diseases	59,664	1,483.1	31,748	1,862.9	27,916	1,184.1
Coronary Heart Disease	15,779	392.0	9,877	559.2	5,902	254.2
Stroke	7,413	183.6	3,626	216.1	3,787	158.1
Heart failure	10,725	259.9	5,331	326.8	5,394	213.8

Source: Connecticut Department of Public Health, Connecticut Hospital Discharge Abstract and Billing Data Base, 2010.

[§]Hospitalization rates were calculated using 2008 Connecticut resident hospitalization discharge data and were age-adjusted based on the 2000 U.S. standard million population.

Hospitalization Rates by Race and Ethnicity

Hospitalization rates differ by race and ethnicity (2008 data). Black residents have significantly higher rates of hospitalizations for CVD, stroke, and HF than both White and Hispanic residents ($p<0.001$ for all comparisons). Black residents' rate of hospitalizations for CHD, however, is not significantly different than that of White and Hispanic residents.[10] Hispanic residents have significantly higher hospitalization rates for CVD ($p<0.001$) and CHD ($p<0.01$) than White residents. In contrast, Hispanic residents have a significantly lower rate of hospitalization for HF compared with White residents ($p<0.05$). Furthermore, the rates of hospitalization for stroke of Hispanic and White residents are not significantly different (Table 4).[10]

Table 4. Hospitalizations and Age-adjusted Hospitalization Rates (AAHR) for Cardiovascular Diseases per 100,000 Population, Connecticut Residents by Race and Ethnicity, 2008

Diagnostic Group	All		White, non-Hispanic		Black, non-Hispanic		Hispanic	
	Discharges	AAHR	Discharges	AAHR	Discharges	AAHR	Discharges	AAHR
All Cardiovascular Diseases	59,664	1,483.1	48,395	1,380.4	5,555	2,114.2	3,667	1,713.6
Coronary Heart Disease	15,779	392.0	13,106	378.2	992	375.9	954	427.2
Stroke	7,413	183.6	6,033	170.5	700	270.5	403	195.7
Heart failure	10,725	259.9	8,568	231.0	1,185	463.9	731	390.1

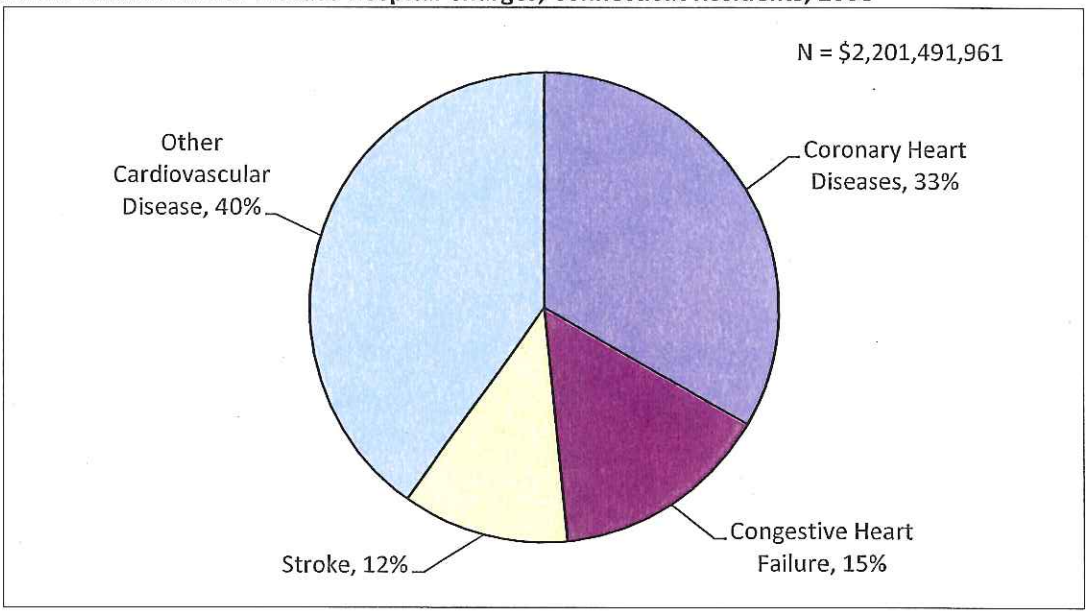
Source: Connecticut Department of Public Health, Connecticut Hospital Discharge Abstract and Billing Data Base, 2010.

Economic Costs

The estimated national annual cost for the medical management of CVD was $503.2 billion in 2010, or about $1600 per person.[2] This estimate includes direct medical costs and indirect costs. The indirect cost of CVD is associated with lost productivity from illness and premature death. Also, CVD are major causes of disability, limiting an individual's ability to live independently and negatively impacting the quality of life for individuals and families. For these reasons, CVD can incur enormous indirect costs. Assuming that disease rates and per person costs are the same in Connecticut as they are nationwide, the estimated economic burden of CVD in the state is about $5.8 billion. A large portion of these costs is attributable to inpatient hospitalizations.

Total Connecticut CVD hospital charges in 2008 were about $2.2 billion, with a median charge of $23,172 (Figure 15). About 33% of total CVD hospitalization charges were for CHD, 12% were for stroke, and 15% were for HF.[10] Median hospital charges were $34,792 for CHD, $19,772 for stroke, and $17,408 for HF. In contrast, the median charge for all hospital discharges in Connecticut was $16,727.[10]

Figure 15. Cardiovascular Disease Hospital Charges, Connecticut Residents, 2008



Source: Connecticut Department of Public Health, Connecticut Hospital Discharge Abstract and Billing Data Base, 2010.

RISK FACTORS

Risk factors for CVD may be non-modifiable (e.g., increasing age or family history) or modifiable (high blood pressure, high cholesterol, smoking, diabetes, obesity, physical inactivity) [Table 5]. Increasing age is a key risk factor for heart disease, stroke, and HF.[1] About 86% of all CVD deaths in Connecticut occur among those aged 65 years and older. About 85% of all CHD deaths, 90% of all stroke deaths, and 96% of all HF deaths in Connecticut occur among persons aged 65 years and older.[7] For men and women, major increases in the CVD mortality rate begin in the 35-to-44-year-old age group.[4] A family history of heart disease and stroke increases one's risk of developing these diseases. A combination of inherited characteristics and behavioral patterns (e.g. similar dietary, smoking, and activity habits) are thought to partially explain increased risk within families.[11]

Lower socioeconomic position (SEP) is an important risk marker for CVD. SEP is commonly measured by personal income, household income, or educational attainment level. Persons of lower SEP have higher CVD morbidity and mortality than do middle- or upper-income persons. Behavioral risk factors such as smoking, hypertension, and obesity are more prevalent in persons of lower SEP and may explain some of the observed disparity; however, other factors, like neighborhood socioeconomic environment, appear to have effects on individuals' risk for CVD.[1] Low-income neighborhood environments may contribute to increased CVD risk and poorer health outcomes because of such factors like poorer air quality, fewer food choices, and lower quality and/or lack of public services. Persons with lower incomes tend to have less access to and/or less effectively use preventive health services that are important to the early detection and treatment of hypertension.[12] While low-socioeconomic position may be considered "modifiable" in the sense that people can move in and out of poverty during a lifetime or over generations, it is not usually within a given individual's control to change his or her social position or neighborhood environment.

Table 5. Risk Factors for Cardiovascular Disease

Modifiable Risk Factors	Non-Modifiable Risk Factors
• High blood pressure • High cholesterol • Smoking • Diabetes • Obesity • Physical inactivity	• Increasing age • Family history

Modifiable Risk Factors

Current Connecticut Behavioral Risk Factor Surveillance System (BRFSS)** data show that about one out of three Connecticut adults report having one modifiable risk factor for CVD.[14] Following are summaries of the six main risk factors (high blood pressure, high blood cholesterol, tobacco use, diabetes, obesity, and physical inactivity) for CVD.

High Blood Pressure

High blood pressure (HBP) is a major risk factor for heart attack and the most important modifiable risk factor for stroke. People with elevated blood pressure (≥140 mmHg systolic / 90 mmHg diastolic) are 2 to 4 times more likely to develop CHD as are people with normal blood pressure (<120 mmHg systolic / 80 mmHg diastolic).[1] Studies have found that individuals with a normal blood pressure have approximately half the lifetime risk of stroke compared to those with high blood pressure.[13]

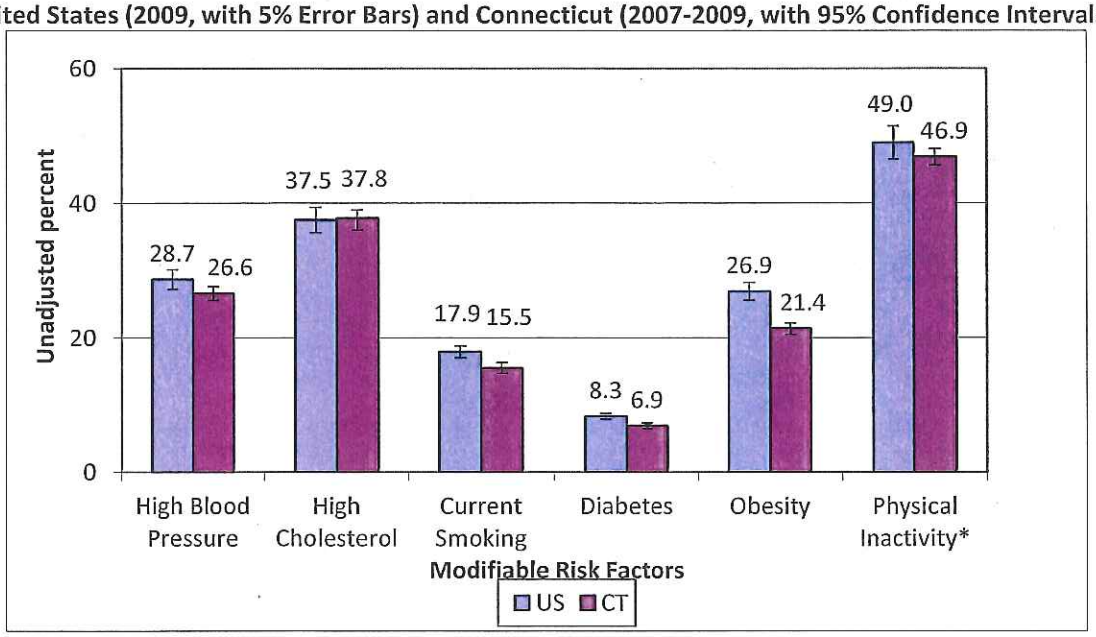
Approximately 27% of Connecticut adults report having HBP (2007-2009 data) compared with about 29% of adults nationwide (2009 data) (Figure 16).[14, 15] The risks for hypertension-related CVD increase markedly with age, as does the prevalence of hypertension, and drug treatment for HBP.[13] For example, 15.4% of Connecticut adults aged 35-44 years report having HBP compared with 57.8% of Connecticut adults aged 65 years and older ($p<0.001$) [data not shown].[14]

The rates of HBP also differ by gender. Approximately 27.4% of Connecticut males have HBP compared with 22.5% of females ($p<0.001$) [data not shown].[14]

The prevalence of HBP varies by race and ethnicity. Black Connecticut adults are more likely to have HBP than White and Hispanic Connecticut adults ($p<0.001$ for both comparisons). The rates of HBP among White and Hispanics adults do not differ significantly. About 25% of White, 36% of Black, and 22% of Hispanic adults report that they were told they had hypertension (Figure 17).[14]

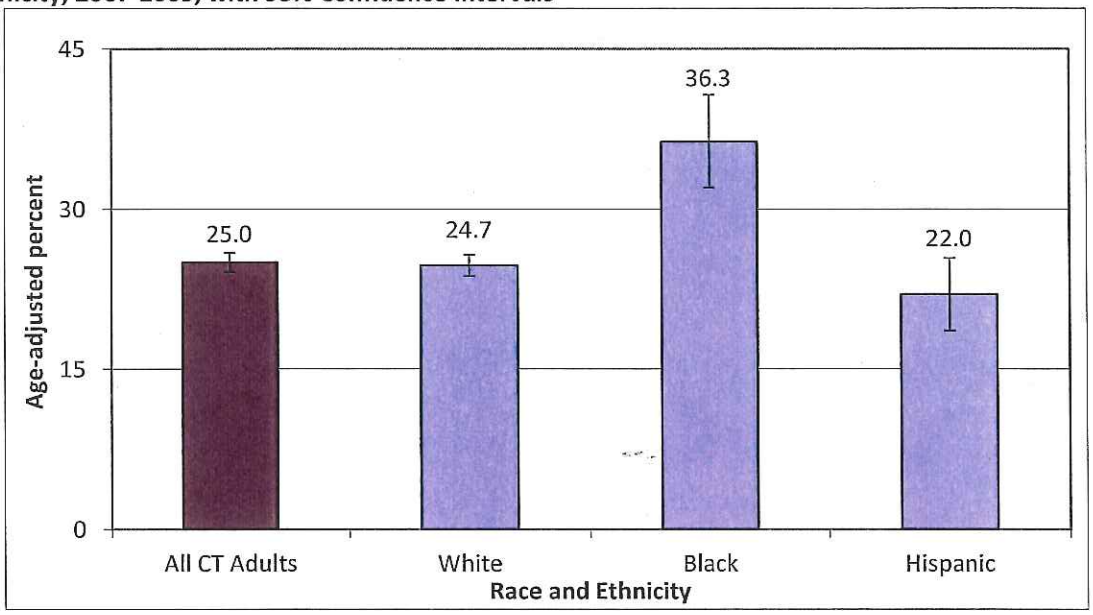
** Unless otherwise stated, the BRFSS data presented in this report are based on 2007-2009 survey responses from non-institutionalized Connecticut adults.

Figure 16. Prevalence of Modifiable Risk Factors for Cardiovascular Diseases among Adults in the United States (2009, with 5% Error Bars) and Connecticut (2007-2009, with 95% Confidence Intervals)



Sources: Centers for Disease Control and Prevention, Behavioral Risk Factor Surveillance System (BRFSS), 2010. Connecticut Department of Public Health, BRFSS, 2010.
*Participated in less than the recommended amount of physical activity.

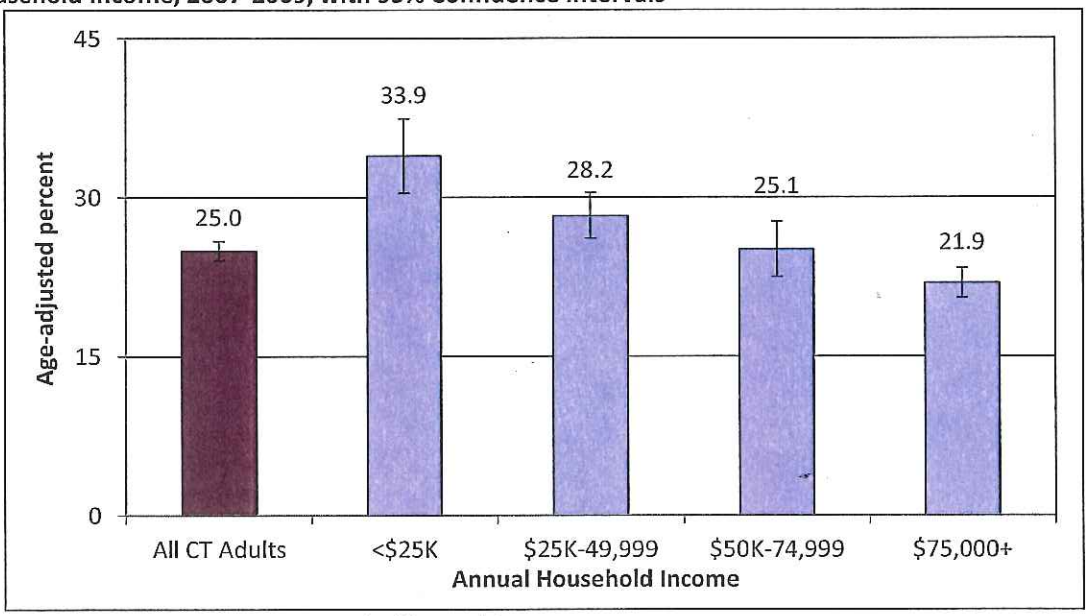
Figure 17. Age-adjusted Prevalence of High Blood Pressure among Connecticut Adults by Race and Ethnicity, 2007-2009, with 95% Confidence Intervals



Source: Connecticut Department of Public Health, BRFSS, 2010.

Connecticut adults with lower annual household incomes tend to have a higher prevalence of HBP compared to Connecticut adults with higher annual household incomes. For example, 33.9% of adults with an annual household income less than $25,000 have diagnosed HBP compared to 21.9% of adults with annual household income of at least $75,000 (p<0.001) [Figure 18].[14]

Figure 18. Age-adjusted Prevalence of High Blood Pressure among Connecticut Adults by Annual Household Income, 2007-2009, with 95% Confidence Intervals



Source: Connecticut Department of Public Health, BRFSS, 2010.

High Blood Cholesterol

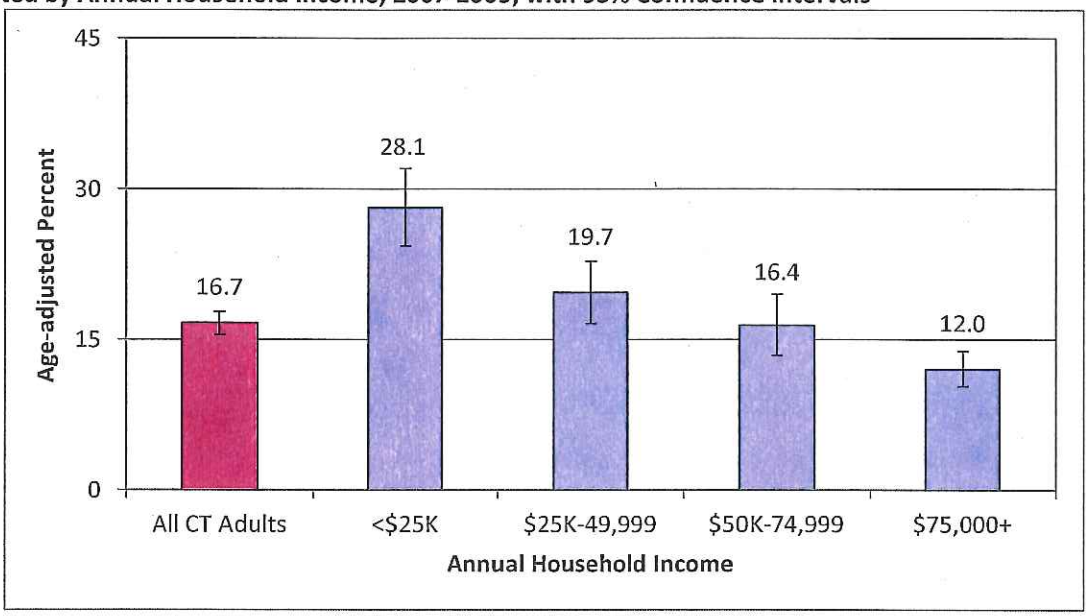
High blood cholesterol (HBC) is considered a major risk factor for CHD.[16, 17] Dyslipidemias, or an abnormal amount of lipids (e.g. high blood cholesterol) in the blood, were not traditionally regarded as a risk factor for stroke; however, a recent meta-analysis of statin therapy found that treatment of dyslipidemia decreases the risk of nonhemorrhagic stroke.[1] Control and reduction of HBC is important. A 10% decrease in total blood cholesterol levels may reduce the incidence of CHD by as much as 30%.[18]

About 38% of adults in Connecticut (2007-2009 data) and nationwide (2009 data) were told they had HBC (Figure 16).[14, 15] The prevalence of HBC increases with age. For example, 38.1% of Connecticut's adults aged 45-54 years report having HBC compared with 53.4% of Connecticut's adults aged 65 years and older ($p<0.001$) [data not shown].[14]

The prevalence of HBC also varies by gender. Approximately, 39.2% of Connecticut males have HBC compared with 29.7% of females ($p<0.001$) [data not shown]. [14]

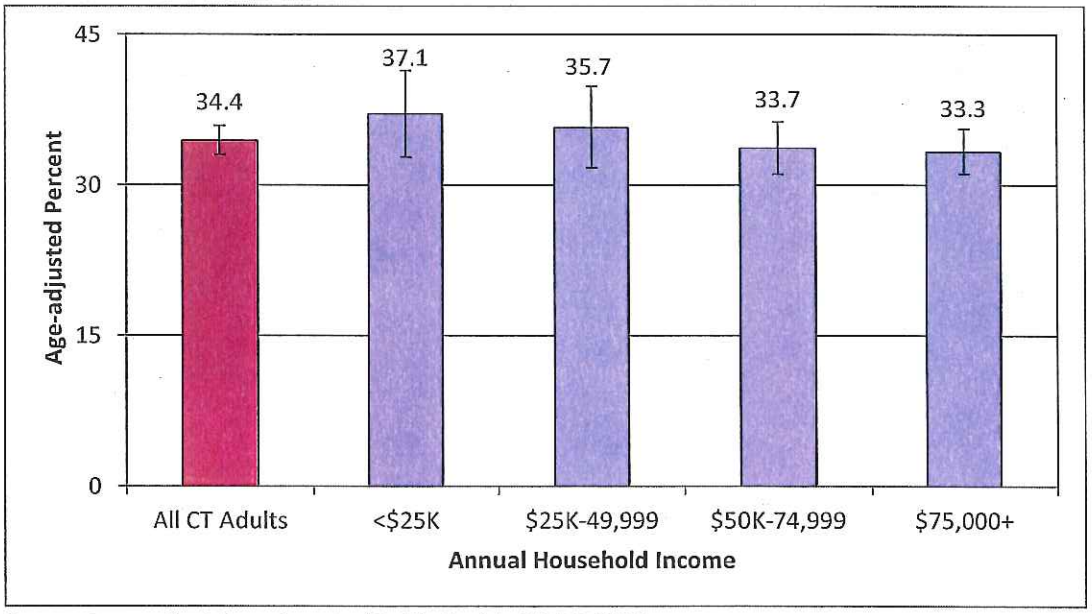
Connecticut adults compare favorably to adults nationwide in terms of cholesterol screening. About 82% of Connecticut adults report having had their blood cholesterol screened within the last five years (2007-2009 data) compared with 77% of adults in the U.S. (2009 data).[14, 15] Connecticut adults with lower incomes are more likely to report that they have never had their blood cholesterol tested compared to adults with higher incomes. For example, adults with annual household incomes less than $25,000 are significantly more likely to report that they have never had their blood cholesterol tested compared to individuals with annual household incomes of $75,000 or more ($p<0.001$) [Figure 19]. In contrast, the prevalence of HBC does not differ significantly by annual household income [Figure 20].[14]

Figure 19. Age-adjusted Percentage of Connecticut Adults Who Have Never Had Their Cholesterol Tested by Annual Household Income, 2007-2009, with 95% Confidence Intervals



Source: Connecticut Department of Public Health, BRFSS, 2010.

Figure 20. Age-adjusted Percentage of Connecticut Adults Who had Their Cholesterol Tested in the Past 5 Years and Were Told It was High by Annual Household Income, 2007-2009, with 95% Confidence Intervals

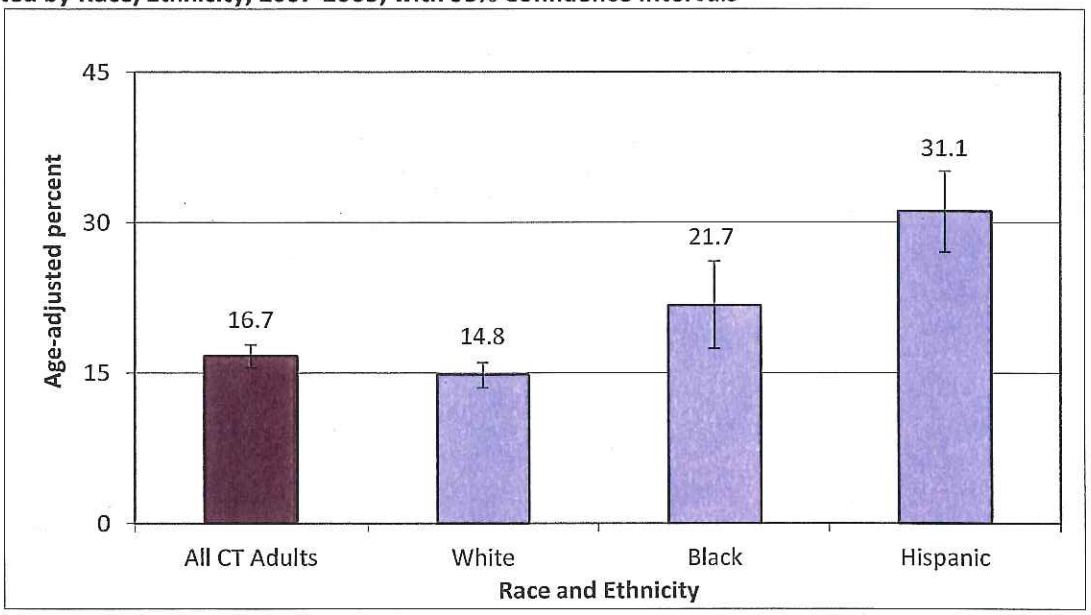


Source: Connecticut Department of Public Health, BRFSS, 2010.

Black and Hispanic adults are significantly more likely than White adults to report never having had their blood cholesterol tested ($p<0.05$ for Black and White comparison; $p<0.001$ for Hispanic and White comparison). Hispanic adults are also more likely than Black adults to report never having had their blood cholesterol tested ($p<0.05$). An estimated 14.8% of White, 21.7% of Black, and 31.1% of Hispanic adults report never having had their blood cholesterol tested [Figure 21]. In contrast, the prevalence of HBC does not differ significantly by race and ethnicity [data not shown].[14]

The rates of never having had blood cholesterol tested do not differ significantly by gender. Approximately, 16.9% of males and 16.4% of females in Connecticut have never had their blood cholesterol tested [data not shown].[14]

Figure 21. Age-adjusted Percentage of Connecticut Adults Who Have Never Had Their Cholesterol Tested by Race/Ethnicity, 2007-2009, with 95% Confidence Intervals



Source: Connecticut Department of Public Health, BRFSS, 2010.

Smoking

Cigarette smoking is a major modifiable risk factor for CVD. Smoking causes reduced blood vessel elasticity by increasing arterial wall stiffness. Smoking increases the risk of heart attack two-fold. Smokers have higher CHD mortality rates than non-smokers and the risk of death increases with greater number of cigarettes smoked. Current smokers have more than twice the risk of stroke compared with those who have never smoked. People who stop smoking decrease their stroke risk and their risk of CHD mortality.[1]

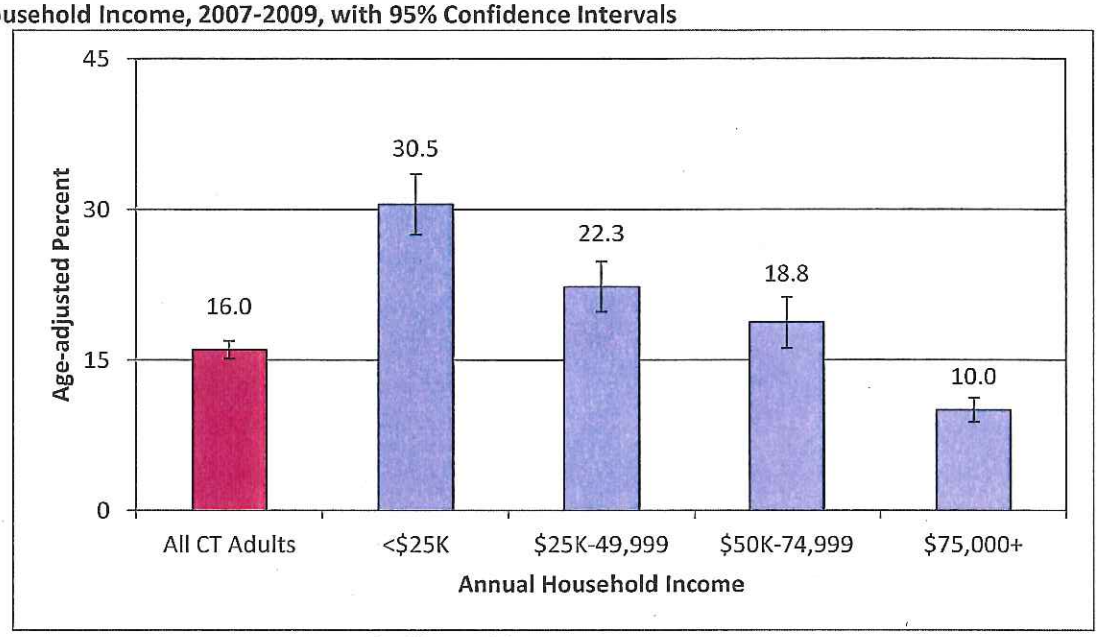
About 16% of Connecticut adults report being current smokers (2007-2009 data) compared with about 18% of adults nationwide (2009 data) [Figure 16].[14,15] According to the 2009 Connecticut School Health Survey (CSHS), 17.8% of high school students report being current smokers.[19]

Among adults, current smokers are more likely to be younger. For example, an estimated 22% of Connecticut adults aged 18 to 24 years old are current smokers compared with 14% of those aged 55 to 64 ($p<0.01$), and 6% of those aged 65 and older ($p<0.001$) [data not shown].[14] Smokers are also more likely to be individuals who have lower incomes and are less educated. For instance, about 31% of Connecticut's adults with annual household incomes under $25,000 are current smokers, compared to 10% of adults with annual household incomes of $75,000 or more ($p<0.001$) [Figure 22].[14] Similarly, about 31% of adults with less than a high school education report being current smokers compared to about 9% of adults who graduated from college ($p<0.001$) [data not shown].[14]

The rates of smoking do not differ significantly by gender. An estimated 16.8% of adult males and 15.2% of adult females are current smokers while an estimated 19.0% of high school males and 16.5% of high school females are current smokers (data not shown).[14,19]

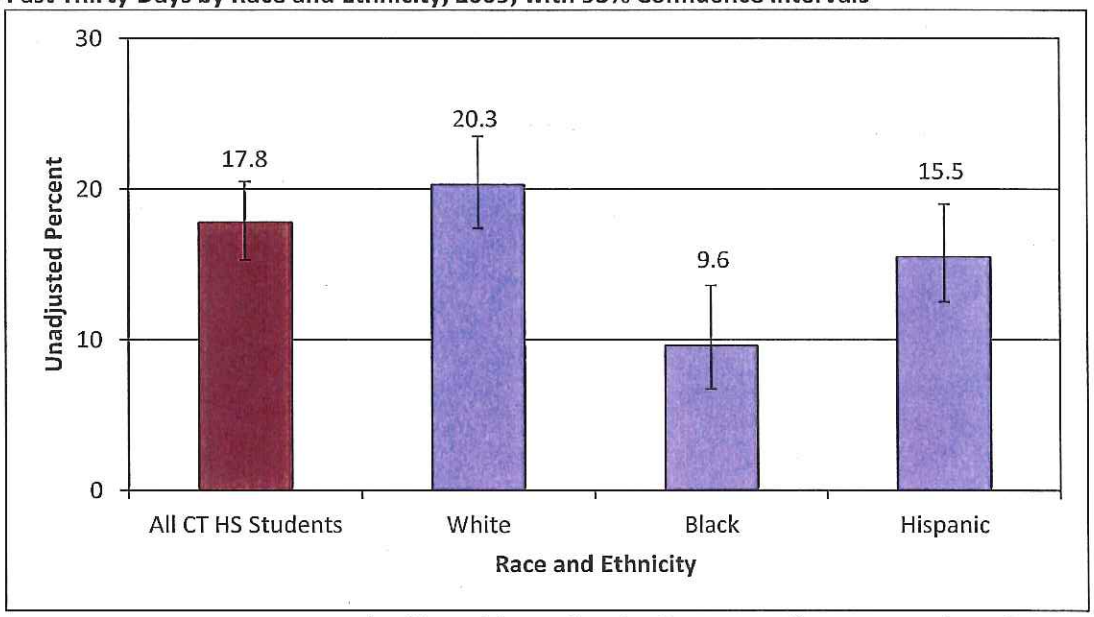
Among Connecticut adults, smoking rates do not differ significantly by race and ethnicity. An estimated 15.8% of White, 19.1% of Black, and 15.6% Hispanic adults report being current smokers [data not shown].[14] However, the rates of smoking among high school students do vary by race and ethnicity. White Connecticut high school students are more likely to be current smokers than Black ($p<0.001$) and Hispanic ($p<0.05$) students. Also, Hispanic students are more likely than Black students to be current smokers ($p<0.05$) [Figure 23].[19]

Figure 22. Age-adjusted Percentage of Connecticut Adults Who Are Current Smokers by Annual Household Income, 2007-2009, with 95% Confidence Intervals



Source: Connecticut Department of Public Health, BRFSS, 2010.

Figure 23. Percentage of Connecticut High School Students Who Smoked Cigarettes on One or More of the Past Thirty Days by Race and Ethnicity, 2009, with 95% Confidence Intervals



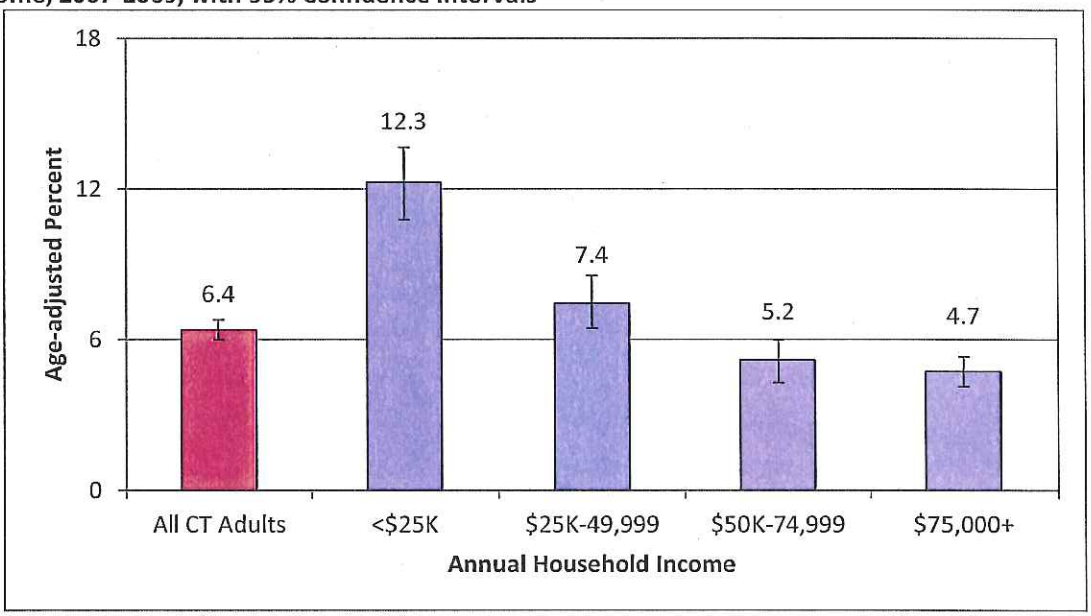
Source: Connecticut Department of Public Health, Youth Risk Behavior Surveillance System (YRBSS), 2010.

Diabetes

Diabetes has been recognized as a major risk factor for CVD. CVD is the primary cause of death for persons with diabetes, accounting for about 65% of the mortality. Individuals with diabetes are 2 to 4 times more likely to develop CHD and 2 to 5 times more likely to have a stroke than the rest of the population. People with diabetes often have HBP, HBC, and are overweight, further increasing their risk for CVD.[1]

An estimated 6.9% of Connecticut adults have diagnosed diabetes (2007-2009 data) compared with about 8% of adults nationwide (2009 data) [Figure 16].[14, 15] The prevalence of diabetes varies by gender, age, race and ethnicity, and SEP.[14, 20] Males are more likely to have diabetes than females. An estimated 7.3% of Connecticut males have diabetes compared with 5.7% of females ($p<0.005$) [data not shown].[14] Also, the prevalence of diabetes increases with age. Approximately 3% of adults aged 35-44 years report having diabetes compared to approximately 16.5% of adults aged 65 years and older ($p<0.001$) [data not shown].[14] Black and Hispanic adults have a significantly higher prevalence of diabetes compared with White adults ($p<0.001$ for both comparisons). The prevalence of diabetes among Black and Hispanic adults does not differ significantly. An estimated 5.6% of White, 14.9% of Black, and 10.5% of Hispanic adults report having diabetes [data not shown].[14] Adults with lower annual household incomes have a higher prevalence of diabetes compared to adults with higher annual household incomes. For example, approximately 12% of adults with annual household incomes under $25,000 report having diabetes, compared with about 5% of adults with household incomes over $75,000 ($p<0.001$) [Figure 24].[14]

Figure 24. Age-adjusted Prevalence of Diabetes among Connecticut Adults by Annual Household Income, 2007-2009, with 95% Confidence Intervals



Source: Connecticut Department of Public Health, BRFSS, 2010.

Diabetes self-management education is essential because improperly controlled diabetes can result in CVD, kidney disease, blindness and loss of limb. It is, therefore, a particular concern that about 52% of Connecticut adults with diabetes report that they have never taken a course to manage the disease.[14]

Obesity

Body mass index (BMI), or weight adjusted for height, is a widely used screening method for obesity. For children and adolescents, BMI is compared to age- and gender-specific percentiles on the Centers for Disease Control and Prevention (CDC) growth charts. Children and adolescents with a BMI greater than or equal to the 85 percentile but less than the 95 percentile are considered overweight. Children and adolescents with a BMI greater than or equal to the 95 percentile are considered obese.[21] Medical guidelines for adults identify normal/desirable weight as a BMI under 25, overweight as a BMI of 25 to 29.9, and obese as a BMI of 30 or more. The prevalence of obesity has more than doubled over the past three decades in the United States.[21] The development of obesity involves social, behavioral, cultural, physiological, metabolic, and genetic factors. High calorie diets, along with less physical activity, have contributed to the obesity epidemic in our society.[21, 22]

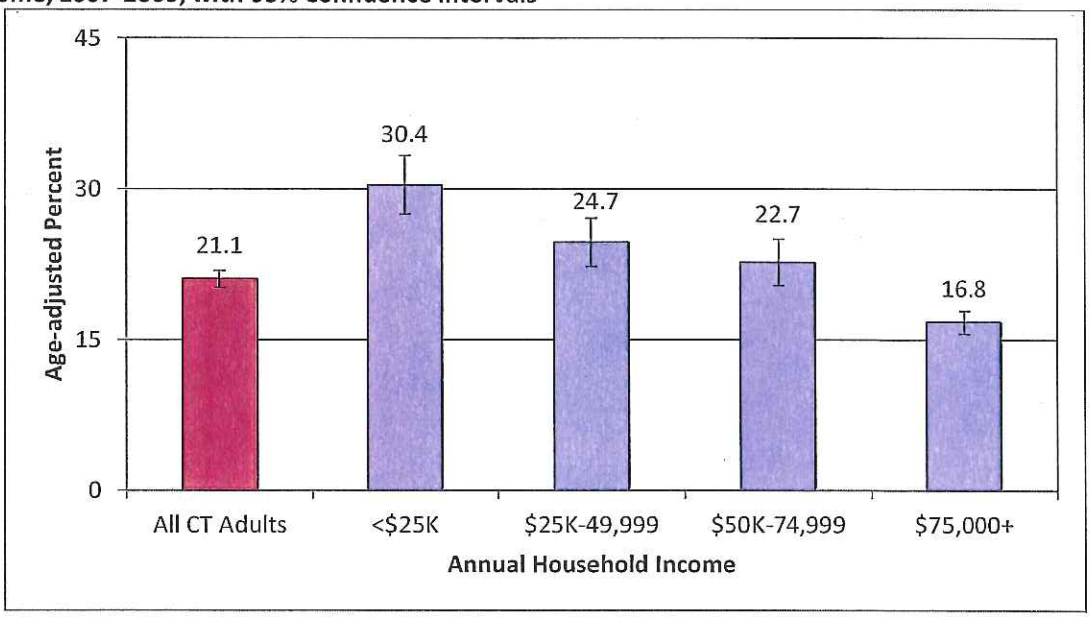
Obesity increases the risk of morbidity from hypertension, dyslipidemia, CHD, and stroke. All-cause mortality increases with increasing body weight.[22] Obesity is also an independent risk factor for CVD. The risk of ischemic stroke increases with increasing BMI. Studies have also suggested that body fat distribution may affect CHD risk. Upper body or abdominal fat seems to increase CHD risk regardless of BMI. Weight reduction can affect several of the modifiable risk factors for stroke thereby reducing the incidence of stroke.[1]

According to responses to the 2009 CSHS, an estimated 14.5% of Connecticut high school students were overweight and 10.4% were obese.[19] Obesity rates among high school students in Connecticut vary by gender and race and ethnicity. Male Connecticut high school students are significantly more likely to be obese than female high school students ($p<0.05$). An estimated 13.8% of male and 6.7% of female high school students in Connecticut are obese [data not shown].[19] Also, Hispanic Connecticut high school students have higher rates of obesity than both White ($p<0.001$) and Black ($p<0.05$) high school students. The difference in the rate of obesity among White and Black high school students does not reach statistical significance. An estimated 8.7% of White, 12.5% of Black, and 17% of Hispanic Connecticut high school students are obese [data not shown].[19]

An estimated 21% of Connecticut adults are obese (2007-2009 data) compared with about 27% of adults nationwide (2009 data) [Figure 16].[14, 15] Approximately 38% of Connecticut adults are overweight and 41% are neither overweight nor obese [data not shown].[14] Rates of obesity differ by SEP. For example, approximately 30% of adults with annual household incomes less than $25,000 are obese compared with 17% of those with annual household incomes over $75,000 ($p<0.001$) [Figure 25].[14] Rates of obesity also differ by race and ethnicity. Black and Hispanic adults are more likely to be obese than White adults ($p<0.001$ for both comparisons) [data not shown]. Black adults are also more likely to be obese than Hispanic adults ($p<0.05$). About 20% of White, 36% of Black, and 27% of Hispanic adults are obese [data not shown].[14] Furthermore, males are more likely to be obese than females. An estimated 27.9% of males are obese compared with 19.2% of females ($p<0.005$) [data not shown].[14] Additionally, older adults are more likely to be obese than younger adults. Approximately 11% of adults age 18-24 years are obese compared with 25% of adults aged 55-64 years ($p<0.001$) [data not shown].[14]

Obese adults are significantly more likely to report that they are in poorer health compared with non-obese adults. About 19% of adults who are obese report that they are in fair or poor health compared with about 9% of Connecticut adults who are not obese ($p<0.001$) [data not shown].[14]

Figure 25. Age-adjusted Prevalence of Obesity among Connecticut Adults by Annual Household Income, 2007-2009, with 95% Confidence Intervals



Source: Connecticut Department of Public Health, BRFSS, 2010.

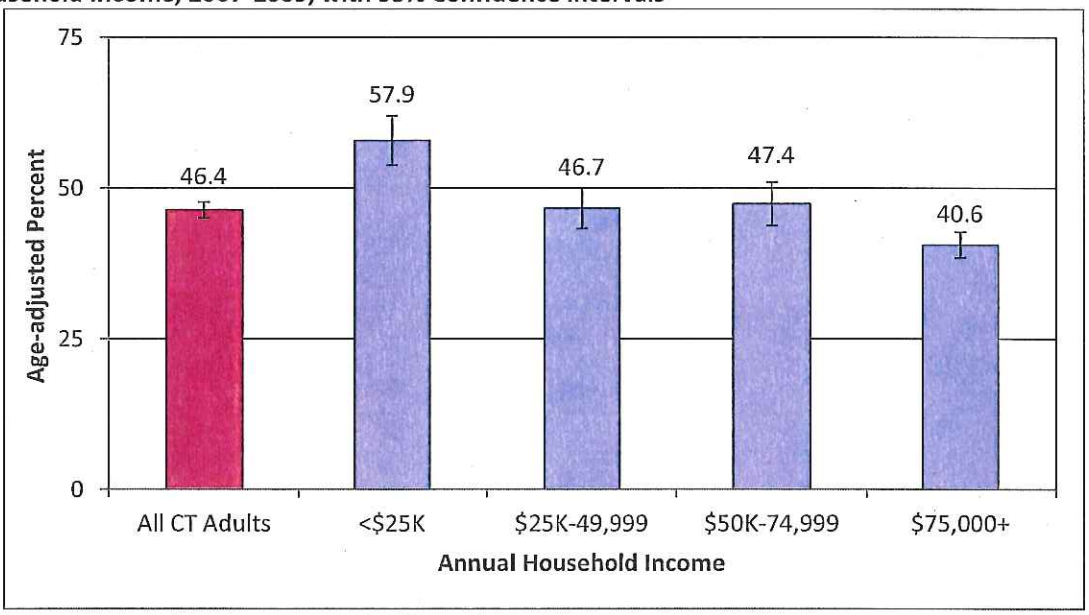
Physical Inactivity

Physical inactivity is associated with an increased risk of a number of chronic health conditions including CHD, diabetes, some cancers, HBP, obesity, and osteoporosis. Studies have shown that physical activity has protective effects on strokes.[1, 23]

The American College of Sports Medicine (ACSM), the American Heart Association (AHA), and the CDC recommend that healthy adults aged 18-65 years participate in moderate-intensity aerobic physical activity for a minimum of 30 minutes on five days per week or vigorous-intensity aerobic physical activity for a minimum of 20 minutes on three days per week.[24, 25] The guidelines are the same for adults aged 65 years and older; however, if older adults are unable to meet these guidelines because of chronic conditions, it is recommended that they participate in as much physical activity as possible.[25]

"Physical inactivity" is defined here as not meeting the recommendations of the ACSM, AHA, and CDC as described above. Approximately 47% of Connecticut adults report participating in less than the recommended amount of physical activity (2007-2009 data) compared with 49% nationwide (2009 data) (Figure 16).[14, 15] Rates of physical inactivity are higher among older adults, women, racial or ethnic minorities, and people with low incomes.[23] Physical inactivity increases with age. About 56% of adults 65 years old and older are physically inactive compared with about 48% of adults aged 45 to 64 years , and 43% of adults aged 18 to 44 years ($p<0.001$ for both comparisons) [data not shown]. Similarly, the physical inactivity rate among adults aged 45 to 64 years is significantly higher than that of adults aged 18 to 44 years ($p<0.005$) [data not shown].[14] Likewise, females are more likely to be physically inactive than males. An estimated 48.5% of adult females are physically inactive compared with 44% of adult males ($p<0.05$) [data not shown].[14] Additionally, Black and Hispanic adults are significantly more likely to report higher rates of physical inactivity than White adults ($p<0.001$ for Black and White comparison; $p<0.005$ for Hispanic and White comparison). The rates of physical inactivity among Black and Hispanic adults do not differ significantly. Approximately 44.5% of White, 59.7% of Black, and 54.2% of Hispanic adults report that they are physically inactive (data not shown).[14] Furthermore, adults with lower incomes are more likely to be physically inactive compared to adults with higher incomes. For example, about 58% of adults with annual household incomes of less than $25,000 are physically inactive compared to 41% of adults with annual household incomes of $75,000 or more ($p<0.001$) [Figure 26].[14]

Figure 26. Age-adjusted Prevalence of Physical Inactivity among Connecticut Adults by Annual Household Income, 2007-2009, with 95% Confidence Intervals



Source: Connecticut Department of Public Health, BRFSS, 2010.

Co-Prevalence of Cardiovascular Risk Factors

The co-prevalence of risk factors places an individual at elevated risk of CHD and stroke.[26] Approximately 42% of Connecticut adults report having two or more and 19% report having three or more modifiable risk factors for CVD.[14] The co-prevalence of risk factors contributes to the complexity of disease management.

RECOGNIZING THE SIGNS AND SYMPTOMS OF HEART ATTACK AND STROKE

The *Healthy People 2010* national objectives for both heart disease and stroke include increasing the proportion of persons who are aware of the early warning signs and symptoms of heart attack and stroke and the necessity of calling 911 when persons are suffering from either of these conditions (Table 6).[8] Early recognition of heart attack and stroke and calling 911 increase the likelihood of immediate emergency transport to the hospital and timely medical care that can reduce disability and death.

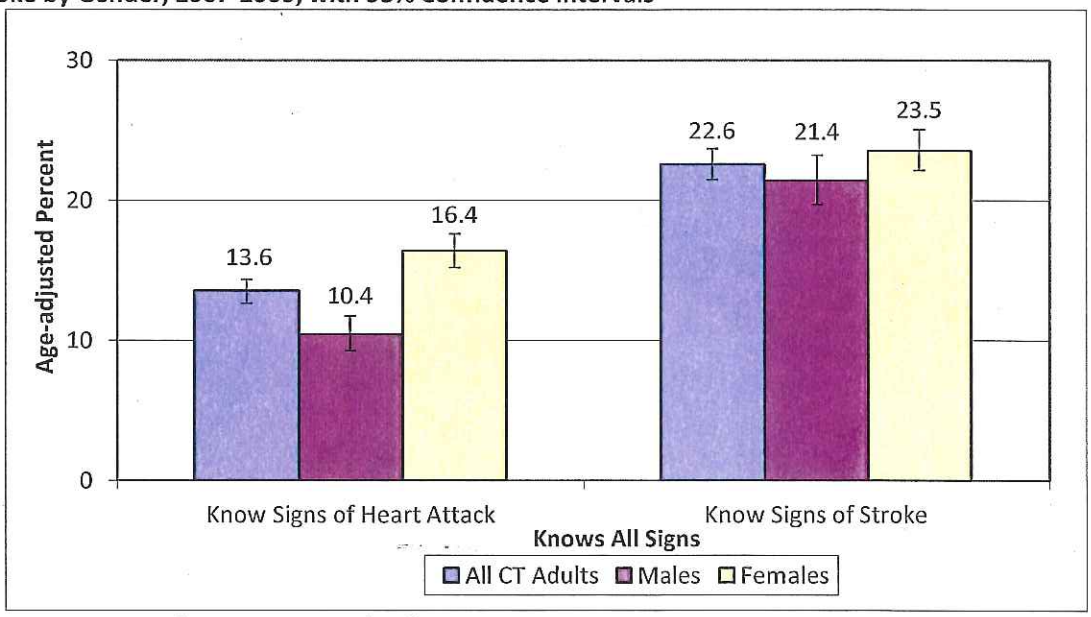
Table 6. Warning Signs for Heart Attack and Stroke

Heart Attack	Stroke
• Jaw, neck, back pain • Lightheaded, faint • Shortness of breath • Arm or shoulder discomfort • Chest pain or discomfort	• Severe headache with no known cause • Trouble seeing in one or both eyes • Confusion, trouble speaking • Trouble walking, dizziness, or loss of balance • Sudden numbness/weakness of face, arm, or leg

Source: American Heart Association, 2010.

The percentage of Connecticut adults who know all the warning signs and symptoms for heart attack and stroke tends to be very low. Only 13.6% of adults can identify all the proper heart attack signs and only 22.6% can identify all the proper stroke signs (2007-2009 data).[14] Women tend to be more knowledgeable than men about the signs and symptoms of heart attack and stroke. An estimated 16.4% of females know all heart attack signs compared with about 10.4% of males ($p<0.001$).[14] Also, approximately 23.5% of females know all signs of stroke compared with about 21.4% of males; however, this difference is not statistically significant [Figure 27].[14] Most adults, 91.4%, know that they should call 911 if they thought that someone was having a heart attack or stroke [data not shown].[14]

Figure 27. Age-adjusted Percentage of Connecticut Adults Who Know All the Signs of Heart Attack and Stroke by Gender, 2007-2009, with 95% Confidence Intervals

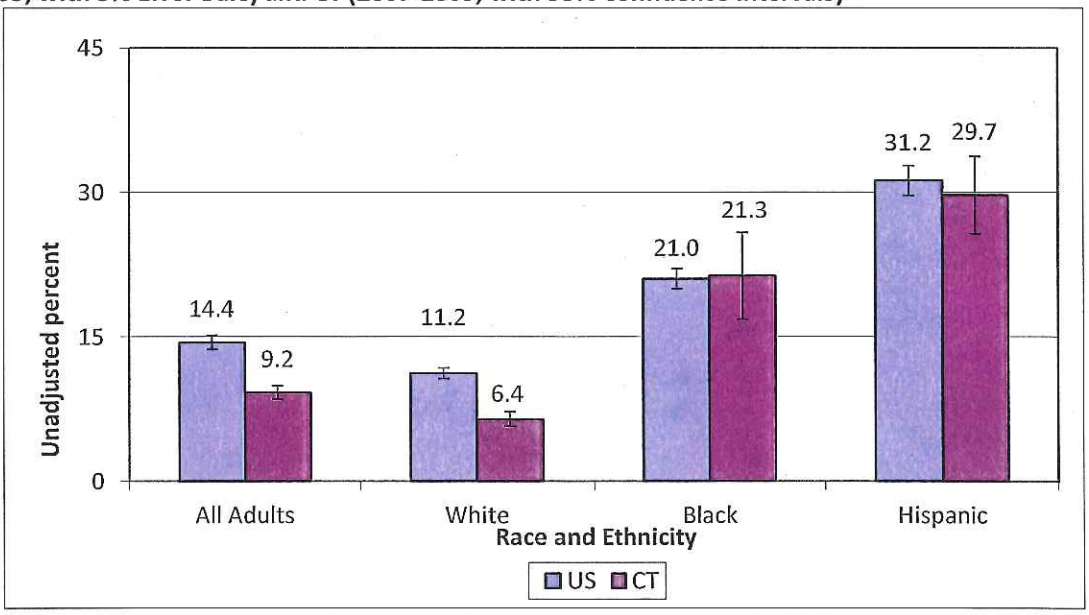


Source: Centers for Disease Control and Prevention, BRFSS, 2010.

ACCESS TO HEALTH CARE

Access to health care is crucial to the prevention, treatment, and management of heart disease and stroke. People without health insurance are less likely than those with health insurance to have a usual source of care, to receive preventive health care services, and to receive appropriate medical management of chronic conditions such as HBP, HBC, and diabetes.[27] About 9% of adults aged 18 and over do not have health insurance (2007-2009 data) compared with approximately 14% of adults nationwide (2009 data).[14, 15] Black and Hispanic Connecticut adults are significantly less likely to have health insurance than White Connecticut adults ($p<0.001$ for both comparisons). Approximately 6% of White, 21% of Black, and 30% of Hispanic adults do not have health insurance.[14] Comparable national figures show that about 11% of White, 21% of Black, and 31% of Hispanic adults report having no health insurance (Figure 28).[15]

Figure 28. Percentage of Adults Who Do Not Have Health Care Coverage by Race and Ethnicity, US (2009, with 5% Error Bars) and CT (2007-2009, with 95% Confidence Intervals)



Source: Centers for Disease Control and Prevention, BRFSS, 2010. Connecticut Department of Public Health, BRFSS, 2010.

TARGETING HIGH-RISK POPULATIONS

The high co-prevalence of modifiable risk factors for CVD indicates the need for public health interventions that focus on the prevention, early detection, and control of modifiable risk factors. The CDC recommends focusing efforts on increasing low dose aspirin therapy according to recognized guidelines; preventing and controlling HBC; reducing sodium intake; preventing and controlling HBC; and increasing the number of smokers counseled to quit and referred to quit lines as well as increasing the availability of no or low-cost cessations products.[28] The CDC also recommends addressing the priority areas through policies, systems, and environmental changes with the potential for broad reach and impact on the general population and high-risk populations.[28]

High-risk populations in Connecticut include Black, Hispanic, and lower-income residents. Black Connecticut residents have higher CVD and stroke mortality rates as well as higher CVD, CHD, and stroke premature mortality rates compared with White Connecticut residents. Black and Hispanic Connecticut residents have significantly higher rates of some important modifiable risk factors for CVD, such as HBC, diabetes, obesity, and physical inactivity compared with White Connecticut residents. Lower-income residents are also more likely to have higher rates of HBC, never having had cholesterol tested, diabetes, current smoking, obesity, and physical inactivity compared with higher-income residents.

Targeted, evidence-based public health interventions are warranted for all Connecticut residents with multiple risk factors. Special emphasis should be placed on interventions that address risk factor reduction among Black, Hispanic, and lower-income Connecticut residents. Evidence-based guidelines for disease prevention in the areas of diabetes, nutrition, physical activity, tobacco, and obesity are provided in the CDC's *Guide to Community Preventive Services*.[29] The 2011 Connecticut Chronic Disease planning process has focused its statewide health promotion and disease prevention efforts on policy, systems, and environmental changes at the state and local levels. Such policy, systems, and environmental changes have the potential to influence health-related behaviors in the general and high-risk populations.

APPENDICES AND REFERENCES

Appendix 1. Data Sources

Connecticut Vital Records Mortality Files

The Connecticut Vital Records Mortality Files are part of the state's vital statistics data base that contains records pertaining to deaths that occur within the state as well as deaths of Connecticut residents occurring in other states, or in Canada. Mortality statistics are compiled in accordance with the World Health Organization (WHO) regulations, which specify that deaths be classified by the current Manual of the International Statistical Classification of Diseases, Injuries, and Causes of Death. Deaths for the 1989-1998 period included in this report are classified by the Ninth Revision of the International Classification of Diseases [ICD-9].[30] Deaths for the 1999-2008 period are classified by the Tenth Revision of the International Classification of Diseases [ICD-10].[31]

The race-ethnicity designation is typically based on report by next of kin, a funeral director, coroner, or other official, often based on observations. As such, the race-ethnicity designation based on observation may be reported incorrectly. Another potential source of error is the fact that death rates are calculated using two different sources of data – the death certificate for the numerator and the U.S. Census Bureau population estimates for the denominator. Errors in under- or over-counting populations by race and/or ethnicity will affect the death rates reported for these groups. Mortality data are reported using racial categories that exclude persons of Hispanic origin (White, non-Hispanic and Black, non-Hispanic) and by Hispanic ethnicity (Hispanics of any race). Death Registry data follow the National Center for Health Statistics guidelines for coding race and Hispanic ethnicity.[5]

Connecticut Hospital Discharge Abstract and Billing Data Base

The Connecticut Hospital Discharge Abstract and Billing Data Base is the source of inpatient hospitalization data. It is maintained by the Connecticut Office of Health Care Access, and it contains patient-level demographic, clinical, and billing data for all non-federal acute care hospitals in the state. In addition to age, gender, and town of residence, the demographic data elements include race and ethnicity. Race and ethnicity may be based upon observation of the patient or self-reporting by the patient. Race is designated as White, non-Hispanic and Black, non-Hispanic; Hispanic ethnicity includes persons of any race.

It should be noted that counts reflect hospitalizations not persons. For example, a patient admitted to a hospital on two separate occasions in 2008 would be counted twice in these data. Another limitation of the data is the fact that it is an administrative data set. It contains diagnoses and procedures based on the International Classification of Diseases, Clinical Modification (ICD-9-CM) codes. The literature contains many reports on the reliability and validity of hospital discharge data with clinical conditions emphasizing discrepancies between ICD-9-CM codes and clinical data.[32]

Behavioral Risk Factor Surveillance System

The Behavioral Risk Factor Surveillance System (BRFSS) survey is a state-based system of health surveys that generate information about health risk behaviors, clinical preventive practices, and health care access and use. The BRFSS, sponsored by the Centers for Disease Control and Prevention, is the world's largest telephone survey, and is conducted in all 50 states. It is an on-going random sample telephone survey of non-institutionalized adults, 18 years and older. Information from the survey is used to improve the health of people nationwide and in Connecticut. Racial and ethnic classifications are based on self-report and include White, non-Hispanic, Black, non-Hispanic, and Hispanic (including persons of any race). Other national and state-specific risk factor data and information regarding BRFSS methodology can be accessed on the CDC's BRFSS Web site at: http://www.cdc.gov/brfss/.

Connecticut School Health Survey

The Connecticut School Health Survey (CSHS) is a comprehensive survey that consists of two components: Youth Tobacco Component (YTC) and the Youth Behavior Component (YBC). The CSHS is conducted by the Connecticut Department of Public Health in cooperation with the CDC, the Connecticut State Department of Education, and partners from local school health districts and local health departments. The YTC is a comprehensive survey of tobacco use, access, cessation, knowledge and attitudes, and exposure among Connecticut students in grades 6-12. The YBC collects data that is used to monitor priority health-risk behaviors and the prevalence of obesity and asthma among high school students in Connecticut. The YBC is administered to a representative sample of all regular public high school students in Connecticut. Racial and ethnic classifications are based on self-report and include White, non-Hispanic; Black, non-Hispanic; and Hispanic (including persons of any race). Further information about the CSHS can be found on the Connecticut Department of Public Health's web site: http://www.ct.gov/dph/cshs. Other national and state-specific youth risk factor data and information can be accessed on the CDC's web site: http://www.cdc.gov/HealthyYouth/YRBS/.

Appendix 2A. ICD-10 Coding for Selected Causes of Death, 1999-2008

Cause of Death	ICD-10 Code
All Causes	A00.0 – Y89.9
All Cancers	C00 – C97
Diabetes Mellitus	E10 – E14
Alzheimer's Disease	G30
Cardiovascular Disease	I00-I78
Diseases of the Heart	I00 – I09, I11, I13, I20 – I51
Coronary Heart Disease	I11, I20-I25
Congestive Heart Failure	I50.0
Essential Hypertension & Hypertensive Renal Disease	I10, I12
Cerebrovascular Disease	I60 – I69
Atherosclerosis	I71
Pneumonia and Influenza	J10 – J18
Chronic Lower Respiratory Diseases	J40 – J47
Unintentional Injuries	V01 – X59, Y85 – Y86

Source: World Health Organization. 1992. Manual of the International Statistical Classification of Diseases, Injuries, and Causes of Death, based on the recommendations of the Tenth Revision Conference, 1992 (ICD-10). World Health Organization, Geneva.

Appendix 2B. ICD-9 Coding for Selected Causes of Death, 1989-1998

Cause of Death	ICD-9 Code
All Causes	1-E999
Cardiovascular Disease Deaths	390-459
Diseases of the Heart	390-398,402,404-429
Coronary Heart Disease	402, 410-414, 429.2
Congestive Heart Failure	428.0
Hypertension without Renal Disease	401, 403
Cerebrovascular Disease	430-438
Atherosclerosis	440

Source: World Health Organization. 1977. Manual of the International Statistical Classification of Diseases, Injuries, and Causes of Death, based on the recommendations of the Ninth Revision Conference, 1975 (ICD-9). World Health Organization, Geneva.

Appendix 2C. ICD-9-CM Coding for Selected Causes of Hospitalizations

Cause of Hospitalization	ICD-9-CM Code
Circulatory	390-459
Coronary Heart Disease	402, 410-414, 429.2
Congestive Heart Failure	428
Cerebrovascular Disease	430-438

Source: Practice Management Information Corporation (PMIC). 2004. The International Classification of Diseases, Ninth Revision, Clinical Modification. 6th ed. PMIC, Los Angeles, CA.

Appendix 3A. Glossary of Statistical Terms

Age-adjustment. "Age adjustment, using the direct method, is the application of observed age-specific rates to a standard age distribution to eliminate differences in crude rates in populations of interest that result from differences in the populations' age distributions. This adjustment is usually done when comparing two or more populations at one point in time or one population at two or more points in time. Age adjustment is particularly relevant when populations being compared have different age structures, for example, the U.S. white and Hispanic populations...."[33]

Age-adjusted BRFSS rates. Some of the Behavioral Risk Factor Surveillance System (BRFSS) rate estimates presented in this report were age-adjusted, using the direct method, in order to eliminate differences in crude rates in populations of interest that result from differences in the populations' age distributions, such as those of Hispanics and Whites. The following age distributions and age-adjustment weights, based on the 2000 projected U.S. population, were used[34]:

Age Distributions and Age-adjustment Weights, 2000 Projected U.S. Population

Age	Population in thousands	Adjustment weight
18 years and over	203,851	1.000000
18 – 24 years	26,258	0.128810
25 – 44 years	81,892	0.401725
45 – 64 years	60,991	0.299194
65 years and over	34,710	0.170271

Age-adjusted Mortality Rates (AAMR) and Age-adjusted Hospitalization Rates (AAHR) are used to compare relative mortality and hospitalization risk, respectively, across groups and over time. They are not actual measures of risk but rather an index of risk. They are weighted statistical averages of the age-specific rates, in which the weights represent the fixed population proportions by age.[35] The AAMR and AAHR were computed by the direct method. The 1940 and 2000 U.S. standard million population distributions are shown below:

Age group	1940	2000
0-4	80,057	69,136
5-9	81,151	72,533
10-14	89,209	73,032
15-19	93,665	72,169
20-24	88,002	66,477
25-29	84,280	64,529
30-34	77,787	71,044
35-39	72,501	80,762
40-44	66,744	81,851
45-49	62,696	72,118
50-54	55,116	62,716
55-59	44,559	48,454
60-64	36,129	38,793
65-69	28,519	34,264
70-74	19,519	31,773
75-79	11,423	26,999
80-84	5,878	17,842
85+	2,765	15,508
Total	1,000,000	1,000,000

Cause-of-death classification. Mortality statistics for this report were compiled in accordance with the World Health Organization (WHO) regulations, which specify that member nations classify causes of death by the current Manual of the International Statistical Classification of Diseases, Injuries, and Causes of Death. Deaths for the 1989-1998 period were classified by the Manual of the International Statistical Classification of Diseases, Injuries, and Causes of Death, Ninth Revision of the International Classification of Diseases (ICD-9).[30] Deaths for the 1999-2008 period were classified according to the Tenth Revision of the International Classification of Diseases (ICD-10).[31]

Healthy People 2010 is part of a national strategy addressing the prevention of major chronic illnesses, injuries, and infectious diseases. It is the product of an effort, involving expert working groups, a consortium of national organizations, all state health departments, and the Institute of Medicine of the National Academy of Sciences to set health objectives for the nation. After extensive national and regional hearings were conducted with a period of public review and comment, the health objectives were published in 1990 as *Healthy People 2000—National Health Promotion and Disease Prevention Objectives.* It established national objectives and served as the basis for the development of state and community plans. *Healthy People 2010* provides a comprehensive view of the nation's health in 2000, and establishes national goals and targets to be achieved by 2010, and monitors progress over time.[36]

Hispanic origin refers to people whose origins are from Spain, the Spanish-speaking countries of Central America, South America, and the Caribbean, or persons of Hispanic origin identifying themselves as Spanish, Spanish-American, Hispanic, Hispano, or Latino. Since 1988, the Connecticut death certificate has had a separate line item for Hispanic ethnicity. Individuals identified as "Hispanic" can be of any race, and are also counted in the race breakdown as either "white," "black," "Asian or Pacific Islander," "American Indian," or other.[5]

International Classification of Diseases 9th and 10th Revisions(ICD-9, ICD-10) have been the internationally accepted coding system for determining cause of death since the early 1900s. It is periodically revised. The Ninth Revision (ICD-9) was in use from 1975 through 1998. Beginning with 1999 deaths, the Tenth Revision (ICD-10) is being used.

Preliminary estimates of the comparability of ICD-9 to ICD-10 have been published and indicate that the discontinuity in trends from 1998 to 1999 for some leading causes of death (septicemia, influenza and pneumonia, Alzheimer's disease, nephritis, nephrotic syndrome, and nephrosis) is substantial.[37]

International Classification of Diseases, Clinical Modification (ICD-9-CM) is a coding system recommended for use in all clinical settings to describe medical procedures and diagnoses. It is required for reporting diagnoses and diseases to all U.S. Public Health Service and Department of Health and Human Services programs, including Medicare and Medicaid. The foundation of the ICD-9-CM is the *International Classification of Diseases, 9th Revision* published by the World Health Organization.[30]

Population bases for computing rates are taken from the U.S. Census Bureau's *Estimates of the population of states by age, sex, race, and Hispanic origin*. These data are estimates of the population of Connecticut by 5-year age groups (age 0 to 4, 5 to 9,...85 and over), sex (male, female), modified race (white; black; Native American including Alaska Natives; Asian and Pacific Islander) and Hispanic origin (Hispanic, non-Hispanic) for each year, July 1, 1999 through July 1, 2009.[5]

Premature mortality. See Years of Potential Life Lost.

Race refers to a population of individuals identified from a common history, nationality, or geographical place. Race is widely considered a valid scientific category, but not a valid biological or genetic category.[38, 39] Available scientific evidence indicates that racial and ethnic classifications do not capture biological distinctiveness, and that there is more genetic variation within racial groups than there is between racial groups.[40, 41] Contemporary race divisions result from historical events and circumstances and reflect current social realities. Thus, racial categories may be viewed more accurately as proxies for social and economic conditions that put individuals at higher risk for certain disease conditions.[32]

Data in this report include two racial groups in Connecticut: white, non-Hispanic and black, non-Hispanic. Individuals identified as "Hispanic" can be of any race.

Socioeconomic position refers to a person's social and economic place in a society, and is operationalized or measured by characteristics such as per capita or household income, educational attainment, or occupation. Historically, lower socioeconomic position has been strongly correlated with less favorable health outcomes such as premature mortality and higher death rates from all causes; conversely, persons of higher socioeconomic position do better on most measures of health status.[12]

Years of potential life lost (YPLL) represents the number of years of potential life lost by each death before a predetermined end point (e.g., 65 or 75 years of age). Whereas the crude and adjusted death rates are heavily influenced by the large number of deaths among the elderly, the YPLL measure provides a picture of premature mortality by weighting deaths that occur at younger ages more heavily than those occurring at older ages, thereby emphasizing different causes of death. Age-adjusted YPLLs are calculated using the methodology of Romeder and McWhinnie.[42] This method consists of a summation of the number of deaths occurring at each age (betweem 1 and 75) multiplied by the remaining years of life had the deceased lived up to age 75.

Appendix 3B. Glossary of Medical Terms

Atherosclerosis: A disease that affects the arteries, particularly those supplying the heart, the brain, the aorta, and the lower extremities. Atherosclerosis underlies the occurrence of heart attacks, many strokes, peripheral arterial disease, and ruptures of the aorta.[43]

Cardiovascular Diseases (CVD): Diseases of the circulatory system, which include acute myocardial infarction, ischemic heart disease, valvular heart disease, peripheral vascular disease, arrhythmias, high blood pressure and stroke.[44]

Coronary Heart Disease (CHD): A form of heart disease resulting from impaired circulation in one or more coronary arteries. Common clinical manifestations of CHD include chest pain (angina pectoris) or "heart attack".[44]

Cerebrovascular Disease: A disease of one or more blood vessels in the brain, which often results in the sudden development of a focal neurologic deficit, or stroke. Stroke, or a "brain attack" is the most severe clinical manifestation of cerebrovascular disease.[1, 45]

Congestive Heart Failure: The inability of the heart to maintain adequate pumping function, which can be caused by a number of factors, such as untreated hypertension, heart attacks, or infections. Heart failure increases the risk for other cardiovascular disease events and often results in physical disability. Congestive Heart Failure is commonly referred to as "heart failure".[43-45]

Diabetes (or diabetes mellitus): A metabolic disorder that results from the body's insufficient production or utilization of insulin. The most common types of diabetes includes "Type 1 diabetes," formerly known as "juvenile diabetes," and "Type 2 diabetes," formerly known as "adult-onset diabetes." Long-term effects of diabetes include cardiovascular complications.[43]

Dyslipidemia: A disorder of lipoprotein metabolism, such as an overproduction or deficiency of lipoprotein. Dyslipidemia is often manifested by elevated levels of total cholesterol, the "bad" or low-density lipoprotein (LDL) cholesterol, and the triglyceride concentrations, as well as decreased levels of the "good" or high-density lipoprotein (HDL) cholesterol concentration in the blood.[46]

Essential Hypertension: high blood pressure without a secondary cause such as renal failure. Approximately 95% of all cases of hypertension are classified as essential hypertension.[47]

Heart Failure: See Congestive Heart Failure.

Hemorrhagic Stroke: Hemorrhagic stroke occurs when a weakened blood vessels ruptures causing bleeding within the brain. The resulting accumulation of blood compresses nearby brain tissue. Hemorrhagic stroke is often associated with high blood pressure. About 13% of all strokes are hemorrhagic.[48]

High Blood Cholesterol: Cholesterol is a substance found in all cells of the body; it is carried in lipoproteins, made of fat (lipid) on the inside and proteins on the outside. Low-density lipoprotein (LDL) cholesterol is sometimes called "bad cholesterol" because it leads to a buildup of cholesterol in arteries. The chance of heart disease increases with increasing LDL levels in the blood. The buildup of cholesterol in the arteries is called plaque, which over time causes the narrowing of the arteries, or "atherosclerosis." Some plaques can burst, releasing fat and cholesterol into the bloodstream, which may cause the blood to clot and block the flow of blood. This blockage can cause angina or a heart attack. Lowering one's cholesterol level decreases the chance of having a plaque burst and a subsequent heart attack. Lowering cholesterol may also slow down, reduce, or even stop plaque from building up.[49]

High Blood Pressure: A condition in which the pressure in the arterial circulation system is greater than clinically recommended, that is a systolic pressure greater than or equal to 140 mm Hg or a diastolic pressure greater than or equal to 90 mm Hg. High blood pressure is associated with increased risk for heart disease, stroke, and chronic kidney disease.[43]

Hypertensive Heart Disease: An abnormality in the structure and function of the heart caused by long-standing high blood pressure. A common, clinical manifestation of hypertensive heart disease is heart failure.[43]

Ischemic Heart Disease: A condition in which heart muscle is damaged or works inefficiently because of an absence or deficiency of its blood supply. Ischemic heart disease is most often caused by atherosclerosis, and includes angina pectoris, acute myocardial infarction, chronic ischemic heart disease, and sudden death.[44]

Ischemic Stroke: The most common type of stroke that results from an obstruction within a blood vessel supplying blood to the brain. Atherosclerosis is the cause of the obstruction. About 87% of strokes are ischemic strokes.[50]

Obesity: Defined in terms of body mass index (BMI), and calculated as body weight in kilograms (1 kg = 2.2 lbs.) divided by height in meters (1 m = 39.37 in) squared. Adults with a BMI of greater than or equal to 30.0 kg/m2 are considered "obese," and those with a BMI of 25–29.9 kg/m2 are considered "overweight".[43]

Classification of Overweight and Obesity in Adults According to BMI.[44] Obesity is classified as BMI $\geq$ 30 kg/m^2.		
Classification	**BMI (kg/m^2)**	**Risk of Health Problems**
Underweight	< 18.5	Low (but risk of other clinical problems increased)
Normal range	18.5-24.9	Average
Overweight	25.0-29.9	Mildly increased
Obese	**> 30.0**	
Class I	30.0-34.9	Moderate
Class II	35.0-39.9	Severe
Class III	> 40.0	Very severe
Note that these values are age-independent and correspond to the same degree of fatness across different populations.		

Serum (Blood) Lipids: Cholesterol and triglycerides are types of lipids circulating in the blood. Over time, elevated cholesterol and triglycerides in the blood can become plaque in artery walls leading to atherosclerosis. Elevated cholesterol and triglyceride levels are often found in individuals with other major risk factors for heart disease (obesity, diabetes, and/or high blood pressure).[51]

Stroke: The most common clinical manifestation of cerebrovascular disease. Stroke describes an interruption of the blood supply in the brain that results in damaged brain tissue. It can be caused by clots or by bleeding in the brain from a ruptured blood vessel or a significant injury.[1, 52]

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ATTACHMENT V

Letters of Support

Cardiovascular Services
of Greenwich

HEART INSTITUTE
GREENWICH
HOSPITAL
YALE NEW HAVEN HEALTH

Harvey Seidenstein, MD, FACC
Medical Director, Clinical Cardiology

Alexander Del Vecchio, MD
Clinical Cardiac Electrophysiology

Christopher J. Howes, MD, FACC
Clinical and Interventional Cardiology

John F. Setaro, MD, FACC
Preventive and Interventional Cardiology, Hypertension

November 8, 2011

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134

Dear Deputy Commissioner Davis:

I am writing this letter to express my support for the proposed elective angioplasty program at Greenwich Hospital as a satellite of the Yale-New Haven Heart and Vascular Center. Since the inception of the primary angioplasty program at Greenwich Hospital, I have been the Medical Director overseeing its daily operation. This program has demonstrated success and has saved lives in the community. The excellent outcomes and safety we have demonstrated with the primary angioplasty program puts us in a unique position to expand our access of high quality care to patients of this community and offer them elective angioplasty at Greenwich Hospital.

We are seeking to build on the unique structure that is already in place at Greenwich Hospital. It is cost effective and efficient to use what is already available for *emergency* angioplasty patients to also provide care to *elective* angioplasty patients. An elective angioplasty program will improve access to care locally. Patient and family satisfaction will improve as Greenwich Hospital patients will no longer have to transfer out of the region despite the availability of equipment and facilities, qualified staff and high volume operators. Currently, the transfer of patients out of the region produces an emotional, financial and occasionally physical hardship on patients and their families.

The elective angioplasty program at Greenwich Hospital would adhere to the standards set forth by the Yale-New Haven Heart and Vascular Center. We will continue the current comprehensive quality and outcome monitoring that we have created for our primary angioplasty program. Approval of an elective angioplasty program at Greenwich Hospital will improve the overall quality of the Greenwich Hospital cardiology program as it will provide the staff and operators with greater number of patients with a broader spectrum of disease to maintain competency and high quality standards.

Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Christopher J. Howes, MD
Medical Director of PAMI Program and Interventional
Cardiology at Greenwich Hospital
Assistant Professor of Medicine,
Yale School of Medicine

Yale University School of Medicine
CARDIOVASCULAR MEDICINE
333 Cedar Street · 3 FMP · PO Box 208017
New Haven CT 06520-8017
T: 203 785-4129 · F: 203 737-2437

Branford Office
11 Harrison Avenue
Branford CT 06405
T: 203 483-8300 · F: 203 483-8314

Henry S. Cabin, MD
Professor of Medicine and Pathology
Clinical Chief of Cardiology
Yale University
Medical Director
Yale-New Haven Hospital Heart Center

November 8, 2011

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134

Dear Deputy Commissioner Davis:

I am writing this letter to express my support for the proposed elective angioplasty program at Greenwich Hospital as a satellite of the Yale-New Haven Heart and Vascular Center. As Clinical Chief of Cardiology for Yale School of Medicine and Medical Director of the Yale-New Haven Heart and Vascular Center, I have played a key role in the implementation of the primary angioplasty program at Greenwich Hospital. This program has demonstrated success and has saved lives in the community. We are seeking to build on the unique structure that is already in place at Greenwich Hospital. This program will improve continuity of care as Greenwich Hospital patients now must be transferred for elective angioplasty despite the availability of equipment and facilities, qualified staff and high volume operators.

The program will be supervised and directed by the Yale Interventional Group and all procedures will be performed by highly qualified physicians. The elective angioplasty program at Greenwich Hospital would adhere to the high standards set forth by the Yale-New Haven Heart and Vascular Center. Quality and outcomes monitoring would be provided by the Yale-New Haven Heart and Vascular Center. The facility, physicians, staff and equipment required to perform elective angioplasty services are already in place at Greenwich Hospital. It is cost effective and efficient to use what is already available for *emergency* angioplasty patients to also provide care to *elective* angioplasty patients.

Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Henry S. Cabin, MD
Clinical Chief of Cardiology,
Yale School of Medicine
Medical Director
Yale-New Haven Heart and Vascular Center

WESTMED
MEDICAL GROUP

Barney Newman, M.D.
Medical Director

November 17, 2011

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134

Dear Deputy Commissioner Davis:

I am writing this letter in support of Greenwich Hospital's application to provide elective angioplasty to the communities it serves. I am the Chief Medical Officer for WESTMED Medical Group, a large multi-specialty group of over 200 physicians with locations throughout Westchester County, New York. Many of our cardiologists are on the medical staff at Greenwich Hospital. It is our experience that our patients in the Greenwich Hospital service area use the Hospital's services for their health care needs including cardiac services. If Greenwich Hospital offered elective angioplasty, we feel confident that these patients would prefer the convenient location of Greenwich Hospital along with the high quality and competent physicians and staff, up-to-date facilities and appropriate safety measures in place at the Hospital.

An elective angioplasty service at Greenwich Hospital will provide cardiac patients with local access to high quality interventional cardiology services. Patients from the Greenwich Hospital service area that need elective angioplasty are currently required to go to another hospital to receive these services since Greenwich Hospital is not approved to provide elective angioplasty services. However, the same facility, physicians, staff and equipment required to perform *elective* angioplasty services are already in place for Greenwich Hospital's approved *emergency* angioplasty program. This is a more cost effective use of resources. In addition, the ability to provide elective angioplasty will improve the continuity of care available to patients at Greenwich Hospital.

Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Barney D. Newman MD

Dr. Barney D. Newman
Chief Medical Officer
WESTMED Medical Group

JOSEPH J. TARTAGLIA, M.D., D-IM (C.D.), (GM) F.A.C.C., P.C.
311 NORTH STREET
WHITE PLAINS, N. Y. 10605
TELEPHONE 946-3388

November 7, 2011

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134

Dear Deputy Commissioner Davis:

I am writing this letter in support of Greenwich Hospital's application to provide elective angioplasty to the communities it serves. I am on the medical staff at Greenwich Hospital. Many of my patients use the Hospital's services for their health care needs including cardiac services. If Greenwich Hospital offered elective angioplasty, I feel confident that my patients in the Greenwich Hospital service area would prefer the convenient location of Greenwich Hospital along with the high quality and competent physicians and staff, up-to-date facilities and appropriate safety measures in place at the Hospital.

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Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Joseph Tartaglia, MD

RYE BROOK CARDIOLOGY
& VASCULAR MEDICINE, P.C.

16 Rye Ridge Plaza
Rye Brook, NY 10573
Telephone: (914) 251-1070
Fax: (914) 935-9047

November 7, 2011

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134

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Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Myung-Ho Lee, MD

Cardiovascular Services
of Greenwich

Harvey Seidenstein, MD, FACC
Medical Director, Clinical Cardiology

Alexander Del Vecchio, MD
Clinical Cardiac Electrophysiology

Christopher J. Howes, MD, FACC
Clinical and Interventional Cardiology

John F. Setaro, MD, FACC
Preventive and Interventional Cardiology, Hypertension

HEART INSTITUTE
GREENWICH
HOSPITAL
YALE NEW HAVEN HEALTH

November 7, 2011

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Deputy Commissioner
Office of Health Care Access
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Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Harvey Seidenstein, MD

PRACTICE LIMITED TO CARDIOLOGY BY APPOINTMENT

KEVIN E. CONBOY, M.D.

38 LAKE AVENUE
GREENWICH, CONNECTICUT 06830

TELEPHONE (203) 622-9102
FAX (203) 622-0508

November 7, 2011

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134

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Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Kevin Conboy MD

Kevin Conboy, MD

Joel M. Blumberg, MD, FACP, FACC
Internal Medicine & Cardiology

Affiliated Physician
MDVIP
PERSONALIZED HEALTHCARE

November 7, 2011

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
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I urge you to approve this application.

Sincerely,

Joel Blumberg, MD

55 Holly Hill Lane, Suite 210, Greenwich, CT 06830 • Phone 203.661.4242 • Fax 203.625.9626

Greenwich **Cardiology** Associates, LLC

67 Holly Hill Lane, Suite 102, Greenwich, CT 06830 | Ph: 203.869.5515 | F: 203.869.5765 | www.gcardiology.com

November 7, 2011

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134

Dear Deputy Commissioner Davis:

I am writing this letter in support of Greenwich Hospital's application to provide elective angioplasty to the communities it serves. I am on the medical staff at Greenwich Hospital. Many of my patients use the Hospital's services for their health care needs including cardiac services. If Greenwich Hospital offered elective angioplasty, I feel confident that my patients in the Greenwich Hospital service area would prefer the convenient location of Greenwich Hospital along with the high quality and competent physicians and staff, up-to-date facilities and appropriate safety measures in place at the Hospital.

An elective angioplasty service at Greenwich Hospital will provide cardiac patients with local access to high quality interventional cardiology services. Patients from the Greenwich Hospital service area that need elective angioplasty are currently required to go to another hospital to receive these services since Greenwich Hospital is not approved to provide elective angioplasty services. However, the same facility, physicians, staff and equipment required to perform *elective* angioplasty services are already in place for Greenwich Hospital's approved *emergency* angioplasty program. This is a more cost effective use of resources. In addition, the ability to provide elective angioplasty will improve the continuity of care available to patients at Greenwich Hospital.

Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Glenn Gandelman, MD

Greenwich **Cardiology** Associates, LLC

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I urge you to approve this application.

Sincerely,

Bartel Crisafi, Sr., MD

Francis J. Neeson , M.D. FACC

Cardiology

75 Holly Hill Lane
Greenwich , CT 06830
Phone (203) 869-6960
Fax (203) 869-5103

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I urge you to approve this application.

Sincerely,

Francis Neeson, MD

ROBERT M. STARK, M.D., P.C.
FELLOW, AMERICAN COLLEGE OF PHYSICIANS
FELLOW, AMERICAN COLLEGE OF CARDIOLOGY
40 WEST ELM STREET
GREENWICH, CONNECTICUT 06830

(203) 622-1102
FAX (203) 622-1508
www.robertstarkmd.com

November 7, 2011

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Office of Health Care Access
Department of Public Health
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P.O. Box 340308
Hartford, CT 06134

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Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Robert Stark, MD

Robert Stark, MD

ATTACHMENT VI

Practice Guidelines
2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions

Executive Summary
The Current Status and Future Direction of Percutaneous Coronary Intervention Without On-Site Surgical Backup: An Expert Consensus Document for the Society for Cardiovascular Angiography and Interventions

Practice Guidelines

Catheterization and Cardiovascular Interventions 00:000–000 (2011)

PRACTICE GUIDELINE

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions

WRITING COMMITTEE MEMBERS*

Glenn N. Levine, MD, FACC, FAHA, Chair[†], **Eric R. Bates,** MD, FACC, FAHA, Vice Chair[*†], **James C. Blankenship,** MD, FACC, FSCAI, Vice Chair[*‡], **Steven R. Bailey,** MD, FACC, FSCAI[*‡], **John A. Bittl,** MD, FACC[†§], **Bojan Cercek,** MD, FACC, FAHA[†], **Charles E. Chambers,** MD, FACC, FSCAI[‡], **Stephen G. Ellis,** MD, FACC[*†], **Robert A. Guyton,** MD, FACC[*‖], **Steven M. Hollenberg,** MD, FACC[*†], **Umesh N. Khot,** MD, FACC[*†], **Richard A. Lange,** MD, FACC, FAHA[§], **Laura Mauri,** MD, MSC, FACC, FSCAI[*†], **Roxana Mehran,** MD, FACC, FAHA, FSCAI[*‡], **Issam D. Moussa,** MD, FACC, FAHA, FSCAI[‡], **Debabrata Mukherjee,** MD, FACC, FSCAI[†], **Brahmajee K. Nallamothu,** MD, FACC[¶], **Henry H. Ting,** MD, FACC, FAHA[†]

ACCF/AHA TASK FORCE MEMBERS

Alice K. Jacobs, MD, FACC, FAHA, Chair, **Jeffrey L. Anderson,** MD, FACC, FAHA, Chair-Elect, **Nancy Albert,** PHD, CCNS, CCRN, FAHA, **Mark A. Creager,** MD, FACC, FAHA, **Steven M. Ettinger,** MD, FACC, **Robert A. Guyton,** MD, FACC, **Jonathan L. Halperin,** MD, FACC, FAHA, **Judith S. Hochman,** MD, FACC, FAHA, **Frederick G. Kushner,** MD, FACC, FAHA, **E. Magnus Ohman,** MD, FACC, **William Stevenson,** MD, FACC, FAHA, **and Clyde W. Yancy,** MD, FACC, FAHA

Key words: ACCF/AHA Practice Guidelines; acute coronarysyndromes; anticoagulants; antiplatelet agents; arrhythmias, cardiac; coronary angiography; coronary artery revascularization interventions: stents; drug therapy; drug delivery systems; heart diseases; myocardial revasularization; platelet aggregation inhibitor; ultrasound

*Writing committee members are required to recuse themselves from voting on sections to which their specific relationships with industry and other entities may apply; see Appendix 1 for recusal information. [†]ACCF/AHA Representative. [‡]SCAI Representative. [§]Joint Revascularization Section Author. [‖]ACCF/AHA Task Force on Practice Guidelines Liaison. [¶]ACCF/AHA Task Force on Performance Measures Liaison.

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PREAMBLE

The medical profession should play a central role in evaluating the evidence related to drugs, devices, and procedures for the detection, management, and prevention of disease. When properly applied, expert analysis of available data on the benefits and risks of these therapies and procedures can improve the quality of care, optimize patient outcomes, and favorably affect costs by focusing resources on the most effective strategies. An organized and directed approach to a thorough review of evidence has resulted in the production of clinical practice guidelines that assist physicians in selecting the best management strategy for an individual patient. Moreover, clinical practice guidelines can provide a foundation for other applications, such as performance measures, appropriate use criteria, and both quality improvement and clinical decision support tools.

The American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) have jointly produced guidelines in the area of cardiovascular disease since 1980. The ACCF/AHA Task Force on Practice Guidelines (Task Force), charged with developing, updating, and revising practice guidelines for cardiovascular diseases and procedures, directs and oversees this effort. Writing committees are charged with regularly reviewing and evaluating all available evidence to develop balanced, patient-centric recommendations for clinical practice.

Experts in the subject under consideration are selected by the ACCF and AHA to examine subject-specific data and write guidelines in partnership with representatives from other medical organizations and specialty groups. Writing committees are asked to perform a formal literature review; weigh the strength of evidence for or against particular tests, treatments, or procedures; and include estimates of expected outcomes where such data exist. Patient-specific modifiers, comorbidities, and issues of patient preference that may influence the choice of tests or therapies are considered. When available, information from studies on cost is considered, but data on efficacy and outcomes constitute the primary basis for the recommendations contained herein.

In analyzing the data and developing recommendations and supporting text, the writing committee uses evidence-based methodologies developed by the Task Force (1). The Class of Recommendation (COR) is an estimate of the size of the treatment effect considering risks versus benefits in addition to evidence and/or agreement that a given treatment or procedure is or is not useful/effective or in some situations may cause harm. The Level of Evidence (LOE) is an estimate of the certainty or precision of the treatment effect. The writing committee reviews and ranks evidence supporting each recommendation with the weight of evidence ranked as LOE A, B, or C according to specific definitions that are included in Table 1. Studies are identified as observational, retrospective, prospective, or randomized where appropriate. For certain conditions for which inadequate data are available, recommendations are based on expert consensus and clinical experience and are ranked as LOE C. When recommendations at LOE C are supported by historical clinical data, appropriate references (including clinical reviews) are cited if available. For issues for which sparse data are available, a survey of current practice among the clinicians on the writing committee is the basis for LOE C recommendations and no references are cited. The schema for COR and LOE is summarized in Table 1, which also provides suggested phrases for writing recommendations within each COR. A new addition to this methodology is separation of the Class III recommendations to delineate if the recommendation is determined to be of "no benefit" or is associated with "harm" to the patient. In addition, in view of the increasing number of comparative effectiveness studies, comparator verbs and suggested phrases for writing recommendations for the comparative effectiveness of one treatment or strategy versus another have been added for COR I and IIa, LOE A or B only. T1

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TABLE 1. Applying Classification of Recommendations and Level of Evidence

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	CLASS I *Benefit >>> Risk* Procedure/Treatment **SHOULD** be performed/ administered	CLASS IIa *Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	CLASS IIb *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	CLASS III *No Benefit* or CLASS III *Harm* COR III: No benefit — Procedure/Test: Not Helpful; Treatment: No Proven Benefit COR III: Harm — Procedure/Test: Excess Cost w/o Benefit or Harmful; Treatment: Harmful to Patients
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care
Suggested phrases for writing recommendations	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR III: No Benefit — is not recommended; is not indicated; should not be performed/ administered/ other; is not useful/ beneficial/ effective COR III: Harm — potentially harmful; causes harm; associated with excess morbidity/mortality; should not be performed/ administered/ other
Comparative effectiveness phrases†	treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B		

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use. †For comparative effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

In view of the advances in medical therapy across the spectrum of cardiovascular diseases, the Task Force has designated the term *guideline-directed medical therapy (GDMT)* to represent optimal medical therapy as defined by ACCF/AHA guideline recommended therapies (primarily Class I). This new term, GDMT, will be used herein and throughout all future guidelines.

Because the ACCF/AHA practice guidelines address patient populations (and healthcare providers) residing in North America, drugs that are not currently available in North America are discussed in the text without a specific COR. For studies performed in large numbers of subjects outside North America, each writing committee reviews the potential influence of different practice patterns and patient populations on the treatment effect and relevance to the ACCF/AHA target population to determine whether the findings should inform a specific recommendation.

The ACCF/AHA practice guidelines are intended to assist healthcare providers in clinical decision making by describing a range of generally acceptable

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approaches to the diagnosis, management, and prevention of specific diseases or conditions. The guidelines attempt to define practices that meet the needs of most patients in most circumstances. The ultimate judgment regarding care of a particular patient must be made by the healthcare provider and patient in light of all the circumstances presented by that patient. As a result, situations may arise for which deviations from these guidelines may be appropriate. Clinical decision making should involve consideration of the quality and availability of expertise in the area where care is provided. When these guidelines are used as the basis for regulatory or payer decisions, the goal should be improvement in quality of care. The Task Force recognizes that situations arise in which additional data are needed to inform patient care more effectively; these areas will be identified within each respective guideline when appropriate.

Prescribed courses of treatment in accordance with these recommendations are effective only if followed. Because lack of patient understanding and adherence may adversely affect outcomes, physicians and other healthcare providers should make every effort to engage the patient's active participation in prescribed medical regimens and lifestyles. In addition, patients should be informed of the risks, benefits, and alternatives to a particular treatment and be involved in shared decision making whenever feasible, particularly for COR IIa and IIb, where the benefit-to-risk ratio may be lower.

The Task Force makes every effort to avoid actual, potential, or perceived conflicts of interest that may arise as a result of industry relationships or personal interests among the members of the writing committee. All writing committee members and peer reviewers of the guideline are asked to disclose all such current relationships, as well as those existing 12 months previously. In December 2009, the ACCF and AHA implemented a new policy for relationships with industry and other entities (RWI) that requires the writing committee chair plus a minimum of 50% of the writing committee to have no *relevant* RWI (Appendix 1 for the ACCF/AHA definition of relevance). These statements are reviewed by the Task Force and all members during each conference call and/or meeting of the writing committee and are updated as changes occur. All guideline recommendations require a confidential vote by the writing committee and must be approved by a consensus of the voting members. Members are not permitted to write, and must recuse themselves from voting on, any recommendation or section to which their RWI apply. Members who recused themselves from voting are indicated in the list of writing committee members, and section recusals are noted in Appendix 1. Authors' and peer reviewers' RWI pertinent to this guideline are disclosed in Appendixes 1 and 2, respectively. Additionally, to ensure complete transparency, writing committee members' comprehensive disclosure information—including RWI not pertinent to this document—is available as an online supplement. Comprehensive disclosure information for the Task Force is also available online at www.cardiosource.org/ACC/ About-ACC/Leadership/Guidelines-and-Documents-Task-Forces.aspx. The work of the writing committee was supported exclusively by the ACCF, AHA, and the Society for Cardiovascular Angiography and Interventions (SCAI) without commercial support. Writing committee members volunteered their time for this activity.

In an effort to maintain relevance at the point of care for practicing physicians, the Task Force continues to oversee an ongoing process improvement initiative. As a result, in response to pilot projects, several changes to these guidelines will be apparent, including limited narrative text, a focus on summary and evidence tables (with references linked to abstracts in PubMed) and more liberal use of summary recommendation tables (with references that support LOE) to serve as a quick reference.

In April 2011, the Institute of Medicine released 2 reports: *Finding What Works in Health Care: Standards for Systematic Reviews* and *Clinical Practice Guidelines We Can Trust* (2, 3). It is noteworthy that the ACCF/AHA guidelines were cited as being compliant with many of the standards that were proposed. A thorough review of these reports and of our current methodology is under way, with further enhancements anticipated.

The recommendations in this guideline are considered current until they are superseded by a focused update or the full-text guideline is revised. Guidelines are official policy of both the ACCF and AHA.

Alice K. Jacobs, MD, FACC, FAHA, Chair
ACCF/AHA Task Force on Practice Guidelines

1. INTRODUCTION

1.1. Methodology and Evidence Review

The recommendations listed in this document are, whenever possible, evidence based. An extensive evidence review was conducted through November 2010, as well as selected other references through August 2011. Searches were limited to studies, reviews, and other evidence conducted in human subjects and that were published in English. Key search words included but were not limited to the following: *ad hoc angioplasty, angioplasty, balloon angioplasty, clinical trial, coronary stenting, delayed angioplasty, meta-analysis,*

percutaneous transluminal coronary angioplasty, randomized controlled trial (RCT), percutaneous coronary intervention (PCI) and angina, angina reduction, antiplatelet therapy, bare-metal stents (BMS), cardiac rehabilitation, chronic stable angina, complication, coronary bifurcation lesion, coronary calcified lesion, coronary chronic total occlusion (CTO), coronary ostial lesions, coronary stent (BMS and drug-eluting stents [DES]; and BMS versus DES), diabetes, distal embolization, distal protection, elderly, ethics, late stent thrombosis, medical therapy, microembolization, mortality, multiple lesions, multi-vessel, myocardial infarction (MI), non—ST-elevation myocardial infarction (NSTEMI), no-reflow, optical coherence tomography, proton pump inhibitor (PPI), return to work, same-day angioplasty and/or stenting, slow flow, stable ischemic heart disease (SIHD), staged angioplasty, STEMI, survival, and *unstable angina (UA)*. Additional searches cross-referenced these topics with the following subtopics: *anticoagulant therapy, contrast nephropathy, PCI-related vascular complications, unprotected left main PCI, multivessel coronary artery disease (CAD), adjunctive percutaneous interventional devices, percutaneous hemodynamic support devices*, and *secondary prevention*. Additionally, the committee reviewed documents related to the subject matter previously published by the ACCF and AHA. References selected and published in this document are representative and not all-inclusive.

To provide clinicians with a comprehensive set of data, whenever deemed appropriate or when published, the absolute risk difference and number needed to treat or harm will be provided in the guideline, along with confidence intervals (CIs) and data related to the relative treatment effects such as odds ratio (OR), relative risk, hazard ratio (HR), or incidence rate ratio.

The focus of this guideline is the safe, appropriate, and efficacious performance of PCI. The risks of PCI must be balanced against the likelihood of improved survival, symptoms, or functional status. This is especially important in patients with SIHD.

1.2. Organization of the Writing Committee

The committee was composed of physicians with expertise in interventional cardiology, general cardiology, critical care cardiology, cardiothoracic surgery, clinical trials, and health services research. The committee included representatives from the ACCF, AHA, and SCAI.

1.3. Document Review and Approval

This document was reviewed by 2 official reviewers nominated by the ACCF, AHA, and SCAI, as well as 21 individual content reviewers (including members of the ACCF Interventional Scientific Council and ACCF Surgeons' Scientific Council). All information on reviewers' RWI was distributed to the writing committee and is published in this document (Appendix 2). This document was approved for publication by the governing bodies of the ACCF, AHA, and SCAI.

1.4. PCI Guidelines: History and Evolution

In 1982, a 2-page manuscript titled "Guidelines for the Performance of Percutaneous Transluminal Coronary Angioplasty" was published in *Circulation* (4). The document, which addressed the specific expertise and experience physicians should have to perform balloon angioplasty, as well as laboratory requirements and the need for surgical support, was written by an ad hoc group whose members included Andreas Grüntzig. In 1980, the ACC and the AHA established the Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures, which was charged with the development of guidelines related to the role of new therapeutic approaches and of specific noninvasive and invasive procedures in the diagnosis and management of cardiovascular disease. The first ACC/ AHA Task Force report on guidelines for coronary balloon angioplasty was published in 1988 (5). The 18-page document discussed and made recommendations about lesion classification and success rates, indications for and contraindications to balloon angioplasty, institutional review of angioplasty procedures, ad hoc angioplasty after angiography, and on-site surgical backup. Further iterations of the guidelines were published in 1993 (6), 2001 (7), and 2005 (8). In 2007 and 2009, focused updates to the guideline were published to expeditiously address new study results and recent changes in the field of interventional cardiology (9, 10). The 2009 focused update is notable in that there was direct collaboration between the writing committees for the STEMI guidelines and the PCI guidelines, resulting in a single publication of focused updates on STEMI and PCI (10).

The evolution of the PCI guideline reflects the growth of knowledge in the field and parallels the many advances and innovations in the field of interventional cardiology, including primary PCI, BMS and DES, intravascular ultrasound (IVUS) and physiologic assessments of stenosis, and newer antiplatelet and anticoagulant therapies. The 2011 iteration of the guideline continues this process, addressing ethical aspects of PCI, vascular access considerations, CAD revascularization including hybrid revascularization, revascularization before noncardiac surgery, optical coherence tomography, advanced hemodynamic support

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devices, no-reflow therapies, and vascular closure devices. Most of this document is organized according to "patient flow," consisting of preprocedural considerations, procedural considerations, and postprocedural considerations. In a major undertaking, the STEMI, PCI, and coronary artery bypass graft (CABG) surgery guidelines were written concurrently, with additional collaboration with the SIHD guideline writing committee, allowing greater collaboration between the different writing committees on topics such as PCI in STEMI and revascularization strategies in patients with CAD (including unprotected left main PCI, multivessel disease revascularization, and hybrid procedures).

In accordance with direction from the Task Force and feedback from readers, in this iteration of the guideline, the text has been shortened, with an emphasis on summary statements rather than detailed discussion of numerous individual trials. Online supplemental evidence and summary tables have been created to document the studies and data considered for new or changed guideline recommendations.

2. CAD REVASCULARIZATION

Recommendations and text in this section are the result of extensive collaborative discussions between the PCI and CABG writing committees, as well as key members of the SIHD and UA/NSTEMI writing committees. Certain issues, such as older versus more contemporary studies, primary analyses versus subgroup analyses, and prospective versus post hoc analyses, have been carefully weighed in designating COR and LOE; they are addressed in the appropriate corresponding text. The goals of revascularization for patients with CAD are to 1) improve survival and/or 2) relieve symptoms.

Revascularization recommendations in this section are predominantly based on studies of patients with symptomatic SIHD and should be interpreted in this context. As discussed later in this section, recommendations on the type of revascularization are, in general, applicable to patients with UA/NSTEMI. In some cases (e.g., unprotected left main CAD), specific recommendations are made for patients with UA/NSTEMI or STEMI.

Historically, most studies of revascularization have been based on and reported according to angiographic criteria. Most studies have defined a "significant" stenosis as $\geq$ 70% diameter narrowing; therefore, for revascularization decisions and recommendations in this section, a "significant" stenosis has been defined as $\geq$ 70% diameter narrowing ($\geq$50% for left main CAD). Physiological criteria, such as an assessment of fractional flow reserve (FFR), has been used in deciding when revascularization is indicated. Thus, for recommendations about revascularization in this section, coronary stenoses with FFR $\leq$ 0.80 can also be considered to be "significant" (11, 12).

As noted, the revascularization recommendations have been formulated to address issues related to 1) improved survival and/or 2) improved symptoms. When one method of revascularization is preferred over the other for improved survival, this consideration, in general, takes precedence over improved symptoms. When discussing options for revascularization with the patient, he or she should understand when the procedure is being performed in an attempt to improve symptoms, survival, or both.

Although some results from the SYNTAX (Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery) study are best characterized as subgroup analyses and "hypothesis generating," SYNTAX nonetheless represents the latest and most comprehensive comparison of PCI and CABG (13, 14). Therefore, the results of SYNTAX have been considered appropriately when formulating our revascularization recommendations. Although the limitations of using the SYNTAX score for certain revascularization recommendations are recognized, the SYNTAX score is a reasonable surrogate for the extent of CAD and its complexity and serves as important information that should be considered when making revascularization decisions. Recommendations that refer to SYNTAX scores use them as surrogates for the extent and complexity of CAD.

Revascularization recommendations to improve survival and symptoms are provided in the following text and are summarized in Tables 2 and 3. References to studies comparing revascularization with medical therapy are presented when available for each anatomic subgroup. T2 T3

See Online Data Supplements 1 and 2 for additional data regarding the survival and symptomatic benefits with CABG or PCI for different anatomic subsets.

2.1. Heart Team Approach to Revascularization Decisions: Recommendations

CLASS I

1. A Heart Team approach to revascularization is recommended in patients with unprotected left main or complex CAD (14–16). *(Level of Evidence: C)*

CLASS IIa

1. Calculation of the Society of Thoracic Surgeons (STS) and SYNTAX scores is reasonable in patients with unprotected left main and complex CAD (13, 14, 17–22). *(Level of Evidence: B)*

One protocol used in RCTs (14–16, 23) often involves a multidisciplinary approach referred to as the Heart Team. Composed of an interventional cardiologist and a cardiac surgeon, the Heart Team 1) reviews the patient's medical condition and coronary anatomy, 2) determines that PCI and/or CABG are technically feasible and reasonable, and 3) discusses revascularization options with the patient before a treatment strategy is selected. Support for using a Heart Team approach comes from reports that patients with complex CAD referred specifically for PCI or CABG in concurrent trial registries have lower mortality rates than those randomly assigned to PCI or CABG in controlled trials (15, 16).

The SIHD, PCI, and CABG guideline writing committees endorse a Heart Team approach in patients with unprotected left main CAD and/or complex CAD in whom the optimal revascularization strategy is not straightforward. A collaborative assessment of revascularization options, or the decision to treat with GDMT without revascularization, involving an interventional cardiologist, a cardiac surgeon, and (often) the patient's general cardiologist, followed by discussion with the patient about treatment options, is optimal. Particularly in patients with SIHD and unprotected left main and/or complex CAD for whom a revascularization strategy is not straightforward, an approach has been endorsed that involves terminating the procedure after diagnostic coronary angiography is completed: this allows a thorough discussion and affords both the interventional cardiologist and cardiac surgeon the opportunity to discuss revascularization options with the patient. Because the STS score and the SYNTAX score have been shown to predict adverse outcomes in patients undergoing CABG and PCI, respectively, calculation of these scores is often useful in making revascularization decisions (13, 14, 17–22).

2.2. Revascularization to Improve Survival: Recommendations

Left Main CAD Revascularization

CLASS I

1. CABG to improve survival is recommended for patients with significant (≥50% diameter stenosis) left main coronary artery stenosis (24–30). *(Level of Evidence: B)*

CLASS IIa

1. PCI to improve survival is reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcome (e.g., a low SYNTAX score [≤22], ostial or trunk left main CAD); and 2) clinical characteristics that predict a significantly increased risk of adverse surgical outcomes (e.g., STS-predicted risk of operative mortality ≥5%) (13, 17, 19, 23, 31–48). *(Level of Evidence: B)*
2. PCI to improve survival is reasonable in patients with UA/NSTEMI when an unprotected left main coronary artery is the culprit lesion and the patient is not a candidate for CABG (13, 36–39, 44, 45, 47–49). *(Level of Evidence: B)*
3. PCI to improve survival is reasonable in patients with acute STEMI when an unprotected left main coronary artery is the culprit lesion, distal coronary flow is less than TIMI (Thrombolysis In Myocardial Infarction) grade 3, and PCI can be performed more rapidly and safely than CABG (33, 50, 51). *(Level of Evidence: C)*

CLASS IIb

1. PCI to improve survival may be reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low to intermediate risk of PCI procedural complications and an intermediate to high likelihood of good long-term outcome (e.g., low-intermediate SYNTAX score of <33, bifurcation left main CAD); and 2) clinical characteristics that predict an increased risk of adverse surgical outcomes (e.g., moderate-severe chronic obstructive pulmonary disease, disability from previous stroke, or previous cardiac surgery; STS-predicted risk of operative mortality >2%) (13, 17, 19, 23, 31–48, 52). *(Level of Evidence: B)*

CLASS III: HARM

1. PCI to improve survival should not be performed in stable patients with significant (≥50% diameter stenosis) unprotected left main CAD who have unfavorable anatomy for PCI and who are good candidates for CABG (13, 17, 19, 24–32). *(Level of Evidence: B)*

Non-Left Main CAD Revascularization

CLASS I

1. CABG to improve survival is beneficial in patients with significant (≥70% diameter) stenoses in 3 major coronary arteries (with or without involvement of the proximal left anterior descending [LAD] artery) or in the proximal LAD plus 1 other major coronary artery (26, 30, 53–56). *(Level of Evidence: B)*

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TABLE 2. Revascularization to Improve Survival Compared With Medical Therapy

Anatomic Setting	COR	LOE	References
UPLM or complex CAD			
CABG and PCI	I—Heart Team approach recommended	C	(14-16)
CABG and PCI	IIa—Calculation of STS and SYNTAX scores	B	(13,14,17-22)
UPLM*			
CABG	I	B	(24-30)
PCI	IIa—For SIHD when *both* of the following are present: • Anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcome (e.g., a low SYNTAX score of ≤22, ostial or trunk left main CAD) • Clinical characteristics that predict a significantly increased risk of adverse surgical outcomes (e.g., STS-predicted risk of operative mortality ≥5%)	B	(13,17,19,23,31-48)
	IIa—For UA/NSTEMI if not a CABG candidate	B	(13,36-39,44,45,47-49)
	IIa—For STEMI when distal coronary flow is TIMI flow grade <3 and PCI can be performed more rapidly and safely than CABG	C	(33,50,51)
	IIb—For SIHD when *both* of the following are present: • Anatomic conditions associated with a low to intermediate risk of PCI procedural complications and an intermediate to high likelihood of good long-term outcome (e.g., low-intermediate SYNTAX score of <33, bifurcation left main CAD) • Clinical characteristics that predict an increased risk of adverse surgical outcomes (e.g., moderate-severe COPD, disability from prior stroke, or prior cardiac surgery; STS-predicted risk of operative mortality >2%)	B	(13,17,19,23,31-48,52)
	III: Harm—For SIHD in patients (versus performing CABG) with unfavorable anatomy for PCI and who are good candidates for CABG	B	(13,17,19,24-32)
3-vessel disease with or without proximal LAD artery disease*			
CABG	I	B	(26,30 53-56)
	IIa—It is reasonable to choose CABG over PCI in patients with complex 3-vessel CAD (e.g., SYNTAX score >22) who are good candidates for CABG.	B	(32,46,56,71,72)
PCI	IIb—Of uncertain benefit	B	(26,46,53,56,82)
2-vessel disease with proximal LAD artery disease*			
CABG	I	B	(26,30,53-56)
PCI	IIb—Of uncertain benefit	B	(26,53,56,82)
2-vessel disease without proximal LAD artery disease*			
CABG	IIa—With extensive ischemia	B	(60-63)
	IIb—Of uncertain benefit without extensive ischemia	C	(56)
PCI	IIb—Of uncertain benefit	B	(26,53,56,82)
1-vessel proximal LAD artery disease			
CABG	IIa—With LIMA for long-term benefit	B	(30,56,69,70)
PCI	IIb—Of uncertain benefit	B	(26,53,56,82)
1-vessel disease without proximal LAD artery involvement			
CABG	III: Harm	B	(30,53,60,61,94-98)
PCI	III: Harm	B	(30,53,60,61,94-98)
LV dysfunction			
CABG	IIa—EF 35% to 50%	B	(30,64-68)
CABG	IIb—EF <35% without significant left main CAD	B	(30,64-68,83,84)
PCI	Insufficient data		N/A
Survivors of sudden cardiac death with presumed ischemia-mediated VT			
CABG	I	B	(57-59)
PCI	I	C	(57)
No anatomic or physiologic criteria for revascularization			
CABG	III: Harm	B	(30,53,60,61,94-98)
PCI	III: Harm	B	(30,53,60,61,94-98)

*In patients with multivessel disease who also have diabetes, it is reasonable to choose CABG (with LIMA) over PCI (62,74–81)(C/ass *IIa; LOE:* B)

CABG indicates coronary artery bypass graft; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; COR, class of recommendation; EF, ejection fraction; LAD, left anterior descending; LIMA, left internal mammary artery; LOE, level of evidence; LV, left ventricular; N/A, not applicable; PCI, percutaneous coronary intervention; SIHD, stable ischemic heart disease; STEMI, ST-elevation myocardial infarction; STS, Society of Thoracic Surgeons; SYNTAX, Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery; TIMI, Thrombolysis In Myocardial Infarction; UA/NSTEMI, unstable angina/non-ST-elevation myocardial infarction; UPLM, unprotected left main disease; and VT, Ventricular tachycardia.

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TABLE 3. Revascularization to Improve Symptoms With Significant Anatomic (≥50% Left Main or ≥70% Non-Left Main CAD) or Physiological (FFR≤0.80) Coronary Artery Stenoses

Clinical Setting	COR	LOE	References
≥1 significant stenoses amenable to revascularization and unacceptable angina despite GDMT	I–CABG I–PCI	A	(82,99–108)
≥1 significant stenoses and unacceptable angina in whom GDMT cannot be implemented because of medication contraindications, adverse effects, or patient preferences	IIa–CABG IIa–PCI	C	N/A
Previous CABG with ≥1 significant stenoses associated with ischemia and unacceptable angina despite GDMT	IIa–PCI	C	(86,89,92)
	IIb–CABG	C	(93)
Complex 3-vessel CAD (e.g., SYNTAX score >22) with or without involvement of the proximal LAD artery and a good candidate for CABG	IIa–CABG preferred over PCI	B	(32,46,56,71,72)
Viable ischemic myocardium that is perfused by coronary arteries that are not amenable to grafting	IIb–TMR as an adjunct to CABG	B	(109–113)
No anatomic or physiologic criteria for revascularization	III: Harm–CABG III: Harm–PCI	C	N/A

CABG indicates coronary artery bypass graft; CAD, coronary artery disease; COR, class of recommendation; FFR, fractional flow reserve; GDMT, guideline-directed medical therapy; LOE, level of evidence; N/A, not applicable; PCI, percutaneous coronary intervention; SYNTAX, Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery; and TMR, transmyocardial laser revascularization.

2. CABG or PCI to improve survival is beneficial in survivors of sudden cardiac death with presumed ischemia-mediated ventricular tachycardia caused by significant (≥70% diameter) stenosis in a major coronary artery. *(CABG Level of Evidence: B* [57–59]; *PCI Level of Evidence: C* [57])

CLASS IIa

1. CABG to improve survival is reasonable in patients with significant (≥70% diameter) stenoses in 2 major coronary arteries with severe or extensive myocardial ischemia (e.g., high-risk criteria on stress testing, abnormal intracoronary hemodynamic evaluation, or >20% perfusion defect by myocardial perfusion stress imaging) or target vessels supplying a large area of viable myocardium (60–63). *(Level of Evidence: B)*
2. CABG to improve survival is reasonable in patients with mild-moderate left ventricular (LV) systolic dysfunction (ejection fraction [EF] 35% to 50%) and significant (≥70% diameter stenosis) multi-vessel CAD or proximal LAD coronary artery stenosis, when viable myocardium is present in the region of intended revascularization (30, 64–68). *(Level of Evidence: B)*
3. CABG with a left internal mammary artery (LIMA) graft to improve survival is reasonable in patients with significant (≥70% diameter) stenosis in the proximal LAD artery and evidence of extensive ischemia (30, 56, 69, 70). *(Level of Evidence: B)*
4. It is reasonable to choose CABG over PCI to improve survival in patients with complex 3-vessel CAD (e.g., SYNTAX score >22), with or without involvement of the proximal LAD artery who are good candidates for CABG (32, 46, 56, 71, 72). *(Level of Evidence: B)*
5. CABG is probably recommended in preference to PCI to improve survival in patients with multivessel CAD and diabetes mellitus, particularly if a LIMA graft can be anastomosed to the LAD artery (62, 74–81). *(Level of Evidence: B)*

CLASS IIb

1. The usefulness of CABG to improve survival is uncertain in patients with significant (≥70%) diameter stenoses in 2 major coronary arteries not involving the proximal LAD artery and without extensive ischemia (56). *(Level of Evidence: C)*
2. The usefulness of PCI to improve survival is uncertain in patients with 2- or 3-vessel CAD (with or without involvement of the proximal LAD artery) or 1-vessel proximal LAD disease (26, 53, 56, 82). *(Level of Evidence: B)*
3. CABG might be considered with the primary or sole intent of improving survival in patients with SIHD with severe LV systolic dysfunction (EF <35%) whether or not viable myocardium is present (30, 64–68, 83, 84). *(Level of Evidence: B)*
4. The usefulness of CABG or PCI to improve survival is uncertain in patients with previous CABG and extensive anterior wall ischemia on noninvasive testing (85–93). *(Level of Evidence: B)*

CLASS III: HARM

1. CABG or PCI should not be performed with the primary or sole intent to improve survival in patients with SIHD with 1 or more coronary stenoses that

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are not anatomically or functionally significant (e.g., <70% diameter non-left main coronary artery stenosis, FFR >0.80, no or only mild ischemia on noninvasive testing), involve only the left circumflex or right coronary artery, or subtend only a small area of viable myocardium (30, 53, 60, 61, 94–98). *(Level of Evidence: B)*

2.3. Revascularization to Improve Symptoms: Recommendations

CLASS I

1. CABG or PCI to improve symptoms is beneficial in patients with 1 or more significant (≥70% diameter) coronary artery stenoses amenable to revascularization and unacceptable angina despite GDMT (82, 99–108). *(Level of Evidence: A)*

CLASS IIa

1. CABG or PCI to improve symptoms is reasonable in patients with 1 or more significant (≥70% diameter) coronary artery stenoses and unacceptable angina for whom GDMT cannot be implemented because of medication contraindications, adverse effects, or patient preferences. *(Level of Evidence: C)*
2. PCI to improve symptoms is reasonable in patients with previous CABG, 1 or more significant (≥70% diameter) coronary artery stenoses associated with ischemia, and unacceptable angina despite GDMT (86, 89, 92). *(Level of Evidence: C)*
3. It is reasonable to choose CABG over PCI to improve symptoms in patients with complex 3-vessel CAD (e.g., SYNTAX score >22), with or without involvement of the proximal LAD artery who are good candidates for CABG (32, 46, 56, 72, 73). *(Level of Evidence: B)*

CLASS IIb

1. CABG to improve symptoms might be reasonable for patients with previous CABG, 1 or more significant (≥70% diameter) coronary artery stenoses not amenable to PCI, and unacceptable angina despite GDMT (93). *(Level of Evidence: C)*
2. Transmyocardial laser revascularization (TMR) performed as an adjunct to CABG to improve symptoms may be reasonable in patients with viable ischemic myocardium that is perfused by arteries that are not amenable to grafting (109–113). *(Level of Evidence: B)*

CLASS III: HARM

1. CABG or PCI to improve symptoms should not be performed in patients who do not meet anatomic (≥50% diameter left main or ≥70% non-left main stenosis diameter) or physiological (e.g., abnormal FFR) criteria for revascularization. *(Level of Evidence: C)*

2.4. CABG Versus Contemporaneous Medical Therapy

In the 1970s and 1980s, 3 RCTs established the survival benefit of CABG compared with contemporaneous (although minimal by current standards) medical therapy without revascularization in certain subjects with stable angina: the Veterans Affairs Cooperative Study (114), European Coronary Surgery Study (55), and CASS (Coronary Artery Surgery Study) (115). Subsequently, a 1994 meta-analysis of 7 studies that randomized a total of 2,649 patients to medical therapy or CABG (30) showed that CABG offered a survival advantage over medical therapy for patients with left main or 3-vessel CAD. The studies also established that CABG is more effective than medical therapy for relieving anginal symptoms. These studies have been replicated only once during the past decade. In MASS II (Medicine, Angioplasty, or Surgery Study II), patients with multivessel CAD who were treated with CABG were less likely than those treated with medical therapy to have a subsequent MI, need additional revascularization, or experience cardiac death in the 10 years after randomization (104).

Surgical techniques and medical therapy have improved substantially during the intervening years. As a result, if CABG were to be compared with GDMT in RCTs today, the relative benefits for survival and angina relief observed several decades ago might no longer be observed. Conversely, the concurrent administration of GDMT may substantially improve long-term outcomes in patients treated with CABG in comparison with those receiving medical therapy alone. In the BARI 2D (Bypass Angioplasty Revascularization Investigation 2 Diabetes) trial of patients with diabetes mellitus, no significant difference in risk of mortality in the cohort of patients randomized to GDMT plus CABG or GDMT alone was observed, although the study was not powered for this endpoint, excluded patients with significant left main CAD, and included only a small percentage of patients with proximal LAD artery disease or LV ejection fraction (LVEF) <0.50 (116). The PCI and CABG guideline writing committees endorse the performance of the ISCHEMIA (International Study of Comparative Health Effectiveness with Medical and Invasive Approaches) trial, which will provide contemporary data on the optimal management strategy (medical therapy or revascularization with CABG or

PCI) of patients with SIHD, including multivessel CAD, and moderate to severe ischemia.

2.5. PCI Versus Medical Therapy

Although contemporary interventional treatments have lowered the risk of restenosis compared with earlier techniques, meta-analyses have failed to show that the introduction of BMS confers a survival advantage over balloon angioplasty (117–119) or that the use of DES confers a survival advantage over BMS (119, 120).

No study to date has demonstrated that PCI in patients with SIHD improves survival rates (26, 53, 56, 82, 116, 119, 121–124). Neither COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) (82) nor BARI 2D (116), which treated all patients with contemporary optimal medical therapy, demonstrated any survival advantage with PCI, although these trials were not specifically powered for this endpoint. Although 1 large analysis evaluating 17 RCTs of PCI versus medical therapy (including 5 trials of subjects with acute coronary syndromes [ACS]) found a 20% reduction in death with PCI compared with medical therapy (123), 2 other large analyses did not (119, 122). An evaluation of 13 studies reporting the data from 5,442 patients with nonacute CAD showed no advantage of PCI over medical therapy for the individual endpoints of all-cause death, cardiac death or MI, or nonfatal MI (124). Evaluation of 61 trials of PCI conducted over several decades shows that despite improvements in PCI technology and pharmacotherapy, PCI has not been demonstrated to reduce the risk of death or MI in patients without recent ACS (119).

The findings from individual studies and systematic reviews of PCI versus medical therapy can be summarized as follows:

- PCI reduces the incidence of angina (82, 99, 104, 107, 108, 125).
- PCI has not been demonstrated to improve survival in stable patients (119, 121, 122).
- PCI may increase the short-term risk of MI (82, 121, 125, 126).
- PCI does not lower the long-term risk of MI (82, 116, 119, 121, 122, 126).

2.6. CABG Versus PCI

The results of 26 RCTs comparing CABG and PCI have been published: Of these, 9 compared CABG with balloon angioplasty (75, 105, 128–142), 14 compared CABG with BMS implantation (88, 143–160), and 3 compared CABG with DES implantation (14, 161, 162).

2.6.1. CABG Versus Balloon Angioplasty or BMS. A systematic review of the 22 RCTs comparing CABG with balloon angioplasty or BMS implantation concluded the following (163):

1. Survival was similar for CABG and PCI (with balloon angioplasty or BMS) at 1 year and 5 years. Survival was similar for CABG and PCI in subjects with 1-vessel CAD (including those with disease of the proximal portion of the LAD artery) or multivessel CAD.
2. Incidence of MI was similar at 5 years after randomization.
3. Procedural stroke occurred more commonly with CABG than with PCI (1.2% versus 0.6%).
4. Relief of angina was accomplished more effectively with CABG than with PCI 1 year after randomization and 5 years after randomization.
5. During the first year after randomization, repeat coronary revascularization was performed less often after CABG than after PCI (3.8% versus 26.5%). This was also demonstrated after 5 years of follow-up (9.8% versus 46.1%). This difference was more pronounced with balloon angioplasty than with BMS.

A collaborative analysis of data from 10 RCTs comparing CABG with balloon angioplasty (6 trials) or with BMS implantation (4 trials) (164) permitted subgroup analyses of the data from the 7,812 patients. No difference was noted with regard to mortality rate 5.9 years after randomization or the composite endpoint of death or MI. Repeat revascularization and angina were noted more frequently in those treated with balloon angioplasty or BMS implantation (164). The major new observation of this analysis was that CABG was associated with better outcomes in patients with diabetes mellitus and in those >65 years old. Of interest, the relative outcomes of CABG and PCI were not influenced by other patient characteristics, including the number of diseased coronary arteries.

The aforementioned meta-analysis and systematic review (163, 164) comparing CABG and balloon angioplasty or BMS implantation were limited in several ways:

1. Many trials did not report outcomes for other important patient subsets. For example, the available data are insufficient to determine if race, obesity, renal dysfunction, peripheral arterial disease, or previous coronary revascularization affected the comparative outcomes of CABG and PCI.
2. Most of the patients enrolled in these trials were male, and most had 1- or 2-vessel CAD and normal LV systolic function (EF >50%)—subjects known

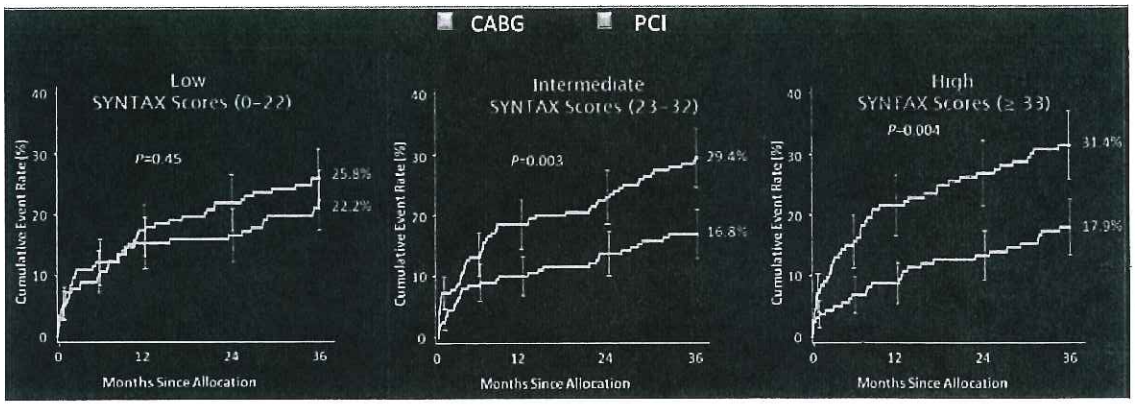

Fig. 1. Cumulative Incidence of MACE in Patients With 3-Vessel CAD Based on SYNTAX Score at 3-Year Follow-Up in the SYNTAX Trial Treated With Either CABG or PCI.

CABG indicates coronary artery bypass graft; CAD, coronary artery disease; MACE, major adverse cardiovascular event; PCI, percutaneous coronary intervention; and SYNTAX, Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery. Adapted with permission from Kappetein (46).

to be unlikely to derive a survival benefit and less likely to experience complications after CABG (30).

3. The patients enrolled in these trials represented only a small fraction (generally <5% to 10%) of those who were screened. For example, most screened patients with 1-vessel CAD and many with 3-vessel CAD were not considered for randomization.

See Online Data Supplements 3 and 4 for additional data comparing CABG with PCI.

2.6.2. CABG Versus DES. Although the results of 9 observational studies comparing CABG and DES implantation have been published (32, 165–172), most of them had short (12 to 24 months) follow-up periods. In a meta-analysis of 24,268 patients with multivessel CAD treated with CABG or DES (173), the incidences of death and MI were similar for the 2 procedures, but the frequency with which repeat revascularization was performed was roughly 4 times higher after DES implantation. Only 1 large RCT comparing CABG and DES implantation has been published. The SYNTAX trial randomly assigned 1,800 patients (of a total of 4,337 who were screened) to receive DES or CABG (14, 46). Major adverse cardiac events (MACE), a composite of death, stroke, MI, or repeat revascularization during the 3 years after randomization, occurred in 20.2% of CABG patients and 28.0% of those undergoing DES implantation ($p<0.001$). The rates of death and stroke were similar; however, MI (3.6% for CABG, 7.1% for DES) and repeat revascularization (10.7% for CABG, 19.7% for DES) were more likely to occur with DES implantation (46).

In SYNTAX, the extent of CAD was assessed using the SYNTAX score, which is based on the location, severity, and extent of coronary stenoses, with a low score indicating less complicated anatomic CAD. In post hoc analyses, a low score was defined as ≤22; intermediate, 23 to 32; and high, ≥33. The occurrence of MACE correlated with the SYNTAX score for DES patients but not for those undergoing CABG. At 12-month follow-up, the primary endpoint was similar for CABG and DES in those with a low SYNTAX score. In contrast, MACE occurred more often after DES implantation than after CABG in those with an intermediate or high SYNTAX score (14). At 3 years of follow-up, the mortality rate was greater in subjects with 3-vessel CAD treated with PCI than in those treated with CABG (6.2% versus 2.9%). The differences in MACE between those treated with PCI or CABG increased with an increasing SYNTAX score (Figure 1) (46). F1

Although the utility of using a SYNTAX score in everyday clinical practice remains uncertain, it seems reasonable to conclude from SYNTAX and other data that outcomes of patients undergoing PCI or CABG in those with relatively uncomplicated and lesser degrees of CAD are comparable, whereas in those with complex and diffuse CAD, CABG appears to be preferable (46).

See Online Data Supplements 5 and 6 for additional data comparing CABG with DES.

2.7. Left Main CAD

2.7.1. CABG or PCI Versus Medical Therapy for Left Main CAD. CABG confers a survival benefit over medical therapy in patients with left main CAD. Subgroup analyses from RCTs performed 3 decades ago included 91 patients with left main CAD in the

Veterans Administration Cooperative Study (28). A meta-analysis of these trials demonstrated a 66% reduction in relative risk in mortality with CABG, with the benefit extending to 10 years (30). The CASS Registry (24) contained data from 1,484 patients with ≥50% diameter stenosis left main CAD initially treated surgically or nonsurgically. Median survival duration was 13.3 years in the surgical group; and 6.6 years in the medical group. The survival benefit of CABG over medical therapy appeared to extend to 53 asymptomatic patients with left main CAD in the CASS Registry (29). Other therapies that subsequently have been shown to be associated with improved long-term outcome, such as the use of aspirin, statins, and internal mammary artery grafting, were not widely used in that era.

RCTs and subgroup analyses that compare PCI with medical therapy in patients with "unprotected" left main CAD do not exist.

2.7.2. Studies Comparing PCI Versus CABG for Left Main CAD. Of all subjects undergoing coronary angiography, approximately 4% are found to have left main CAD (175), >80% of whom have significant (≥70% diameter) stenoses in other epicardial coronary arteries.

Published cohort studies have found that major clinical outcomes are similar with PCI or CABG 1 year after revascularization and that mortality rates are similar at 1, 2, and 5 years of follow-up; however, the risk of needing target-vessel revascularization is significantly higher with stenting than with CABG.

In the SYNTAX trial, 45% of screened patients with unprotected left main CAD had complex disease that prevented randomization; 89% of these underwent CABG (13, 14). In addition, 705 of the 1,800 patients who were randomized had revascularization for unprotected left main CAD. The majority of patients with left main CAD and a low SYNTAX score had isolated left main CAD or left main CAD plus 1-vessel CAD; the majority of those with an intermediate score had left main CAD plus 2-vessel CAD; and most of those with a high SYNTAX score had left main CAD plus 3-vessel CAD. At 1 year, rates of all-cause death and MACE were similar for the 2 groups (13). Repeat revascularization rates were higher in the PCI group than the CABG group (11.8% versus 6.5%), but stroke occurred more often in the CABG group (2.7% versus 0.3%). At 3 years of follow-up, the incidence of death in those undergoing left main CAD revascularization with low or intermediate SYNTAX scores (≤32) was 3.7% after PCI and 9.1% after CABG (p=0.03), whereas in those with a high SYNTAX score (≥33), the incidence of death after 3 years was 13.4% after PCI and 7.6% after CABG (p=0.10) (46). Because the primary endpoint of SYNTAX was not met (i.e., noninferiority comparison of CABG and PCI), these subgroup analyses need to be considered in that context.

In the LE MANS (Study of Unprotected Left Main Stenting Versus Bypass Surgery) trial (23), 105 patients with left main CAD were randomized to receive PCI or CABG. Although a low proportion of patients treated with PCI received DES (35%) and a low proportion of patients treated with CABG received internal mammary grafts (72%), the outcomes at 30 days and 1 year were similar between the groups. In the PRECOMBAT (Premier of Randomized Comparison of Bypass Surgery versus Angioplasty Using Sirolimus-Eluting Stent in Patients with Left Main Coronary Artery Disease) trial of 600 patients with left main disease, the composite endpoint of death, MI, or stroke at 2 years occurred in 4.4% of patients treated with PCI patients and 4.7% of patients treated with CABG, but ischemia-driven target-vessel revascularization was more often required in the patients treated with PCI (9.0% versus 4.2%) (52).

The results from these 3 RCTs suggest (but do not definitively prove) that major clinical outcomes in *selected* patients with left main CAD are similar with CABG and PCI at 1- to 2-year follow-up, but repeat revascularization rates are higher after PCI than after CABG. RCTs with extended follow-up of ≥5 years are required to provide definitive conclusions about the optimal treatment of left main CAD. In a meta-analysis of 8 cohort studies and 2 RCTs (41), death, MI, and stroke occurred with similar frequency in the PCI- and CABG-treated patients at 1, 2, and 3 years of follow-up. Target-vessel revascularization was performed more often in the PCI group at 1 year (OR: 4.36), 2 years (OR: 4.20), and 3 years (OR: 3.30).

See Online Data Supplements 7 to 12 for additional data comparing PCI with CABG for left main CAD.

2.7.3. Revascularization Considerations for Left Main CAD. Although CABG has been considered the "gold standard" for unprotected left main CAD revascularization, more recently PCI has emerged as a possible alternative mode of revascularization in carefully selected patients. Lesion location is an important determinant when considering PCI for unprotected left main CAD. Stenting of the left main ostium or trunk is more straightforward than treating distal bifurcation or trifurcation stenoses, which generally requires a greater degree of operator experience and expertise (176). In addition, PCI of bifurcation disease is associated with higher restenosis rates than when disease is confined to the ostium or trunk (39, 177). Although lesion location influences technical success and long-term outcomes after PCI, location exerts a negligible influence on the success of CABG. In subgroup analyses, patients with left main CAD and a SYNTAX score ≥33 with more

complex or extensive CAD had a higher mortality rate with PCI than with CABG (46). Physicians can estimate operative risk for all CABG candidates using a standard instrument, such as the risk calculator from the STS database. The above considerations are important factors when choosing among revascularization strategies for unprotected left main CAD and have been factored into revascularization recommendations. Use of a Heart Team approach has been recommended in cases in which the choice of revascularization is not straightforward. As discussed in Section 2.9.7, the ability of the patient to tolerate and comply with dual antiplatelet therapy (DAPT) is also an important consideration in revascularization decisions.

The 2005 PCI guideline (8) recommended routine an-giographic follow-up 2 to 6 months after stenting for unprotected left main CAD. However, because angiography has limited ability to predict stent thrombosis and the results of SYNTAX suggest good intermediate-term results for PCI in subjects with left main CAD, this recommendation was removed in the 2009 STEMI/PCI focused update (10).

Experts have recommended immediate PCI for unprotected left main CAD in the setting of STEMI (51). The impetus for such a strategy is greatest when left main CAD is the site of the culprit lesion, antegrade coronary flow is diminished (e.g., TIMI flow grade 0, 1, or 2), the patient is hemodynamically unstable, and it is believed that PCI can be performed more quickly than CABG. When possible, the interventional cardiologist and cardiac surgeon should decide together on the optimal form of revascularization for these subjects, although it is recognized that these patients are usually critically ill and therefore not amenable to a prolonged deliberation or discussion of treatment options.

2.8. Proximal LAD Artery Disease

A cohort study (53) and a meta-analysis (30) from the 1990s suggested that CABG confers a survival advantage over contemporaneous medical therapy for patients with disease in the proximal segment of the LAD artery. Cohort studies and RCTs (30, 133, 146, 148, 161, 178–181) as well as collaborative- and meta-analyses (164, 182–184) showed that PCI and CABG result in similar survival rates in these patients.

See Online Data Supplement 13 for additional data regarding proximal LAD artery revascularization.

2.9. Clinical Factors That May Influence the Choice of Revascularization

2.9.1. Diabetes Mellitus. An analysis performed in 2009 of data on 7,812 patients (1,233 with diabetes) in 10 RCTs demonstrated a worse long-term survival rate in patients with diabetes mellitus after balloon angioplasty or BMS implantation than after CABG (164). The BARI 2D trial (116) randomly assigned 2,368 patients with type 2 diabetes and CAD to undergo intensive medical therapy or prompt revascularization with PCI or CABG, according to whichever was thought to be more appropriate. By study design, those with less extensive CAD more often received PCI, whereas those with more extensive CAD were more likely to be treated with CABG.

The study was not designed to compare PCI with CABG. At 5-year follow-up, no difference in rates of survival or MACE between the medical therapy group and those treated with revascularization was noted. In the PCI stratum, no significant difference in MACE between medical therapy and revascularization was demonstrated (DES in 35%; BMS in 56%); in the CABG stratum, MACE occurred less often in the revascularization group. One-year follow-up data from the SYNTAX study demonstrated a higher rate of repeat revascularization in patients with diabetes mellitus treated with PCI than with CABG, driven by a tendency for higher repeat revascularization rates in those with higher SYNTAX scores undergoing PCI (76). In summary, in subjects requiring revascularization for multivessel CAD, current evidence supports diabetes mellitus as an important factor when deciding on a revascularization strategy, particularly when complex or extensive CAD is present (Figure 2). F2

See Online Data Supplements 14 and 15 for additional data regarding diabetes mellitus.

2.9.2. Chronic Kidney Disease. Cardiovascular morbidity and mortality rates are markedly increased in patients with chronic kidney disease (CKD) when compared with age-matched controls without CKD. The mortality rate for patients on hemodialysis is >20% per year, and approximately 50% of deaths among these patients are due to a cardiovascular cause (187, 188).

To date, randomized comparisons of coronary revascularization (with CABG or PCI) and medical therapy in patients with CKD have not been reported. Some, but not all, observational studies or subgroup analyses have demonstrated an improved survival rate with revascularization compared with medical therapy in patients with CKD and multivessel CAD (189–191), despite the fact that the incidence of periprocedural complications (e.g., death, MI, stroke, infection, renal failure) is increased in patients with CKD compared with those without renal dysfunction. Some studies have shown that CABG is associated with a greater survival benefit than PCI among patients with severe renal dysfunction (190–196).

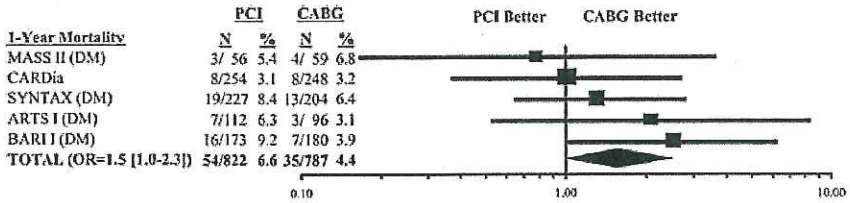

Fig. 2. 1-Year Mortality After Revascularization for Multivessel Disease and Diabetes Mellitus.

An OR of >1 suggests an advantage of CABG over PCI. ARTS I indicates Arterial Revascularization Therapy Study I (185); BARI I, Bypass Angioplasty Revascularization Investigation I (74); CABG, coronary artery bypass graft; CAD, coronary artery disease; CARDia, Coronary Artery Revascularization in Diabetes (186); CI, confidence interval; MASS II, Medicine, Angioplasty, or Surgery Study II (78); OR, odds ratio; PCI, percutaneous coronary intervention; SYNTAX, Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery; and W, weighted (76).

2.9.3. Completeness of Revascularization. Most patients undergoing CABG receive complete or nearly complete revascularization, which seems to influence long-term prognosis positively (197). In contrast, complete revascularization is accomplished less often in subjects receiving PCI (e.g., in <70% of patients), but the extent to which the absence of complete initial revascularization influences outcome is less clear. Rates of late survival and survival free of MI appears to be similar in patients with and without complete revascularization after PCI. Nevertheless, the need for subsequent CABG is usually higher in those whose initial revascularization procedure was incomplete (compared with those with complete revascularization) after PCI (198–200).

2.9.4. LV Systolic Dysfunction. Several older studies and a meta-analysis of the data from these studies reported that patients with LV systolic dysfunction (predominantly mild to moderate in severity) had better survival with CABG than with medical therapy alone (30, 64–68). For patients with more severe LV systolic dysfunction, however, the evidence that CABG results in better survival compared with medical therapy is lacking. In the STICH (Surgical Treatment for Ischemic Heart Failure) trial of subjects with LVEF <35% with or without viability testing, CABG and GDMT resulted in similar rates of survival (death from any cause, the study's primary outcome) after 5 years of follow-up. For a number of secondary outcomes at this time point, including 1) death from any cause or hospitalization for heart failure, 2) death from any cause or hospitalization for cardiovascular causes, 3) death from any cause or hospitalization for any cause, or 4) death from any cause or revascularization with PCI or CABG, CABG was superior to GDMT. Although the primary outcome (death from any cause) was similar in the 2 treatment groups after an average of 5 years of follow-up, the data suggest the possibility that outcomes would differ if the follow-up were longer in duration; as a result, the study is being continued to provide follow-up for up to 10 years (83, 84).

Only very limited data comparing PCI with medical therapy in patients with LV systolic dysfunction are available (68). In several ways, these data are suboptimal, in that many studies compared CABG with balloon angioplasty, many were retrospective, and many were based on cohort or registry data. Some of the studies demonstrated a similar survival rate in patients having CABG and PCI (71, 164, 201–203), whereas others showed that those undergoing CABG had better outcomes (32). The data that exist at present on revascularization in patients with CAD and LV systolic dysfunction are more robust for CABG than for PCI, although data from contemporary RCTs in this patient population are lacking. Therefore, the choice of revascularization in patients with CAD and LV systolic dysfunction is best based on clinical variables (e.g., coronary anatomy, presence of diabetes mellitus, presence of CKD), magnitude of LV systolic dysfunction, patient preferences, clinical judgment, and consultation between the interventional cardiologist and the cardiac surgeon.

2.9.5. Previous CABG. In patients with recurrent angina after CABG, repeat revascularization is most likely to improve survival in subjects at highest risk, such as those with obstruction of the proximal LAD artery and extensive anterior ischemia (85–93). Patients with ischemia in other locations and those with a patent LIMA to the LAD artery are unlikely to experience a survival benefit from repeat revascularization (92).

Cohort studies comparing PCI and CABG among post-CABG patients report similar rates of mid- and long-term survival after the 2 procedures (85, 88–91, 93, 204). In the patient with previous CABG who is referred for revascularization for medically refractory ischemia, factors that may support the choice of repeat CABG include vessels unsuitable for PCI, number of diseased bypass grafts, availability of the internal mammary artery for grafting chronically occluded coronary arteries, and good distal targets for bypass graft placement. Factors favoring PCI over CABG include limited areas of ischemia causing symptoms, suitable

PCI targets, a patent graft to the LAD artery, poor CABG targets, and comorbid conditions.

2.9.6. Unstable Angina/Non-ST-Elevation Myocardial Infarction. The main difference between management of the patient with SIHD and the patient with UA/NSTEMI is that the impetus for revascularization is stronger in the setting of UA/NSTEMI, because myocardial ischemia occurring as part of an ACS is potentially life threatening, and associated anginal symptoms are more likely to be reduced with a revascularization procedure than with GDMT (205–207). Thus, the indications for revascularization are strengthened by the acuity of presentation, the extent of ischemia, and the ability to achieve full revascularization. The choice of revascularization method is generally dictated by the same considerations used to decide on PCI or CABG for patients with SIHD.

2.9.7. DAPT Compliance and Stent Thrombosis: Recommendation

CLASS III: HARM

1. PCI with coronary stenting (BMS or DES) should not be performed if the patient is not likely to be able to tolerate and comply with DAPT for the appropriate duration of treatment based on the type of stent implanted (208–211). *(Level of Evidence: B)*

The risk of stent thrombosis is increased dramatically in patients who prematurely discontinue DAPT, and stent thrombosis is associated with a mortality rate of 20% to 45% (208). Because the risk of stent thrombosis with BMS is greatest in the first 14 to 30 days, this is the generally recommended minimum duration of DAPT therapy for these individuals. Consensus in clinical practice is to treat DES patients for at least 12 months with DAPT to avoid late (after 30 days) stent thrombosis (208, 212). Therefore, the ability of the patient to tolerate and comply with at least 30 days of DAPT with BMS treatment and at least 12 months of DAPT with DES treatment is an important consideration in deciding whether to use PCI to treat patients with CAD.

2.10. TMR as an Adjunct to CABG

TMR has been used on occasion in patients with severe angina refractory to GDMT in whom complete revascularization cannot be achieved with PCI and/or CABG. Although the mechanism by which TMR might be efficacious in these patients is unknown (213, 214), several RCTs of TMR as sole therapy demonstrated a reduction in anginal symptoms compared with intensive medical therapy alone (109–111, 215–217). A single randomized multicenter comparison of TMR (with a holmium: YAG laser) plus CABG and CABG alone in patients in whom some myocardial segments were perfused by arteries considered not amenable to grafting (112) showed a significant reduction in perioperative mortality rate (1.5% versus 7.6%, respectively), and the survival benefit of the TMR–CABG combination was present after 1 year of follow-up (112). At the same time, a large retrospective analysis of data from the STS National Cardiac Database as well as a study of 169 patients from the Washington Hospital Center who underwent combined TMR–CABG, showed no difference in adjusted mortality rate compared with CABG alone (113, 218). In short, a TMR–CABG combination does not appear to improve survival compared with CABG alone. In selected patients, however, such a combination may be superior to CABG alone in relieving angina.

2.11. Hybrid Coronary Revascularization: Recommendations

CLASS IIa

1. Hybrid coronary revascularization (defined as the planned combination of LIMA-to-LAD artery grafting and PCI of ≥1 non-LAD coronary arteries) is reasonable in patients with 1 or more of the following (219–225) *(Level of Evidence: B):*
   a. Limitations to traditional CABG, such as heavily calcified proximal aorta or poor target vessels for CABG (but amenable to PCI);
   b. Lack of suitable graft conduits;
   c. Unfavorable LAD artery for PCI (i.e., excessive vessel tortuosity or CTO).

CLASS IIb

Hybrid coronary revascularization (defined as the planned combination of LIMA-to-LAD artery grafting and PCI of ≥1 non-LAD coronary arteries) may be reasonable as an alternative to multivessel PCI or CABG in an attempt to improve the overall risk-benefit ratio of the procedures. *(Level of Evidence: C)*

Hybrid coronary revascularization, defined as the planned combination of LIMA-to-LAD artery grafting and PCI of ≥1 non-LAD coronary arteries (226), is intended to combine the advantages of CABG (i.e., durability of the LIMA graft) and PCI (227). Patients with multivessel CAD (e.g., LAD and ≥1 non-LAD stenoses) and an indication for revascularization are potentially eligible for this approach. Hybrid revascularization is ideal in patients in whom technical or anatomic limitations to CABG or PCI alone may be present and for whom minimizing the invasiveness (and therefore the risk of morbidity and mortality) of surgical intervention is preferred (221) (e.g., patients with

severe preexisting comorbidities, recent MI, a lack of suitable graft conduits, a heavily calcified ascending aorta, or a non-LAD coronary artery unsuitable for bypass but amenable to PCI, and situations in which PCI of the LAD artery is not feasible because of excessive tortuosity or CTO).

Hybrid coronary revascularization may be performed in a hybrid suite in one operative setting or as a staged procedure (i.e., PCI and CABG performed in 2 different operative suites, separated by hours to 2 days, but typically during the same hospital stay). Because most hospitals lack a hybrid operating room, staged procedures are usually performed. With the staged procedure, CABG before PCI is preferred, because this approach allows the interventional cardiologist to 1) verify the patency of the LIMA-to-LAD artery graft before attempting PCI of other vessels and 2) minimize the risk of perioperative bleeding that would occur if CABG were performed after PCI (i.e., while the patient is receiving DAPT). Because minimally invasive CABG may be associated with lower graft patency rates compared with CABG performed through a midline sternotomy, it seems prudent to angiographically image all grafts performed through a minimally invasive approach to confirm graft patency (221).

To date, no RCTs involving hybrid coronary revascularization have been published. Over the past 10 years, several small, retrospective series of hybrid revascularization using minimally invasive CABG and PCI have reported low mortality rates (0 to 2%) and event-free survival rates of83% to 92% at 6 to 12 months of follow-up. The few series that have compared the outcomes of hybrid coronary revascularization with standard CABG report similar outcomes at 30 days and 6 months (219–225).

3. PCI OUTCOMES

3.1. Definitions of PCI Success

The success of a PCI procedure is best defined by 3 interrelated components: angiographic findings, procedural events, and clinical outcomes.

3.1.1. Angiographic Success. A successful PCI produces sufficient enlargement of the lumen at the target site to improve coronary artery blood flow. A successful balloon angioplasty is defined as the reduction of a minimum stenosis diameter to <50% with a final TIMI flow grade 3 (visually assessed by angiography) without side branch loss, flow-limiting dissection, or angiographic thrombus (7). For coronary stents, a minimum stenosis diameter of <20% (as visually assessed by angiography) has previously been the clinical benchmark of an optimal angiographic result. Given improvements in technology and techniques, as well as recognition of the importance of an adequately deployed stent to decrease the risks of stent restenosis and thrombosis (12, 228, 229), the writing committee concluded that a minimum diameter stenosis of < 10% (with an optimal goal of as close to 0% as possible) should be the new benchmark for lesions treated with coronary stenting. As with balloon angioplasty, there should be final TIMI flow grade 3, without occlusion of a significant side branch, flow-limiting dissection, distal embolization, or angiographic thrombus. Problems with determining angiographic success include disparities between the visual assessment and computer-aided quantitative stenosis measurement and self-reporting of success in clinical reports or databases.

3.1.2. Procedural Success. A successful PCI should achieve angiographic success without associated in-hospital major clinical complications (e.g., death, MI, stroke, emergency CABG) (7, 8). Issues regarding the diagnosis and prognostic implications of procedure-related MI are discussed in Sections 3.3 and 5.10.

3.1.3. Clinical Success. In the short term, a clinically successful PCI requires both anatomic and procedural success along with relief of signs and/or symptoms of myocardial ischemia. Long-term clinical success requires that the short-term clinical success remain durable and that relief of signs and symptoms of myocardial ischemia persist >9 months after the procedure. Restenosis is the principal cause of lack of long-term clinical success after a short-term clinical success has been achieved. Restenosis is not a complication; it is the expected biological response to vascular injury. The frequency of clinically important restenosis may be judged by the frequency with which subsequent revascularization procedures are performed on target arteries after the index procedure.

3.2. Predictors of Clinical Outcome After PCI

Factors associated with increased PCI complication rates include advanced age, diabetes, CKD, ACS, congestive heart failure, and multivessel CAD (8, 230–232). Several models have been developed and refined over the past 2 decades to predict mortality with PCI (230, 233–236). At present, perhaps the best accepted system is from the ACC National Cardiovascular Data Registry (NCDR) CathPCI Risk Score system, which uses clinical variables and PCI setting to predict inpatient mortality (Appendix 4A)(236). In general, these models perform very well (C statistic: approximately 0.90), although predictive capability decreases in high-risk patients.

Models have also been developed to predict procedural success. Presently, the modified ACC/AHA score

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(230) and the SCAI score (Appendix 4B)(237) are both in use, with the latter slightly outperforming the former. Discrimination as measured by the C statistic is generally good to very good (0.70 to 0.82), depending on the outcome variable and patient population.

The angiographic SYNTAX score (238) has been developed to predict long-term risk of MACE after multivessel intervention. The SYNTAX score and its potential utility in helping guide revascularization strategies are discussed in Section 2. Composite models including angiographic and clinical variables have been developed but generally require validation in larger cohorts of patients.

3.3. PCI Complications

In an analysis of the NCDR CathPCI database of patients undergoing PCI between 2004 and 2007, the overall in-hospital mortality rate was 1.27%, ranging from 0.65% in elective PCI to 4.81% in STEMI (236). Factors associated with an increased risk of PCI-related death include advanced age, comorbidities (e.g., diabetes, CKD, congestive heart failure), multivessel CAD, high-risk lesions, and the setting of PCI (e.g., STEMI, urgent or emergency procedure, cardiogenic shock) (56, 230–232, 236).

Causes of procedural and periprocedural MI include acute artery closure, embolization and no-reflow, side branch occlusion, and acute stent thrombosis. The incidence of procedure-related MI depends to a great degree on the definition of MI used, the patient population studied, and whether or not cardiac biomarkers are routinely assessed after PCI. The definition and clinical significance of PCI-related MI have been controversial. Criteria for defining a PCI-related MI have evolved over time (8, 239, 240). The 2007 universal definition of MI (240) states that after PCI, elevations of cardiac biomarkers above the 99th percentile upper reference limit indicate periprocedural myocardial necrosis. Increases of biomarkers >3 times the 99th percentile upper reference limit were designated as defining PCI-related MI (240). According to this definition, ≥15% of patients undergoing PCI would be defined as having periprocedural MI (241, 242). Issues in procedure-related MI are discussed in Section 5.10.

The need for emergency CABG has dramatically decreased with advances in PCI technology, particularly coronary stents (243, 244). Recently the NCDR reported the rate of emergency CABG at 0.4% (244). Procedure-related indications for CABG in 1 large series included coronary dissection (27%), acute artery closure (16%), perforation (8%), and failure to cross the lesion (8%) (245). The strongest predictors of the need for emergency CABG in several analyses are cardiogenic shock (OR: 11.4), acute MI or emergency PCI (OR: 3.2 to 3.8), multivessel disease (OR: 2.3 to 2.4), and type C lesion (OR: 2.6) (243, 245). In-hospital mortality for emergency CABG ranges from 7.8% to 14% (243, 245, 246).

In a contemporary analysis from the NCDR, the incidence of PCI-related stroke was 0.22% (247). In-hospital mortality in patients with PCI-related stroke is 25% to 30% (247, 248). Factors associated with an increased risk of stroke include fibrinolytic therapy administered before PCI (OR: 4.7), known cerebrovascular disease (OR: 2.20), STEMI as the indication for PCI (OR: 3.2), use of an intra-aortic balloon pump (IABP) (OR: 2.6), older age (OR: 1.17 per 5-year increase), and female sex (247–249). Initial imaging after a stroke in 1 small series revealed hemorrhagic etiology in 18%, ischemic etiology in 58%, and no clear etiology in 24% (248). One potential algorithm for the treatment of catheterization-related stroke has been recently proposed (250). This document includes no specific recommendations for the management of PCI-related stroke but refers the reader to the AHA/American Stroke Association guidelines for the management of adults with stroke (251).

Vascular complications from PCI are primarily related to vascular access. Important femoral vascular complications include access site hematoma, retroperitoneal hematoma, pseudoaneurysm, arteriovenous fistula, and arterial dissection and/or occlusion (252). The incidence of these vascular complications in various reports generally ranges from 2% to 6% and has decreased with time (249, 253–257). Factors associated with an increased risk of vascular complication include age ≥70 years, body surface area <1.6 m^2, emergency procedures, peripheral artery disease, periprocedural use of glycoprotein (GP) IIb/IIIa inhibitors, and female sex (if not corrected for body surface area) (249, 253, 254, 257, 258). Ultrasound guidance has been used for femoral artery access to potentially decrease complications (259). As discussed in Section 5.11, vascular closure devices have not been clearly demonstrated to decrease vascular complication rates. Radial site access decreases the rate of access-related bleeding and complications compared with femoral access (255, 260). Loss of the radial pulse has been reported in ≤5% of radial procedures (261). Infrequent to rare complications occurring with the radial artery approach include compartment syndrome, pseudoaneurysm (<0.01%), and sterile abscess (occurring with previous-generation hydrophilic sheaths) (262). Radial artery spasm may occur and treatment at times may be challenging. Local hematomas may occur from small-branch vessel hydrophilic wire perforation or inexperience with wristband use.

The risk of coronary perforation is approximately 0.2%, most commonly by wire perforation during PCI for CTO or by ablative or oversized devices during PCI of heavily diseased or tortuous coronary arteries (263). The risk of tamponade and management of the perforation varies with the type of perforation (264).

Periprocedural bleeding is now recognized to be associated with subsequent mortality (265, 266), and the avoidance of bleeding complications has become an important consideration in performing PCI. The risk of bleeding is associated with patient factors (e.g., advanced age, low body mass index, CKD, baseline anemia), as well as the degree of platelet and thrombin inhibition, vascular access site, and sheath size (267–269). Issues of periprocedural bleeding are discussed in Section 4.7.

The incidence of contrast-induced acute kidney injury (AKI) or "contrast nephropathy" in published reports depends on the definition of contrast nephropathy used and the frequency of risk factors for contrast-induced AKI in the patient population studied. Important risk factors for contrast-induced AKI include advanced age, CKD, congestive heart failure, diabetes, and the volume of contrast administered. Contrast-induced AKI and strategies to prevent it are discussed in Section 4.4.

4. PREPROCEDURAL CONSIDERATIONS

T4 Table 4 contains recommendations for preprocedural considerations and interventions in patients undergoing PCI.

4.1. Cardiac Catheterization Laboratory Requirements

4.1.1. Equipment. Defibrillators are considered by The Joint Commission to be life-support equipment requiring routine assessment and completion of appropriate logs. Many hospitals require periodic inspection of consoles for ancillary devices used in coronary intervention (e.g., Doppler wires, pressure-tipped sensor wires, and IVUS catheters). Point-of-care testing devices (e.g., activated clotting time and arterial blood gas machines) require routine calibration. Duration of storage of digital cine images is often mandated by law. Operating parameters for x-ray imaging equipment are adjusted at installation and periodically assessed by a qualified physicist in cooperation with the equipment manufacturer. Familiarity with radiation dose-reducing features of catheterization laboratory equipment and assistance from a qualified physicist are important for radiation dose minimization and image optimization.

4.1.2. Staffing. An interventional cardiologist must be present in the laboratory for the duration of each procedure and is responsible for procedure outcome. Nursing and technical personnel are also required to be present in the catheterization laboratory, with specific staffing dependent on state requirements and laboratory caseload and mix. Catheterization laboratory technical staff may include nurse practitioners, registered nurses, licensed vocational or practical nurses, physician assistants, nursing assistants, radiology technicians, or catheterization laboratory technicians. All catheterization laboratory staff are usually certified in basic life support, advanced cardiovascular life support, and, where appropriate, pediatric advanced life support. Catheterization laboratory personnel have a nursing degree/certification or invasive cardiovascular credentials such as registered cardiovascular invasive specialist or American Society of Radiation technologists (305).

4.1.3. 'Time-Out' Procedures. In 2003, The Joint Commission mandated a universal protocol requiring proper preoperative identification of the patient by the members of the catheterization laboratory team, marking of the operative site, and a final time-out just before the procedure (306). Although initially intended to prevent wrong-site surgery, this has been expanded to include all invasive procedures despite limited scientific evidence of its effectiveness (307). The intent of the time-out is for all members of the team to improve patient care by collectively discussing the case. The content of a time-out includes confirmation of the correct patient, correct side and site, agreement on the procedure to be performed, correct patient position, and availability of needed equipment, supplies, and implants. The timeout may be checklist driven or conversational, depending on laboratory preferences (308). The writing committee strongly endorses the practice of conducting a time-out before all PCI procedures.

4.2. Ethical Aspects

The 3 principles of medical ethics are beneficence, autonomy, and justice. Beneficence involves the physician's duty to act in the best interests of the patient and avoid maleficence, or harm *(primum non nocere)*. Autonomy describes the physician's duty to help the patient maintain control over his or her medical treatments. Justice describes the physician's duty to treat the individual patient responsibly with due consideration of other patients and stakeholders in the healthcare system. Ethical considerations specific to PCI have been previously discussed (309) and are highlighted below:

- Place the patient's best interest first and foremost when making clinical decisions (beneficence).
- Ensure that patients actively participate in decisions affecting their care (autonomy).

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TABLE 4. Summary of Recommendations for Preprocedural Considerations and Interventions in Patients Undergoing PCI

Recommendations	COR	LOE	References
Contrast-Induced AKI			
Patients should be assessed for risk of contrast-induced AKI before PCI.	I	C	(270,271)
Patients undergoing cardiac catheterization with contrast media should receive adequate preparatory hydration.	I	B	(272–275)
In patients with CKD (creatinine clearance <60 mL/min), the volume of contrast media should be minimized.	I	B	(276–278)
Administration of N-acetyl-L-cysteine is not useful for the prevention of contrast-induced AKI.	III: No Benefit	A	(279–283)
Anaphylactoid reactions			
Patients with prior evidence of an anaphylactoid reaction to contrast media should receive appropriate prophylaxis before repeat contrast administration.	I	B	(252,284–286)
In patients with a prior history of allergic reactions to shellfish or seafood, anaphylactoid prophylaxis for contrast reaction is not beneficial.	III: No Benefit	C	(287–289)
Statins			
Administration of a high-dose statin is reasonable before PCI to reduce the risk of periprocedural MI.	IIa	A: Statin naive	(290–296)
		B: Chronic statin therapy	(297)
Bleeding risk			
All patients should be evaluated for risk of bleeding before PCI.	I	C	N/A
CKD			
In patients undergoing PCI, the glomerular filtration rate should be estimated and the dosage of renally cleared medications should be adjusted.	I	B	(298–300)
Aspirin			
Patients already on daily aspirin therapy should take 81 mg to 325 mg before PCI.	I	B	(301–304)
Patients not on aspirin therapy should be given nonenteric aspirin 325 mg before PCI.	I	B	(301,303,304)

AKI indicates acute kidney injury; CKD, chronic kidney disease; COR, class of recommendation; LOE, level of evidence; MI, myocardial infarction; N/A, not applicable; and PCI, percutaneous coronary intervention.

- Consider how decisions regarding one patient may also affect other patients and providers (justice).
- Plan and perform procedures and provide care with the intention of improving the patient's quality of life and/or decreasing the risk of mortality, independent of reimbursement considerations and without inappropriate bias or influence from industry, administrators, referring physicians, or other sources.
- Before performing procedures, obtain informed consent after giving an explanation regarding the details of the procedure and the risks and benefits of both the procedure and alternatives to the procedure.
- Plan and perform procedures according to standards of care and recommended guidelines, and deviate from them when appropriate or necessary in the care of individual patients.
- Seek advice, assistance, or consultation from colleagues when such consultation would benefit the patient.

4.2.1. Informed Consent. Obtaining informed consent for procedures is a legal and ethical necessity. Ideally, informed consent is obtained long enough before the procedure that the patient can fully consider informed consent issues and discuss them with family or other providers, avoiding any sense of coercion. Ad hoc PCI, or PCI immediately following diagnostic procedures, presents special problems. When informed consent for PCI is obtained before diagnostic catheterization is performed, it is impossible to predict the levels of risk and benefit from an ad hoc PCI (310, 311). If diagnostic catheterization reveals anatomy that poses a particularly high risk or for which the superiority of PCI compared with other strategies is unclear, the precatheterization informed consent discussion may be inadequate. In such cases, deferral of PCI until additional informed consent discussions and/or consultations occur may be appropriate, even though it inconveniences the patient and the healthcare system. It is the responsibility of the interventionalist to act in the patient's best interest in these circumstances.

Informed consent before emergency procedures is particularly difficult (312–314). The patient presenting with STEMI is usually in distress and often sedated, making true informed consent impossible. Rapid triage, transport, and treatment of STEMI patients create a pressured atmosphere that by necessity limits a prolonged and detailed informed consent process. Nevertheless, the interventionist must attempt to provide information about the risks and benefits of different strategies to the patient and family and balance the benefit of thorough discussion with the benefits of rapid intervention.

4.2.2. Potential Conflicts of Interest. Decisions about the performance and timing of PCI may pose additional ethical dilemmas. When considering whether to perform multivessel PCI in 1 stage versus 2 stages, safety and convenience for the patient must guide the decision, regardless of payment policies that maximize reimbursement when PCI is staged (311). A separate issue is self-referral, through which diagnostic catheterization often leads seamlessly to PCI by the same operator (315). The interventionist has an ethical obligation to the patient to consider all treatment options, consult with additional specialists (e.g., cardiac surgeons) when their input would be helpful to the patient, avoid unnecessary interventional procedures, and allow the patient to consult family members and other physicians (311).

4.3. Radiation Safety: Recommendation

CLASS I

1. Cardiac catheterization laboratories should routinely record relevant available patient procedural radiation dose data (e.g., total air kerma at the international reference point [$K_{a,r}$], air kerma air product [P_{KA}], fluoroscopy time, number of cine images), and should define thresholds with corresponding follow-up protocols for patients who receive a high procedural radiation dose. *(Level of Evidence: C)*

The issue of radiation exposure during imaging procedures has received increased attention, and the writing committee believes that radiation safety should be addressed in this guideline. Current standards for cardiac catheterization laboratories include the following:

- Specific procedures and policies are in place to minimize patient (and operator) risk.
- A radiation safety officer coordinates all radiation safety issues and works conjointly with the medical or health physicist.
- Patient radiation exposure is reduced to as low a level as reasonably can be achieved.
- Patients at increased risk for high procedural radiation exposure are identified.
- Informed consent includes radiation safety information, particularly for the high-risk patient.

A basic primer on the physics of x-ray imaging, essential to the safe practice of radiation dose management, has been published in an ACCF/AHA/Heart Rhythm Society/SCAI clinical competence statement (316). Appendix 4C summarizes strategies to minimize patient and operator radiation exposure. Adverse radiation effects are now well recognized as infrequent but potentially serious complications of prolonged interventional procedures (317). Fluoroscopic time does not include cine acquisition imaging and is therefore not an accurate measure of patient radiation dose. Total air kerma at the interventional reference point ($K_{a,r}$, in G_y) and air kerma area product (P_{KA}, in $Gycm^2$) are required to be reported on interventional x-ray systems since 2006.These are useful in the assessment of potential tissue adverse effects or long-term radiation sequelae, respectively, and it is reasonable to include them in the catheterization record at the conclusion of each procedure. Appendix 4D summarizes considerations for patient follow-up based on radiation dose during the procedure (317).

4.4. Contrast-Induced AKI: Recommendations

CLASS I

1. Patients should be assessed for risk of contrast-induced AKI before PCI (270, 271). *(Level of Evidence: C)*
2. Patients undergoing cardiac catheterization with contrast media should receive adequate preparatory hydration (272–275). *(Level of Evidence: B)*
3. In patients with CKD (creatinine clearance <60 mL/min), the volume of contrast media should be minimized (276–278). *(Level of Evidence: B)*

CLASS III: NO BENEFIT

1. Administration of N-acetyl-L-cysteine is not useful for the prevention of contrast-induced AKI (279–283). *(Level of Evidence: A)*

See Online Data Supplements 16 to 18 for additional data regarding contrast-induced AKI.

Contrast-induced AKI or "contrast nephropathy" is one of the leading causes of hospital-acquired AKI. Major risk factors for contrast-induced AKI include advanced age, CKD, congestive heart failure, diabetes, and the volume of contrast administered. A risk-scoring system is available to predict the risk of contrast nephropathy using these risk factors and additional variables (270). Thus far, the only strategies clearly shown to reduce the risk of contrast-induced AKI are hydration and minimizing the amount of contrast media. Other than saline hydration, measures that were believed to reduce the risk of contrast-induced AKI have been found to be neutral, to have deleterious effects, or to be characterized by heterogeneous and conflicting data.

Studies of hydration to reduce the risk of contrast-induced AKI suggest that isotonic saline is preferable to half isotonic saline, intravenous (IV) hydration is preferable to oral hydration, hydration for hours before and after exposure to contrast media is preferable to a

bolus administration of saline immediately before or during contrast media exposure, and administration of isotonic saline alone is preferable to administration of isotonic saline plus mannitol or furosemide (272–275, 320). On the basis of these studies, a reasonable hydration regimen would be isotonic crystalloid (1.0 to 1.5 mL/kg per hour) for 3 to 12 hours before the procedure and continuing for 6 to 24 hours after the procedure (272–275, 284, 320, 321).

Prior studies of N-acetyl-L-cysteine and sodium bicarbonate have produced conflicting results. Some, often small, earlier studies suggested benefit, but many other more contemporary studies and meta-analyses found no clear evidence of benefit, and there are potential issues of publication bias and poor methodology issues in several analyses (279–282, 322–332). The recently completed largest randomized study on N-acetyl-L-cysteine and contrast nephropathy in patients undergoing angiographic procedures, ACT (Acetylcysteine for Contrast-Induced Nephropathy Trial), demonstrated no benefit in primary or secondary endpoints. An updated meta-analysis using only high-quality trials similarly demonstrated no benefit (283). Taken as a whole, these studies do not support any recommendation for the use of N-acetyl-L-cysteine, they do, however, provide sufficient data to conclude that N-acetyl-L-cysteine does not prevent contrast-induced AKI in patients undergoing angiographic procedures.

The correlation between the volume of contrast media and the risk of contrast-induced AKI has been documented in several studies (276, 277). Thus, minimization of contrast media volume is important to prevent contrast-induced AKI in patients undergoing angiography. The volume of contrast already administered during diagnostic catheterization is an important factor when considering possible "ad hoc" PCI.

Comparative studies of different contrast media (e.g., low-osmolar versus iso-osmolar, one agent versus another agent) have produced variable and sometimes contradictory results (334–339). Thus, current data are insufficient to justify specific recommendations about low- and isoosmolar contrast media. This issue is discussed in detail in the 2011 UA/NSTEMI focused update (340). For a further discussion of contrast media and PCI, the reader is referred to a position statement by the SCAI (284).

4.5. Anaphylactoid Reactions: Recommendations

CLASS I

1. Patients with prior evidence of an anaphylactoid reaction to contrast media should receive appropriate steroid and antihistamine prophylaxis before repeat contrast administration (252, 284–286). *(Level of Evidence: B)*

CLASS III: NO BENEFIT

1. In patients with a prior history of allergic reactions to shellfish or seafood, anaphylactoid prophylaxis for contrast reaction is not beneficial (287–289). *(Level of Evidence: C)*

The incidence of anaphylactoid reactions to contrast media is $\leq$1%, and the incidence of severe reactions may be as low as 0.04% (284). Limited data suggest that in patients with a history of prior anaphylactoid reaction, the recurrence rate without prophylaxis is in the range of 16% to 44% (341). Adequate pretreatment of patients with prior anaphylactoid reactions reduces the recurrence rate to close to zero (284–286). A regimen of 50 mg of prednisone administered 13 hours, 7 hours, and 1 hour before the procedure (as well as 50 mg of diphenhydramine 1 hour before the procedure) has been shown to reduce the risk of recurrent anaphylactoid reaction (286). In practice, a regimen of 60 mg of prednisone the night before and morning of the procedure (as well as 50 mg of diphenhydramine 1 hour before the procedure) is often used (252). There are minimal data on the "pretreatment" of patients undergoing emergency PCI (342). One group has suggested IV steroids (e.g., 80 mg to 125 mg of methylprednisolone, 100 mg of hydrocortisone sodium succinate), as well as oral or IV diphenhydramine and possible IV cimetidine (284). For a more detailed discussion of issues related to contrast-induced anaphylactoid reactions, the reader is referred to several dedicated discussions on contrast agents (284, 341).

There are no data to suggest that those patients with seafood or shellfish allergies are at risk for an anaphylactoid reaction from exposure to contrast media. Iodine does not mediate seafood, shellfish, or contrast media reactions. The common misconception that seafood allergies and contrast reactions are cross-reactions to iodine probably arose from a survey published in 1975 in which 15% of patients with a history of contrast reaction reported a personal history of shellfish allergy, but nearly identical proportions of patients reported allergies to other foods, such as milk and egg, in the same survey (287). Pretreatment of patients with steroids based only on a history of seafood or shellfish allergy has a small but non-zero risk of adverse effect (e.g., hyperglycemia in a patient with diabetes) without any demonstrated benefit (288, 289).

4.6. Statin Treatment: Recommendation

CLASS IIa

1. Administration of a high-dose statin is reasonable before PCI to reduce the risk of periprocedural MI. *(Level of Evidence: A for statin-naive patients* [290–296]; *Level of Evidence: B for those on chronic statin therapy* [297])

See Online Data Supplement 19 for additional data regarding preprocedural statin treatment.

Statins have long-term benefits in patients with CAD (343, 344) and ACS (345, 346). The benefits of statins in ACS begin early, before substantial lipid lowering has occurred (345, 347), suggesting pleiotropic effects of statins. These might include anti-inflammatory effects, improvement of endothelial function, decrease of oxidative stress, or inhibition of thrombogenic responses (348). Statins were beneficial when pretreatment was started from 7 days to just before PCI (290–297).

4.7. Bleeding Risk: Recommendation

CLASS I

1. All patients should be evaluated for risk of bleeding before PCI. *(Level of Evidence: C)*

Periprocedural bleeding is now recognized as a major risk factor for subsequent mortality (265, 266). Bleeding may lead to mortality directly (because of the bleeding event) or through ischemic complications that occur when antiplatelet or anticoagulant agents are withdrawn in response to the bleeding. Bleeding may also be a marker of comorbidities associated with worse prognosis (e.g., occult cancer). The risk of bleeding is associated with a number of patient factors (e.g., advanced age, low body mass index, CKD, baseline anemia), as well as the degree of platelet and thrombin inhibition, vascular access site, and sheath size (267–269). The overall approach to PCI should be individualized to minimize both ischemic and bleeding risks.

Measures to minimize the risks of bleeding complications are discussed in several sections of this guideline. These include use of anticoagulation regimens associated with a lower risk of bleeding, weight-based dosing of heparin and other agents, use of activated clotting times to guide unfractionated heparin (UFH) dosing, avoidance of excess anticoagulation (349), dosing adjustments in patients with CKD (e.g., eptifibatide, tirofiban, bivalirudin) (350), use of radial artery access site (255), and avoidance of femoral vein cannulation when possible. Vascular closure devices have not been clearly demonstrated to decrease bleeding complications and are discussed in detail in Section 5.11.

4.8. PCI in Hospitals Without On-Site Surgical Backup: Recommendations

CLASS IIa

1. Primary PCI is reasonable in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished (351, 352). *(Level of Evidence: B)*

CLASS IIb

1. Elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection (352–354). *(Level of Evidence: B)*

CLASS III: HARM

1. Primary or elective PCI should not be performed in hospitals without on-site cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without appropriate hemodynamic support capability for transfer. *(Level of Evidence: C)*

See Online Data Supplement 20 for additional data regarding hospitals without on-site surgical backup.

Primary and elective PCI can be performed at hospitals without on-site cardiac surgical backup with a high success rate, low in-hospital mortality rate, and low rate for emergency CABG (351, 353, 354). The best outcomes for patients with STEMI are achieved at hospitals with 24/7 access to primary PCI (355). Criteria for the performance of PCI without on-site surgical backup have been proposed in an SCAI expert consensus document (352). Consideration of elective PCI without on-site cardiac surgical backup is thought to be appropriate only when performed by experienced operators with complication rates and outcomes equivalent or superior to national benchmarks. Accurate assessment of complication rates and patient outcomes via a regional or national data registry, so that outcomes can be compared with established benchmarks, is an important quality control component of any PCI program. Desires for personal or institutional financial gain, prestige, market share, or other similar motives are not appropriate considerations for initiation of PCI programs without on-site cardiac surgery. It is only appropriate to consider initiation of a PCI program without on-site cardiac surgical backup if this program will clearly fill a void in the healthcare needs of the community. Competition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interests of the community.

Tables 5 and 6 list the SCAI expert consensus document requirements for PCI programs without on-site surgical backup. Table 7 gives the requirements for primary PCI and emergency CABG at hospitals without on-site cardiac surgery, and Table 8 lists the requirements for patient and lesion selection and backup strategy for nonemergency PCI (352). T6 T5 T7 T8

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TABLE 5. SCAI Expert Consensus Document Personnel and Facility Requirements for PCI Programs Without On-Site Surgical Backup

Experienced nursing and technical laboratory staff with training in interventional laboratories. Personnel must be comfortable treating acutely ill patients with hemodynamic and electrical instability.
On-call schedule with operation of laboratory 24 h/d, 365 d/y.*
Experienced coronary care unit nursing staff comfortable with invasive hemodynamic monitoring, operation of temporary pacemaker, and management of IABP. Personnel capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.
Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services (e.g., respiratory care, blood bank).
Written agreements for emergency transfer of patients to a facility with cardiac surgery. Transport protocols should be developed and tested a minimum of 2 times per year.
Well-equipped and maintained cardiac catheterization laboratory with high-resolution digital imaging capability and IABP equipment compatible with transport vehicles. The capability for real-time transfer of images and hemodynamic data (via T-1 transmission line) as well as audio and video images to review terminals for consultation at the facility providing surgical backup support is ideal.
Appropriate inventory of interventional equipment, including guide catheters, balloons, and stents in multiple sizes; thrombectomy and distal protection devices; covered stents; temporary pacemakers; and pericardiocentesis trays. Pressure wire device and IVUS equipment are optimal but not mandatory. Rotational or other atherectomy devices should be used cautiously in these facilities because of the greater risk of perforation.
Meticulous clinical and angiographic selection criteria for PCI (Tables 6 and 7).
Performance of primary PCI as the treatment of first choice for STEMI to ensure streamlined care paths and increased case volumes. Door-to-balloon times should be tracked, and <90 min outlier cases should be carefully reviewed for process improvement opportunities. On-site rigorous data collection, outcomes analysis, benchmarking, quality improvement, and formalized periodic case review.
Participation in a national data registry where available, such as the ACC NCDR in the United States.

*Required for U.S. facilities but may not be possible for all facilities worldwide.

ACC indicates American College of Cardiology; IABP, intra-aortic balloon pump; IVUS, intravascular ultrasound; NCDR, National Cardiovascular Data Registry; PCI, percutaneous coronary intervention; SCAI, Society for Cardiovascular Angiography and Interventions; and STEMI, ST-elevation myocardial infarction.

Adapted with permission from Dehmer et al. (352).

TABLE 6. SCAI Expert Consensus Document Requirements for Off-Site Surgical Backup

Interventional cardiologists establish a working relationship with cardiac surgeons at the receiving facility.
1. Cardiac surgeon must have privileges at the referring facility to allow review of treatment options as time allows.
2. Cardiac surgeon and receiving hospital agree to provide cardiac surgical backup for urgent cases at all hours and for elective cases at mutually agreed hours.
3. Surgeon and receiving facility ensure that patients will be accepted based on medical condition, capacity of surgeon to provide services at the time of request, and availability of resources. If this cannot be ensured before the start of an elective procedure, the case should not be done at this time.
4. Interventional cardiologists must review with surgeons the immediate needs and status of any patient transferred for urgent surgery.
5. Hospital administrations from both facilities endorse transfer agreement.
6. Transferring and receiving facilities establish a rigorous protocol for rapid transfer of patients, including the proper personnel with appropriate experience.
7. A transport provider is available to begin transport within 20 min of the request and provide vehicle/helicopter with necessary life-sustaining equipment, including IABP and monitoring capability.
8. Transferring physician obtains consent for surgery from patient or appropriate surrogate.
9. Initial informed consent for PCI discloses that the procedure is being done without on-site surgical backup and acknowledges the possibility of risks related to transfer. The consent process should include the risk of urgent surgery (approximately 0.3%) and state that a written plan for transfer exists.
10. As part of the local continuous quality improvement program, a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of any improvement opportunities.

IABP indicates intra-aortic balloon pump; PCI, percutaneous coronary intervention; and SCAI, Society for Cardiovascular Angiography and Interventions.

Adapted with permission from Dehmer et al. (352).

5. PROCEDURAL CONSIDERATIONS

5.1. Vascular Access: Recommendation

CLASS IIa

1. The use of radial artery access can be useful to decrease access site complications (255, 260, 356–362). *(Level of Evidence: A)*

See Online Data Supplement 21 for additional data regarding radial access.

Femoral artery access remains the most commonly used approach in patients undergoing PCI in the United States. Choosing a femoral artery puncture site is facilitated by fluoroscopic landmark identification or ultrasound guidance. Low punctures have a high incidence of peripheral artery complications, whereas high punctures have an increased risk of retroperitoneal hemorrhage. In patients with a synthetic graft, arterial access is possible after the graft is a few months old and complication rates are not increased (254).

Radial site access is used frequently in Europe and Canada but not in the United States (260). A learning curve exists for the radial approach that will affect procedure time and radiation dose, with a trend toward lower procedural success rates for radial versus femoral access (255). However, compared with femoral access, radial access decreases the rate of access-related bleeding and complications (255, 260, 363). In a recent large RCT comparing radial and femoral access in patients with ACS undergoing PCI, there was no difference in the primary composite endpoint (death, MI, stroke, major bleeding), although there was a lower rate of vascular complications with the use of radial access (362).

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TABLE 7. SCAI Expert Consensus Document Requirements for Primary PCI and Emergency Aortocoronary Bypass Surgery at Hospitals Without On-Site Cardiac Surgery

Avoid intervention in patients with

- >50% diameter stenosis of left main artery proximal to infarct-related lesion, especially if the area in jeopardy is relatively small and overall LV function is not severely impaired
- Long, calcified, or severely angulated target lesions at high risk for PCI failure with TIMI flow grade 3 present during initial diagnostic angiography
- Lesions in other than the infarct artery (unless they appeared to be flow limiting in patients with hemodynamic instability or ongoing symptoms)
- Lesions with TIMI flow grade 3 that are not amenable to stenting in patients with left main or 3-vessel disease that will require coronary bypass surgery
- Culprit lesions in more distal branches jeopardizing only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention

Transfer emergently for coronary bypass surgery patients with

- High-grade left main or 3-vessel coronary disease with clinical or hemodynamic instability after successful or unsuccessful PCI of an occluded vessel and preferably with IABP support
- Failed or unstable PCI result and ongoing ischemia, with IABP support during transfer

IABP indicates intra-aortic balloon pump; LV, left ventricular; PCI, percutaneous coronary intervention; SCAI, Society for Cardiovascular Angiography and Interventions; and TIMI, Thrombolysis In Myocardial Infarction.

Adapted with permission from Dehmer et al. (352).

Radial artery access is particularly appealing in patients with coagulopathy, elevated international normalized ratio due to warfarin, or morbid obesity.

5.2. PCI in Specific Clinical Situations

5.2.1. UA/NSTEMI: Recommendations

CLASS I

1. An early invasive strategy (i.e., diagnostic angiography with intent to perform revascularization) is indicated in UA/NSTEMI patients who have refractory angina or hemodynamic or electrical instability (without serious comorbidities or contraindications to such procedures) (207, 364, 365). *(Level of Evidence: B)*
2. An early invasive strategy (i.e., diagnostic angiography with intent to perform revascularization) is indicated in initially stabilized UA/ NSTEMI patients (without serious comorbidities or contraindications to such procedures) who have an elevated risk for clinical events (207, 365–367). *(Level of Evidence: A)*
3. The selection of PCI or CABG as the means of revascularization in the patient with ACS should generally be based on the same considerations as those without ACS (53, 156, 207, 368). *(Level of Evidence: B)*

TABLE 8. SCAI Expert Consensus Document Requirements for Patient and Lesion Selection and Backup Strategy for Nonemergency PCI by Experienced Operators at Hospitals Without On-Site Cardiac Surgery

Patient risk: expected clinical risk in case of occlusion caused by procedure

High patient risk: Patients with any of the following:

- Decompensated congestive heart failure (Killip Class 3) without evidence for active ischemia, recent CVA, advanced malignancy, known clotting disorders
- LVEF <25%
- Left main stenosis (≥50% diameter) or 3-vessel disease unprotected by prior bypass surgery (>70% stenoses in the proximal segment of all major epicardial coronary arteries)
- Single-target lesion that jeopardizes >50% of remaining viable myocardium

Lesion risk: probability that procedure will cause acute vessel occlusion

Increased lesion risk: lesions in open vessels with any of the following characteristics:

- Diffuse disease (>2 cm in length) and excessive tortuosity of proximal segments
- More than moderate calcification of a stenosis or proximal segment
- Location in an extremely angulated segment (>90%)
- Inability to protect major side branches
- Degenerated older vein grafts with friable lesions
- Substantial thrombus in the vessel or at the lesion site
- Any other feature that may, in the operator's judgment, impede successful stent deployment Aggressive measures to open CTOs are also discouraged because of an increased risk of perforation.

Strategy for surgical backup based on lesion and patient risk:

- **High-risk patients with high-risk lesions** should not undergo nonemergency PCI at a facility without on-site surgery.
- **High-risk patients with non-high-risk lesions:** Nonemergency patients with this profile may undergo PCI, but confirmation that a cardiac surgeon and operating room are immediately available is necessary.
- **Non-high-risk patients with high-risk lesions** require no additional precautions.
- **Non-high-risk patients with non-high-risk lesions** require no additional precautions. Best scenario for PCI without on-site surgery.

CTO indicates chronic total occlusion; CVA, cerebrovascular accident; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; and SCAI, Society for Cardiovascular Angiography and Interventions.

Adapted with permission from Dehmer et al. (352).

CLASS III: NO BENEFIT

1. An early invasive strategy (i.e., diagnostic angiography with intent to perform revascularization) is not recommended in patients with extensive comorbidities (e.g., liver or pulmonary failure, cancer) in whom *(Level of Evidence: C)*
   a. The risks of revascularization and comorbid conditions are likely to outweigh the benefits of revascularization,
   b. There is a low likelihood of ACS despite acute chest pain, or
   c. Consent to revascularization will not be granted regardless of the findings.

The goals of coronary angiography and revascularization in UA/NSTEMI patients are to reduce the risk of death and MI and provide symptom relief. To improve prognosis, early risk stratification is essential for selection of medical and/or invasive treatment strategies. Indications for revascularization depend on the patient's clinical risk characteristics and coronary anatomy and are in general stronger in the presence of high-risk clinical presentation (e.g., dynamic electrocardiogram [ECG] changes, elevated troponin, high Global Registry of Acute Coronary Events score), recurrent symptoms, threatened viable myocardium, CKD, and larger ischemic burden (Appendix 4E). For choice of revascularization technique, the anatomical considerations are generally those used for stable CAD, although PCI may initially be performed in the index lesion to stabilize the patient (Section 2).

Contemporary studies variably comparing strategies of very early (within hours of admission), early (within 24 hours of admission), and delayed (1 to 7 days after admission) cardiac catheterization and revascularization support a strategy of *early* angiography and revascularization to reduce the risk of recurrent ischemia and MI, particularly among those at high risk (e.g., Global Registry of Acute Coronary Events score >140) (367, 369, 370), whereas a delayed approach is reasonable in low-intermediate risk patients (based on clinical course). There is no evidence that incremental benefit is derived by angiography and PCI performed within the first few hours of hospital admission (207, 367, 371–378).

5.2.2. ST-Elevation Myocardial Infarction

5.2.2.1. CORONARY ANGIOGRAPHY STRATEGIES IN STEMI: RECOMMENDATIONS

CLASS I

1. A strategy of immediate coronary angiography with intent to perform PCI (or emergency CABG) in patients with STEMI is recommended for
   a. Patients who are candidates for primary PCI (351, 379–382). *(Level of Evidence: A)*
   b. Patients with severe heart failure or cardiogenic shock who are suitable candidates for revascularization (383, 384). *(Level of Evidence: B)*

CLASS IIa

1. A strategy of immediate coronary angiography (or transfer for immediate coronary angiography) with intent to perform PCI is reasonable for patients with STEMI, a moderate to large area of myocardium at risk, and evidence of failed fibrinolysis (385, 386). *(Level of Evidence: B)*
2. A strategy of coronary angiography (or transfer for coronary angiography) 3 to 24 hours after initiating fibrinolytic therapy with intent to perform PCI is reasonable for hemodynamically stable patients with STEMI and evidence for successful fibrinolysis when angiography and revascularization can be performed as soon as logistically feasible in this time frame (387–391). *(Level of Evidence: A)*

CLASS IIb

1. A strategy of coronary angiography performed before hospital discharge might be reasonable in stable patients with STEMI who did not undergo cardiac catheterization within 24 hours of STEMI onset. *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. A strategy of coronary angiography with intent to perform PCI is not recommended in patients with STEMI in whom the risks of revascularization are likely to outweigh the benefits or when the patient or designee does not want invasive care. *(Level of Evidence: C)*

The historical reperfusion strategies of "primary PCI," "immediate PCI," "rescue PCI," "deferred PCI," "facilitated PCI," and the "pharmacoinvasive strategy" have evolved in parallel with advances in antithrombotic therapy and STEMI prehospital and hospital systems of care. The clinical challenge in primary PCI is achieving rapid time to treatment and increasing patient access to this preferred reperfusion strategy. The clinical challenge in patients treated with fibrinolytic therapy is deciding for whom and when to perform coronary angiography.

In unstable patients (e.g., severe heart failure or cardiogenic shock, hemodynamically compromising ventricular arrhythmias) not treated initially with primary PCI, a strategy of immediate coronary angiography with intent to perform PCI is implemented unless invasive management is considered futile or unsuitable given the clinical circumstances (383, 384).

In stable patients treated with fibrinolytic therapy and clinical suspicion of reperfusion failure, a strategy of immediate coronary angiography followed by PCI improves outcome in those at high risk (385, 386). Such a strategy is also implemented in patients with evidence for infarct artery reocclusion (Table 9). The T9
clinical diagnosis of failed fibrinolysis is difficult but is best made when there is <50% ST-segment resolution 90 minutes after initiation of therapy in the lead showing the greatest degree of ST-segment elevation at presentation. Given the association between bleeding events and adverse cardiac events, a reasonable approach is to select moderate- and high-risk patients for PCI and treat low-risk patients with medical therapy. ECG and clinical findings of anterior MI or

TABLE 9. Indications for Coronary Angiography in STEMI

Indications	COR	LOE	References
Immediate coronary angiography			
Candidate for primary PCI	I	A	(351,379–382)
Severe heart failure or cardiogenic shock (if suitable revascularization candidate)	I	B	(383,384)
Moderate to large area of myocardium at risk and evidence of failed fibrinolysis	IIa	B	(385,386)
Coronary angiography 3 to 24 h after fibrinolysis			
Hemodynamically stable patients with evidence for successful fibrinolysis	IIa	A	(387–391)
Coronary angiography before hospital discharge			
Stable patients	IIb	C	N/A
Coronary angiography at any time			
Patients in whom the risks of revascularization are likely to outweigh the benefits or the patient or designee does not want invasive care	III: No Benefit	C	N/A

COR indicates class of recommendation; LOE, level of evidence; N/A, not applicable; PCI, percutaneous coronary intervention; and STEMI, ST-elevation myocardial infarction.

inferior MI with right ventricular involvement or precordial ST-segment depression, as well as ongoing pain, usually predicts increased risk and the greatest potential benefit (392). Conversely, patients with symptom resolution, improving ST-segment elevation, or inferior MI localized to 3 ECG leads probably gain little benefit.

In stable patients treated with fibrinolytic therapy and clinical evidence for successful reperfusion, an early invasive strategy with cardiac catheterization performed within 24 hours decreases reinfarction and recurrent ischemic events (388, 390, 391). Because of the associated increased bleeding risk, very early (<2 to 3 hours) catheterization after administration of fibrinolytic therapy with intent to perform revascularization should be reserved for patients with evidence of failed fibrinolysis and significant myocardial jeopardy for whom immediate angiography and revascularization would be appropriate (393).

5.2.2.2. PRIMARY PCI OF THE INFARCT ARTERY: RECOMMENDATIONS

CLASS I

1. Primary PCI should be performed in patients within 12 hours of onset of STEMI (379–382). *(Level of Evidence: A)*
2. Primary PCI should be performed in patients with STEMI presenting to a hospital with PCI capability within 90 minutes of first medical contact as a systems goal (394, 395). *(Level of Evidence: B)*
3. Primary PCI should be performed in patients with STEMI presenting to a hospital without PCI capability within 120 minutes of first medical contact as a systems goal (396–398). *(Level of Evidence: B)*
4. Primary PCI should be performed in patients with STEMI who develop severe heart failure or cardiogenic shock and are suitable candidates for revascularization as soon as possible, irrespective of time delay (383, 384). *(Level of Evidence: B)*
5. Primary PCI should be performed as soon as possible in patients with STEMI and contraindications to fibrinolytic therapy with isch-emic symptoms for less than 12 hours (399, 400). *(Level of Evidence: B)*

CLASS IIa

1. Primary PCI is reasonable in patients with STEMI if there is clinical and/or electrocardiographic evidence of ongoing ischemia between 12 and 24 hours after symptom onset (401–403). *(Level of Evidence: B)*

CLASS IIb

1. Primary PCI might be considered in asymptomatic patients with STEMI and higher risk presenting between 12 and 24 hours after symptom onset. *(Level of Evidence: C)*

CLASS III: HARM

1. PCI should not be performed in a noninfarct artery at the time of primary PCI in patients with STEMI without hemodynamic compromise (404–408). *(Level of Evidence: B)*

Primary PCI is preferred to fibrinolytic therapy when time-to-treatment delays are short and the patient presents to a high-volume, well-equipped center staffed with expert interventional cardiologists and skilled support staff. Compared with fibrinolytic therapy in RCTs, primary PCI produces higher rates for infarct artery patency, TIMI flow grade 3, and lower rates for recurrent ischemia, reinfarction, emergency repeat revascularization procedures, intracranial hemorrhage, and death (379). Early, successful PCI also greatly decreases the complications of STEMI that result from longer ischemic times or unsuccessful fibrinolytic therapy, allowing earlier hospital discharge and resumption of daily activities. The greatest

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TABLE 10. Indications for PCI in STEMI

Indications	COR	LOE	References
Primary PCI*			
STEMI symptoms within 12 h	I	A	(379–382)
Severe heart failure or cardiogenic shock	I	B	(383,384)
Contraindications to fibrinolytic therapy with ischemic symptoms <12 h	I	B	(399,400)
Clinical and/or electrocardiographic evidence of ongoing ischemia between 12 and 24 h after symptom onset	IIa	B	(401–403)
Asymptomatic patients presenting between 12 and 24 h after symptom onset and higher risk	IIb	C	N/A
Noninfarct artery PCI at the time of primary PCI in patients without hemodynamic compromise	III: Harm	B	(404–408)
Delayed or elective PCI in patients with STEMI			
Clinical evidence for fibrinolytic failure or infarct artery reocclusion	IIa	B	(385,386)
Patent infarct artery 3 to 24 h after fibrinolytic therapy	IIa	B	(390,391)
Ischemia on noninvasive testing	IIa	B	(410,411)
Hemodynamically significant stenosis in a patent infarct artery >24 h after STEMI	IIb	B	(413–417)
Totally occluded infarct artery >24 h after STEMI in a hemodynamically stable asymptomatic patient without evidence of severe ischemia	III: No Benefit	B	(418–420)

*Systems goal of performing primary PCI within 90 min of first medical contact when the patient presents to a hospital with PCI capability (394, 395)(Class *I; LOE: B)* and within 120 min when the patient presents to a hospital without PCI capability (396–398) (Class *I; LOE:* B).
COR indicates class of recommendation; LOE, level of evidence; N/A, not applicable; PCI, percutaneous coronary intervention; and STEMI, ST-elevation myocardial infarction.

mortality benefit of primary PCI is in high-risk patients. PCI outcomes may not be as successful with prolonged time-to-treatment or low-volume hospitals and operators (Table 10).

Several reports have shown excellent outcomes for patients with STEMI undergoing interhospital transfer where first medical contact-to-door balloon time modestly exceeded the systematic goal of <90 minutes (396–398, 409). In these reports, the referring hospital and the receiving hospital established a transfer protocol that minimized transfer delays, and outcomes were similar to those of direct-admission patients. On the basis of these results, the PCI and STEMI guideline writing committees have modified the first medical contact-to-device time goal from 90 minutes to 120 minutes for interhospital transfer patients (397), while emphasizing that systems should continue to strive for times ≤90 minutes. Hospitals that cannot meet these criteria should use fibrinolytic therapy as their primary reperfusion strategy.

PCI of a noninfarct artery at the time of primary PCI in stable patients is associated with worse clinical outcomes unless the patient is in cardiogenic shock where PCI of a severe stenosis in a coronary artery supplying a large territory of myocardium might improve hemodynamic stability (404, 406, 408). Delayed PCI can be performed in noninfarct arteries at a later time if clinically indicated (410–412).

5.2.2.3. DELAYED OR ELECTIVE PCI IN PATIENTS WITH STEMI: RECOMMENDATIONS

CLASS IIa

1. PCI is reasonable in patients with STEMI and clinical evidence for fibrinolytic failure or infarct artery reocclusion (385, 386). *(Level of Evidence: B)*
2. PCI is reasonable in patients with STEMI and a patent infarct artery 3 to 24 hours after fibrinolytic therapy (390, 391). *(Level of Evidence: B)*
3. PCI is reasonable in patients with STEMI who demonstrate ischemia on noninvasive testing (410, 411). *(Level of Evidence: B)*

CLASS IIb

1. PCI of a hemodynamically significant stenosis in a patent infarct artery greater than 24 hours after STEMI may be considered as part of an invasive strategy (413–417). *(Level of Evidence: B)*

CLASS III: NO BENEFIT

1. PCI of a totally occluded infarct artery greater than 24 hours after STEMI should not be performed in asymptomatic patients with 1- or 2-vessel disease if patients are hemodynamically and electrically stable and do not have evidence of severe ischemia (418–420). *(Level of Evidence: B)*

Studies and meta-analyses suggest potential benefit for PCI in fibrinolytic failure (385, 386). In stable

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patients treated with fibrinolytic therapy and clinical evidence for successful reperfusion, an early invasive strategy with cardiac catheter-ization performed within 24 hours decreases reinfarction and recurrent ischemic events (388, 390, 391).

PCI for a hemodynamically significant stenosis in a patent infarct artery >24 hours after STEMI as part of a revascularization strategy improves outcome (410, 411, 413–417). PCI of an occluded infarct artery 1 to 28 days after MI in asymptomatic patients without evidence of myocardial ischemia has no incremental benefit beyond optimal medical therapy with aspirin, beta blockers, angiotensin-converting enzyme inhibitors, and statins in preserving LV function and preventing subsequent cardiovascular events (418–420). It is important to note that elective PCI of an occluded infarct artery has not been studied in patients with New York Heart Association functional class III or IV heart failure, rest angina, serum creatinine >2.5 mg/dL, left main or 3-vessel CAD, clinical instability, or severe inducible ischemia on stress testing in an infarct zone that is not akinetic or dyskinetic.

5.2.3. Cardiogenic Shock: Recommendations

CLASS I

1. PCI is recommended for patients with acute MI who develop cardiogenic shock and are suitable candidates (384, 421–423). *(Level of Evidence: B)*
2. A hemodynamic support device is recommended for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy (384, 424–427). *(Level of Evidence: B)*

See Online Data Supplement 22 for additional data regarding cardiogenic shock.

Cardiogenic shock is the leading cause of in-hospital mortality complicating STEMI. Revascularization is the only treatment proven to decrease mortality rates (384, 421–423). Although revascularization is almost always accomplished through PCI, selected patients with severe 3-vessel or left main disease can benefit from emergency CABG. Revascu-larization attempts may be futile and not indicated in cases of severe multiorgan failure (427). Patient selection for revascularization is more important in the elderly, but several observational reports demonstrate acceptable outcomes in patients with few comorbidities and a reasonable potential for survival (428–431). Patients who present to hospitals without PCI capability are usually emergently transported to a PCI center, because mortality without transfer is markedly elevated (432).

5.2.3.1. PROCEDURAL CONSIDERATIONS FOR CARDIOGENIC SHOCK. Patients with cardiogenic shock should receive standard pharmacological therapies, including aspirin, a $P2Y_{12}$ receptor antagonist, and anticoagulation (427, 433). Inotropic and vasopressor therapy improves perfusion pressure. Historically, negative inotropes and vasodilators are avoided. IV GP IIb/IIIa inhibitors have been shown to provide benefit in observational studies but not in 1 small RCT (433).

Endotracheal intubation and mechanical ventilation with positive end-expiratory pressure is usually necessary in patients with respiratory failure. Placement of a temporary pacemaker is indicated for patients with bradycardia or high-degree atrioventricular heart block. A pulmonary artery catheter can provide information to dose and titrate inotropes and pressors. Further hemodynamic support is available with IABP counterpulsation or percutaneous LV assist devices, although no data support a reduction in mortality rates (434).

Contrast medium injections should be minimized. Orthogonal angiograms of the left coronary artery and a left anterior oblique angiogram of the right coronary artery are usually sufficient to identify the infarct artery (435). Although most patients undergoing revascularization will receive a stent as part of the procedure, there are conflicting data on the impact of stenting over balloon angioplasty. Some studies reveal lower mortality rates (436–438), whereas others reveal no benefit (439) or higher mortality rates (440). There are no data comparing the choice ofBMS versus DES in cardiogenic shock; however, BMS are often used because compliance with long-term DAPT is often unclear in the emergency setting.

In patients with multivessel disease, revascularization of the noninfarct artery may be necessary to maximize myocardial perfusion. Alternatively, in patients with multivessel disease and particularly left main disease, emergency CABG as a primary reperfusion strategy may be preferred (50, 441). Refractory cardiogenic shock unresponsive to revascularization may necessitate institution of more intensive cardiac support with a ventricular assist device or other hemodynamic support devices to allow for myocardial recovery or subsequent cardiac transplantation in suitable patients.

5.2.4. Revascularization Before Noncardiac Surgery: Recommendations

CLASS IIa

1. For patients who require PCI and are scheduled for elective noncardiac surgery in the subsequent 12 months, a strategy of balloon angioplasty, or BMS implantation followed by 4 to 6 weeks of DAPT, is reasonable (442–448). *(Level of Evidence: B)*
2. For patients with DES who must undergo urgent surgical procedures that mandate the discontinuation of DAPT, it is reasonable to continue aspirin if possible and restart the $P2Y_{12}$ inhibitor as soon as possible in the immediate postoperative period (444). *(Level of Evidence: C)*

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CLASS III: HARM

1. Routine prophylactic coronary revascularization should not be performed in patients with stable CAD before noncardiac surgery (449, 450). *(Level of Evidence: B)*
2. Elective noncardiac surgery should not be performed in the 4 to 6 weeks after balloon angioplasty or BMS implantation or the 12 months after DES implantation in patients in whom the $P2Y_{12}$ inhibitor will need to be discontinued perioperatively (208, 447, 451, 452). *(Level of Evidence: B)*

The 2007 and 2009 ACC/AHA Guidelines on Perioperative Cardiovascular Evaluation and Care for Noncardiac Surgery gave detailed recommendations for the evaluation of patients undergoing noncardiac surgery (444). Patients with evidence of ACS should receive standard therapy, including early revascularization, to minimize the risk of adverse events. Patients with known significant left main or 3-vessel CAD who would otherwise benefit from revascularization in terms of survival or symptomatic relief also generally undergo revascularization before elective noncardiac surgery.

Two RCTs (449, 450) found no benefit with routine preoperative revascularization before noncardiac surgery. Noncardiac surgery early after coronary stenting, particularly in the first 4 weeks, is associated with a high risk of stent thrombosis and death (444, 446, 448). When emergency surgery is necessary, the patient should proceed to surgery without prior PCI. When surgery is required within 30 days and coronary revascularization is required before surgery, many clinicians perform balloon angioplasty alone to avoid the need for DAPT. In situations where preoperative revascularization is required and surgery can be deferred for at least 30 days, many clinicians use BMS and discontinue DAPT after 30 days. If surgery is elective and can be deferred for 1 year, most clinicians would consider DES to reduce the long-term risk of restenosis. A dilemma occurs when a patient has undergone PCI and then unexpectedly requires noncardiac surgery. Many patients can undergo surgery on DAPT, where the risk-benefit ratio will favor continued dual antiplatelet inhibition. If it is necessary to hold $P2Y_{12}$ inhibitor therapy, most clinicians will still continue aspirin uninterrupted during the perioperative period if the bleeding risk is not prohibitive. When the risk of delaying surgery or performing surgery while the patient is on DAPT exceeds the risk of stent thrombosis from stopping DAPT, the $P2Y_{12}$ inhibitor is stopped before surgery and resumed as soon as possible afterward. No $P2Y_12$ inhibitor "bridging" strategy (e.g., GP IIb/IIIa inhibitor, antithrombin therapy) has been validated.

5.3. Coronary Stents: Recommendations

CLASS I

1. Before implantation of DES, the interventional cardiologist should discuss with the patient the need for and duration of DAPT and the ability of the patient to comply with and tolerate DAPT (212). *(Level of Evidence: C)*
2. DES are useful as an alternative to BMS to reduce the risk of restenosis in cases in which the risk of restenosis is increased and the patient is likely to be able to tolerate and comply with prolonged DAPT *(Level of Evidence: A for elective PCI* [453,453a,454–456]; *Level of Evidence: C for UA/NSTEMI* (453); *Level of Evidence: A for STEMI* [453,456–459]).
3. Balloon angioplasty or BMS should be used in patients with high bleeding risk, inability to comply with 12 months of DAPT, or anticipated invasive or surgical procedures within the next 12 months, during which time DAPT may be interrupted (208, 460–462). *(Level of Evidence: B)*

CLASS III: HARM

1. PCI with coronary stenting should not be performed if the patient is not likely to be able to tolerate and comply with DAPT (208–211). *(Level of Evidence: B)*
2. DES should not be implanted if the patient is not likely to be able to tolerate and comply with prolonged DAPT or this cannot be determined before stent implantation (208, 460–462). *(Level of Evidence: B)*

Coronary stent implantation is commonly performed during PCI to prevent recoil, abrupt closure, and late restenosis (463, 464). BMS are composed of either stainless steel or cobalt chromium alloys. Because the risk of stent thrombosis is greatest within the first 30 days after implantation, the use of DAPT is required for 30 days after implantation of BMS (208).

In the United States, 4 types of DES are currently approved: sirolimus-eluting stents, paclitaxel-eluting stents, zotarolimus-eluting stents, and everolimus-eluting stents. DES vary according to stent scaffold material and design, drug content, and the polymer used for drug elution; however, several common clinical features are present. First, sirolimus-eluting stents, paclitaxel-eluting stents, and zotarolimus-eluting stents have been demonstrated in RCTs to be associated with a reduced need for repeat revascularization and no increase in death or MI compared with BMS at 4 years' follow-up (465). Everolimus-eluting stents have been demonstrated in RCTs to be associated with a lower need for repeat revascularization than paclitaxel-

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eluting stents, and, by inference, a lower risk for repeat revascularization than BMS (466, 467), with no increase in death or MI at 2-year follow-up (468). Second, each of these stents is presumed to be associated with delayed healing based on pathologic studies and longer periods of risk for thrombosis compared with BMS and require longer duration of DAPT (469). In the RCTs that led to the U.S. Food and Drug Administration (FDA) approval of these stents, the recommended minimum duration of DAPT therapy was 3 to 6 months. Recently, the consensus of clinical practice has been 12 months of DAPT following DES implantation to avoid late (after 30 days) thrombosis (208), based on observational studies of paclitaxel-eluting stents and sirolimus-eluting stents that indicate lower risk of late stent thrombosis with >6 months of therapy (212). Extending DAPT beyond 1 year is considered reasonable by some practitioners based on observational data analysis (212), but RCTs to determine whether longer DAPT is associated with reduction in stent thrombosis risk have not been completed. Finally, DES therapy is more expensive than BMS. Cost-effectiveness analysis has shown a reduction in total cost associated with DES because of avoidance of repeat procedures, yet it may be reasonable to consider use of BMS in patient subsets in which the risk of restenosis is low (470).

This risk-benefit profile is most favorable for DES over BMS when the risk of restenosis with BMS is high (Table 11). Pooled and meta-analyses have demonstrated that in patients with diabetes, use of DES decreases the risk of restenosis compared with BMS (471, 472). DES may be more appealing for unprotected left main PCI, given the rate and clinical consequences of restenosis in this location (473–475). The risk of stent thrombosis is higher in populations or lesion types excluded from RCTs of DES (e.g., STEMI, smaller arteries [<2.5 mm diameter], longer lesions, bifurcations) (210, 465). Importantly, these features also predict both stent thrombosis (476) and restenosis in BMS (477). The greatest risk of stent thrombosis is within the first year, ranging from 0.7% to 2.0%, depending on patient and lesion complexity. Late stent thrombosis risk after 1 year with DES is observed at a rate of 0.2% to 0.4% per year (210, 478).

Compared with balloon angioplasty, routine BMS implantation during primary PCI decreases risk for target-vessel revascularization and possibly reduces MI rates but does not reduce mortality rates (479). More recent primary PCI studies and meta-analyses have demonstrated lower restenosis rates without increased risk of adverse stent outcome with DES compared with BMS. Although stent thrombosis rates in trials ofSTEMI are higher than in trials of elective PCI, the rates of stent thrombosis are not higher with DES compared with BMS in STEMI (453, 456–459).

TABLE 11. Clinical Situations Associated With DES or BMS Selection Preference

DES Generally Preferred Over BMS (Efficacy Considerations)	BMS Preferred Over DES (Safety Considerations)
• Left main disease	• Unable to tolerate or comply with DAPT
• Small vessels	• Anticipated surgery requiring discontinuation of DAPT within 12 mo
• In-stent restenosis	• High risk of bleeding
• Bifurcations	
• Diabetes	
• Long lesions	
• Multiple lesions	
• Saphenous vein grafts	

BMS indicates bare-mental stent(s); DAPT, dual antiplatelet therapy; and DES, drug-eluting stent(s).

The greatest risk for DES thrombosis is early discontinuation of DAPT (208, 460–462). It is therefore important to determine that the patient will likely be able to tolerate and comply with DAPT before implantation of DES. Therefore, DES should not be used in the presence of financial barriers to continuing prolonged DAPT, social barriers that may limit patient compliance, or medical issues involving bleeding risks or the need for invasive or surgical procedures in the following year that would interrupt antiplatelet therapy. The need for use of long-term warfarin and the associated increased risk ofbleeding with long-term "triple therapy" is also a consideration in deciding on DES versus BMS (480).

Patients implanted with most contemporary coronary stents can undergo magnetic resonance imaging (MRI) examination any time after implantation (481, 482). The effect of the MRI examination on heating of the drug or polymer coating used in DES is unknown. There is no indication for antibiotic prophylaxis before dental or invasive procedures in patients with coronary stents (483).

5.4. Adjunctive Diagnostic Devices

5.4.1. FFR: Recommendation

CLASS IIa

1. FFR is reasonable to assess angiographic intermediate coronary lesions (50% to 70% diameter stenosis) and can be useful for guiding revascularization decisions in patients with SIHD (12, 97, 484–486). *(Level of Evidence: A)*

See Online Data Supplement 23 for additional data regarding FFR.

The limitations of coronary angiography for determination of lesion severity have been well described. Angiography may under- or overestimate lesion stenosis. Various physiologic measurements can be made in the catheterization laboratory, including

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coronary flow reserve and FFR. The correlation of ischemia on stress testing with FFR values of <0.75 has been established in numerous comparative studies with high sensitivity (88%), specificity (100%), positive predictive value (100%), and overall accuracy (93%) (487). The 5-year outcomes for patients with medical therapy based on an FFR >0.75 were superior compared with PCI in the DEFER (Deferral Versus Performance of Balloon Angioplasty in Patients Without Documented Ischemia) study (485). The FAME (Fractional Flow Reserve Versus Angiography for Multivessel Evaluation) study identified the benefit for deferring PCI in patients with multivessel disease and lesion FFR >0.80, with reduced rates of cardiac events at both 1 and 2 years (97, 486). Whereas both FFR and IVUS have been used for assessment of intermediate angiographic stenosis with favorable outcomes, FFR may reduce the need for revascularization when compared with IVUS (488). Although IVUS is often considered in the assessment ofequivocal left main stenosis, FFR may be similarly effective (484).

5.4.2. IVUS: Recommendations

CLASS IIa

1. IVUS is reasonable for the assessment of angiographically indeterminant left main CAD (489–491). *(Level of Evidence: B)*
2. IVUS and coronary angiography are reasonable 4 to 6 weeks and 1 year after cardiac transplantation to exclude donor CAD, detect rapidly progressive cardiac allograft vasculopathy, and provide prognostic information (492–494). *(Level of Evidence: B)*
3. IVUS is reasonable to determine the mechanism of stent restenosis (495). *(Level of Evidence: C)*

CLASS IIb

1. IVUS may be reasonable for the assessment of non-left main coronary arteries with angiographically intermediate coronary stenoses (50% to 70% diameter stenosis) (489, 496, 497). *(Level of Evidence: B)*
2. IVUS may be considered for guidance of coronary stent implantation, particularly in cases of left main coronary artery stenting (490, 495, 498). *(Level of Evidence: B)*
3. IVUS may be reasonable to determine the mechanism of stent thrombosis (495). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. IVUS for routine lesion assessment is not recommended when revascularization with PCI or CABG is not being contemplated. *(Level of Evidence: C)*

IVUS provides a unique coronary artery assessment of lesion characteristics, minimal and maximal lumen diameters, cross-sectional area, and plaque area. Diagnostic uses for IVUS include the assessment of angiographic indeterminant coronary artery stenoses, determination of the mechanism of stent restenosis or thrombosis, and postcardiac transplantation surveillance of CAD (488, 490–492, 499). For left main coronary artery stenoses, a minimal lumen diameter of <2.8 mm or a minimal lumen area of <6mm^2 suggests a physiologically significant lesion for which patients may benefit from revascularization. A minimal lumen area >7.5 mm^2 suggests that revascularization may be safely deferred (490). A minimal lumen area between 6 and 7.5 mm^2 requires further physiological assessment, such as measurement of FFR (487, 500). For non-left main stenoses, minimal lumen diameter >2.0 mm and minimal lumen area > 4.0 mm^2 correlate with low event rates (489). However, in smaller-diameter arteries (minimal lumen area <3.0 mm^2), measurement of FFR may more accurately reflect a significant stenosis (488). Studies correlating IVUS measures with ischemia have not specified the size of coronary arteries for which such correlations are valid (488, 489, 497).

IVUS assessment after stent thrombosis may serve to identify stent underexpansion or malapposition (499). IVUS is superior to angiography in the early detection of the diffuse, immune-mediated, cardiac allograft vasculopathy; recommendations about the use of IVUS for this purpose were published in 2010 by the International Society of Heart and Lung Transplantation (492). Whereas IVUS has been an important research tool in interventional cardiology, most clinical studies of IVUS have not been able to demonstrate that its routine use results in a reduction of MACE or restenosis rates (498, 501, 502). IVUS has been inappropriately used in clinical practice to justify implanting stents in mildly diseased segments that may require no intervention (503).

5.4.3. Optical Coherence Tomography. Compared with IVUS, optical coherence tomography has greater resolution (10 to 20 micronmeter axially) but more limited depth of imaging (1 to 1.5 mm) (504, 505). Unlike IVUS, optical coherence tomography requires that the artery be perfused with saline solution or crystalloid during image acquisition and therefore does not permit imaging of ostial lesions. Clinical studies have shown low optical coherence tomography complication rates (506, 507), similar to those of IVUS (508). The excellent resolution of optical coherence tomography permits detailed in vivo 2-dimensional imaging of plaque morphological characteristics (e.g., calcification, lipid, thrombus, fibrous cap thickness, and plaque ulceration or rupture) (508–510) and evaluation of the arterial response to stent implantation (e.g., stent strut neointimal thickness and apposition) (511–513) and

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may be of value in clinical research. The appropriate role for optical coherence tomography in routine clinical decision making has not been established.

5.5. Adjunctive Therapeutic Devices

5.5.1. Coronary Atherectomy: Recommendations

CLASS IIa

1. Rotational atherectomy is reasonable for fibrotic or heavily calcified lesions that might not be crossed by a balloon catheter or adequately dilated before stent implantation (514, 515). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. Rotational atherectomy should not be performed routinely for de novo lesions or in-stent restenosis (516–519). *(Level of Evidence: A)*

Rotational atherectomy in RCTs was associated with higher rates of MACE at 30 days and no reduction in restenosis. It has a limited role in facilitating the dilation or stenting of lesions that cannot be crossed or expanded with PCI (520, 521). Devices for directional coronary atherectomy are no longer marketed in the United States.

5.5.2. Thrombectomy: Recommendation

CLASS IIa

1. Aspiration thrombectomy is reasonable for patients undergoing primary PCI (522–524). *(Level of Evidence: B)*

The benefit of thrombectomy in patients with STEMI appears to be dependent on the type of thrombectomy technique used (522–526). No clinical benefit for routine rheolytic thrombectomy (AngioJet device, MEDRAD Interventional, Minneapolis, MN and Pittsburgh, PA) has been demonstrated in primary PCI (524–526). Two RCTs (522, 523) and a meta-analysis (524) support the use of manual aspiration thrombectomy during primary PCI to improve microvascular reperfusion and decrease MACE. It is not known whether a strategy of selective thrombus aspiration in patients with a large thrombus burden might be equivalent to routine thrombus aspiration.

5.5.3. Laser Angioplasty: Recommendations

CLASS IIb

1. Laser angioplasty might be considered for fibrotic or moderately calcified lesions that cannot be crossed or dilated with conventional balloon angioplasty (527). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. Laser angioplasty should not be used routinely during PCI (516, 518, 528). *(Level of Evidence: A)*

RCTs of laser angioplasty have not demonstrated improved clinical or angiographic PCI outcomes, although some practitioners think that laser angioplasty may be of use in the treatment of lesions that are difficult to dilate with balloon angioplasty (527).

5.5.4. Cutting Balloon Angioplasty: Recommendations

CLASS IIb

1. Cutting balloon angioplasty might be considered to avoid slippage-induced coronary artery trauma during PCI for in-stent restenosis or ostial lesions in side branches (529). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. Cutting balloon angioplasty should not be performed routinely during PCI (516, 529, 530). *(Level of Evidence: A)*

Although some small, single-center trials have suggested that cutting balloon angioplasty was more efficacious than balloon angioplasty, it was not found to be safer or more effective in several large trials (516, 529, 531). When balloon dilation is required for in-stent restenosis, however, cutting balloons are less likely to slip and may offer a technical advantage over conventional balloons (529). Scoring balloons have been used by some cardiologists as an alternative to cutting balloons, but no RCTs have been reported (531).

5.5.5. Embolic Protection Devices: Recommendation

CLASS I

1. Embolic protection devices (EPDs) should be used during saphenous vein graft (SVG) PCI when technically feasible (532–535). *(Level of Evidence: B)*

The incidence of MACE doubles in SVG PCI compared with native-artery PCI (536). A distal balloon occlusion EPD decreased the 30-day composite outcome of death, MI, emergency CABG, or target-lesion revascularization (9.6% versus 16.5%) in the only RCT (532). Subsequent noninferiority comparisons have demonstrated similar benefit with proximal occlusion and distal filter EPDs, with benefit limited to reduction in periprocedural MI (534, 535) (Section 5.10). Distal EPDs do not improve survival or reinfarction rates in patients undergoing native-artery PCI (524, 537).

5.6. Percutaneous Hemodynamic Support Devices: Recommendation

CLASS IIb

1. Elective insertion of an appropriate hemodynamic support device as an adjunct to PCI may be

reasonable in carefully selected high-risk patients. *(Level of Evidence: C)*

IABP counterpulsation is frequently used as an adjunct to PCI in hemodynamically unstable patients (538, 539). In single-center series, the routine prophylactic use of IABP during PCI in high-risk patients was associated with lower mortality and fewer major complications compared with rescue use of IABP (540, 541). In the only RCT in high-risk PCI patients (BCIS-1 [Balloon Pump-Assisted Coronary Intervention Study]) (542), there was no difference in the primary composite outcome between routine and provisional use of IABP. There were also no differences in major secondary endpoints except major procedural complications (e.g., prolonged hypotension, ventricular tachycardia/ fibrillation, cardiopulmonary arrest), which were lower in the routine IABP group. Bleeding and access site complication rates tended to be higher in the routine IABP group. The "bailout" rate of IABP insertion in the provisional IABP group was 12%, mostly for procedural hypotension (542). A meta-analysis of IABP therapy in patients with STEMI did not show improved outcomes with the use of IABP (434).

The Impella Recover LP 2.5 System (Abiomed, Aachen, Germany/Danvers, Massachusetts) is a 12.5 Fr catheter that is inserted percutaneously through a 13 Fr femoral artery sheath and placed across the aortic valve into the left ventricle, through which a transaxial blood pump provides flows of up to 2.5 L/min. This has been used in patients with cardiogenic shock (543, 544) as well as elective PCI (545). The hemodynamic effects of the Impella 2.5 have been studied in high-risk PCI patients, demonstrating beneficial LV unloading effect (decreased end-diastolic pressure and wall stress) with no change in global or systolic LV function (546). The PROTECT I (A Prospective Feasibility Trial Investigating the Use of the IMPELLA Recover LP 2.5 System in Patients Undergoing High-Risk PCI) trial in 20 patients undergoing high-risk PCI with the Impella 2.5 system concluded that this device was safe, easy to implant, and hemodynamically effective (547). The Europella Registry included 144 patients undergoing high-risk PCI and reported the safety, feasibility, and potential usefulness of the device and that RCTs were warranted (548). The randomized PROTECT II (A Prospective, Multicenter, Randomized Controlled Trial of the IMPELLA Recover LP 2.5 System Versus Intra Aortic Balloon Pump in Patients Undergoing Non Emergent High Risk PCI) trial, which was designed to demonstrate superiority ofImpella over IABP in terms of 1-month adverse events, was halted for futility after interim analysis of study results (549).

The TandemHeart (CardiacAssist, Inc, Pittsburgh, PA) is a left atrial to aorta catheter-based system that includes a centrifugal blood pump providing flows of up to 4 L/min. This device uses a 21 Fr cannula percutaneously inserted into the femoral vein for transseptal access of the left atrium with a 15 Fr catheter placed in the contralateral femoral artery and positioned above the aortic bifurcation. An extracorporeal pump then returns oxygenated blood from the left atrium to the arterial system, thereby unloading the left ventricle (550, 551). The hemodynamic effects have been studied in patients undergoing high-risk PCI (552). Several small studies have addressed the clinical efficacy of the TandemHeart in high-risk patients undergoing PCI (551, 553–556). In a single-center report of 68 patients undergoing high-risk PCI using either TandemHeart or Impella Recover 2.5, success rates (>90%) and vascular complications (7%) were similar (553).

High-risk patients may include those undergoing unprotected left main or last-remaining-conduit PCI, those with severely depressed EF undergoing PCI of a vessel supplying a large territory, and/or those with cardiogenic shock. Patient risk, hemodynamic support, ease of application/ removal, and operator and laboratory expertise are all factors involved in consideration of use of these devices. With devices that require large cannula insertion, the risk of vascular injury and related complications are important considerations regarding necessity and choice of device.

5.7. Interventional Pharmacotherapy

5.7.1. Procedural Sedation. The term *conscious sedation* is falling out of favor with the recognition that there is a spectrum of procedural sedation levels. Most patients undergoing PCI fall under the definition of either minimal sedation (anxiolysis) or moderate sedation (depressed consciousness with the ability to respond purposefully to verbal commands) (557). Nonetheless, an underlying principle of procedural sedation is that the physician should be prepared to manage one level of sedation deeper than the level intended. Thus, cardiologists should be cognizant of the principles of managing deep sedation (depressed consciousness without easy arousal that may require assistance in maintaining airway patency or spontaneous ventilation).

A full review of procedural sedation is beyond the scope of this document, but practice guidelines for sedation and analgesia by nonanesthesiologists, along with The Joint Commission standards, provides a reasonable framework. These guidelines outline several general principles (558, 559). Before the procedure the patient should be assessed for predictors of difficult

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intubation or a history of prior difficult intubation. The patient should be monitored by someone dedicated to observing the level and effects of sedation. Level of consciousness, respiratory rate, blood pressure, cardiac rhythm, and oxygen saturation by pulse oximetry should be monitored. Available equipment should include a high-flow oxygen source, suction, airway management equipment, a defibrillator, resuscitation drugs, and reversal agents appropriate for the drugs being used. A free-flowing IV line should be established. Supplemental oxygen is usually administered, even in the absence of preexisting hypoxia, to provide a margin of safety.

Agents used for sedation are best given in incremental doses, allowing adequate time for the development and assessment of peak effect. The most commonly used agents are listed in Appendix 4F.

5.7.2. Oral Antiplatelet Therapy: Recommendations

CLASS I

1. Patients already taking daily aspirin therapy should take 81 mg to 325 mg before PCI (301–304). *(Level of Evidence: B)*
2. Patients not on aspirin therapy should be given non-enteric aspirin 325 mg before PCI (301, 303, 304). *(Level of Evidence: B)*
3. After PCI, use of aspirin should be continued indefinitely (560–563). *(Level of Evidence: A)*
4. A loading dose of a $P2Y_{12}$ receptor inhibitor should be given to patients undergoing PCI with stenting (564–568) *(Level of Evidence: A)*. Options include
   a. Clopidogrel 600 mg (ACS and non-ACS patients) (564–566) *(Level of Evidence: B)*
   b. Prasugrel 60 mg (ACS patients) (567) *(Level of Evidence: B)*
   c. Ticagrelor 180 mg (ACS patients) (568) *(Level of Evidence: B)*
5. The loading dose of clopidogrel for patients undergoing PCI after fibrinolytic therapy should be 300 mg within 24 hours and 600 mg more than 24 hours after receiving fibrinolytic therapy (565, 569). *(Level of Evidence: C)*
6. Patients should be counseled on the need for and risks of DAPT before placement of intracoronary stents, especially DES, and alternative therapies should be pursued if patients are unwilling or unable to comply with the recommended duration of DAPT (208). *(Level of Evidence: C)*
7. The duration of $P2Y_{12}$ inhibitor therapy after stent implantation should generally be as follows:
   a. In patients receiving a stent (BMS or DES) during PCI for ACS, $P2Y_{12}$ inhibitor therapy should be given for at least 12 months. Options include clopidogrel 75 mg daily (570), prasugrel 10 mg daily (567), and ticagrelor 90 mg twice daily (568). *(Level of Evidence: B)*
   b. In patients receiving DES for a non-ACS indication, clopidogrel 75 mg daily should be given for at least 12 months if patients are not at high risk of bleeding (208, 212, 571). *(Level of Evidence: B)*
   c. In patients receiving BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 month and ideally up to 12 months (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks) (208, 572). *(Level of Evidence: B)*

CLASS IIa

1. After PCI, it is reasonable to use aspirin 81 mg per day in preference to higher maintenance doses (302, 573–576). *(Level of Evidence: B)*
2. If the risk of morbidity from bleeding outweighs the anticipated benefit afforded by a recommended duration of $P2Y_{12}$ inhibitor therapy after stent implantation, earlier discontinuation (e.g., <12 months) of $P2Y_{12}$ inhibitor therapy is reasonable. *(Level of Evidence: C)*

CLASS IIb

1. Continuation of DAPT beyond 12 months may be considered in patients undergoing DES implantation (567, 568). *(Level of Evidence: C)*

CLASS III: HARM

1. Prasugrel should not be administered to patients with a prior history of stroke or transient ischemic attack (567). *(Level of Evidence: B)*

Aspirin reduces the frequency of ischemic complications after PCI. Although the minimum effective aspirin dosage in the setting of PCI has not been established, aspirin 325 mg given at least 2 hours, and preferably 24 hours, before PCI is recommended (302, 303), after which aspirin 81 mg daily should be continued indefinitely.

Several investigations have explored various loading doses of clopidogrel before or during PCI. Compared with a 300-mg loading dose, doses of either 600 mg or 900 mg achieve greater degrees of platelet inhibition with fewer low responders (577). A meta-analysis of 7 studies that included 25,383 patients undergoing PCI demonstrated that intensified loading of clopidogrel with 600 mg reduces the rate of MACE without an increase in major bleeding compared with 300 mg (578). Another study suggested that a 600-mg loading dose of clopidogrel is associated with improvements in procedural angiographic endpoints and 1-year clinical outcomes in patients with STEMI who undergo

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primary PCI compared with a 300-mg dose (579). There is no benefit with increasing the loading dose to 900 mg compared with 600 mg (577). Clopidogrel 75 mg daily should be given for a minimum of 4 weeks after balloon angioplasty or BMS implantation (a minimum of 2 weeks if increased bleeding risk is present) (580) and for at least 12 months after DES implantation (unless the risk of bleeding outweighs the anticipated benefit). Patients should be counseled on the need for and risks of DAPT before stent implantation, especially DES implantation, and alternative therapies pursued (BMS or balloon angioplasty) if they are unwilling or unable to comply with the recommended duration of DAPT.

The efficacy of clopidogrel pretreatment remains controversial. Although some studies have suggested that pretreatment with clopidogrel is associated with decreased platelet aggregation and a significantly lower incidence of periprocedural MI after elective PCI, others have suggested no benefit to pretreatment compared with administration of the drug in the catheterization laboratory (572, 581, 582).

When prasugrel was compared with clopidogrel in patients with ACS in TRITON-TIMI 38 (Trial to Assess Improvement in Therapeutic Outcomes by Optimizing Platelet Inhibition with Prasugrel-Thrombolysis In Myocardial Infarction), prasugrel was associated with a significant 2.2% reduction in absolute risk and a 19% reduction in relative risk in the composite endpoint of cardiovascular death, nonfatal MI, or nonfatal stroke, and a significant increase in the rate of TIMI major hemorrhage (1.8% versus 2.4%) (567). Prasugrel is contraindicated in patients with a history of transient ischemic attack or stroke. Patients weighing <60 kg have an increased risk of bleeding on the 10 mg daily maintenance dose. The package insert suggests that consideration should be given to lowering the maintenance dose to 5 mg daily, although the effectiveness and safety of the 5-mg dose has not been studied. Prasugrel is not recommended for patients >75 years of age because of the increased risk of fatal and intracranial bleeding and lack of benefit, except in patients with diabetes or a history of prior MI. Prasugrel should not be started in patients likely to undergo urgent CABG. Prasugrel has not been studied in elective PCI, and thus no recommendation can be made regarding its use in this clinical setting.

Ticagrelor reversibly binds the $P2Y_{12}$ receptor. Unlike clopidogrel or prasugrel, ticagrelor is not a thienopyridine. It also does not require metabolic conversion to an active metabolite. Compared with clopidogrel in patients with ACS in the PLATO (Platelet Inhibition and Patient Outcomes) trial, ticagrelor was associated with a significant 1.9% reduction in absolute risk and a 16% reduction in relative risk in the primary composite endpoint of vascular death, nonfatal MI, or nonfatal stroke (568). Importantly, a significant reduction in vascular mortality and all-cause mortality was observed. Although CABG-related bleeding was not significantly increased with ticagrelor compared with clopidogrel, a significantly greater incidence of major bleeding was observed in patients not undergoing CABG. Ticagrelor was associated with higher rates of transient dyspnea and bradycardia compared with clopidogrel, although only a very small percentage of patients discontinued the study drug because of dyspnea. Based on post hoc analysis of the PLATO study, specifically the results in the U.S. patient cohort, a black box warning states that maintenance doses of aspirin above 100 mg reduce the effectiveness of ticagrelor and should be avoided. After any initial dose, ticagrelor should be used with aspirin 75 mg to 100 mg per day (583). Given the twice-daily dosing and reversible nature of the drug, patient compliance may be a particularly important issue to consider and emphasize. Ticagrelor has not been studied in elective PCI or in patients who received fibrinolytic therapy; thus, no recommendations about its use in these clinical settings can be made.

5.7.3. IV Antiplatelet Therapy: Recommendations STEMI

CLASS IIa

1. In patients undergoing primary PCI treated with UFH, it is reasonable to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban), whether or not patients were pretreated with clopidogrel (584–590). *(For GP IIb/IIIa inhibitor administration in patients not pretreated with clopidogrel, Level of Evidence: A; for GP IIb/IIIa inhibitor administration in patients pretreated with clopidogrel, Level of Evidence: C)*

CLASS IIb

1. In patients undergoing primary PCI with abciximab, it may be reasonable to administer intracoronary abciximab (589, 591–604). *(Level of Evidence: B)*

CLASS III: NO BENEFIT

1. Routine precatheterization laboratory (e.g., ambulance or emergency department) administration of GP IIb/IIIa inhibitors as part of an upstream strategy for patients with STEMI undergoing PCI is not beneficial (605–612). *(Level of Evidence: B)*

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UA/NSTEMI

CLASS I

1. In UA/NSTEMI patients with high-risk features (e.g., elevated tro-ponin level) not treated with bivalirudin and not adequately pre-treated with clopidogrel, it is useful at the time of PCI to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban) in patients treated with UFH (613–618). *(Level of Evidence: A)*

CLASS IIa

1. In UA/NSTEMI patients with high-risk features (e.g., elevated troponin level) treated with UFH and adequately pretreated with clopidogrel, it is reasonable at the time of PCI to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban) (616, 619). *(Level of Evidence: B)*

SIHD

CLASS IIa

1. In patients undergoing elective PCI treated with UFH and not pretreated with clopidogrel, it is reasonable to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban) (619–621). *(Level of Evidence: B)*

CLASS IIb

1. In patients undergoing elective PCI with stent implantation treated with UFH and adequately pretreated with clopidogrel, it might be reasonable to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban) (619, 622–624). *(Level of Evidence: B)*

See Online Data Supplement 24 for additional data regarding IV antiplatelet therapy.

In the era before DAPT, trials of adequately dosed GP IIb/IIIa inhibitors in patients undergoing balloon angioplasty and coronary stent implantation demonstrated a reduction in the incidence of composite ischemic events with GP IIb/IIIa treatment, primarily through a reduction of enzymatically defined MI (613, 615, 618, 620, 621). Earlier RCTs of GP IIb/IIIa inhibitors were generally conducted in patients treated with UFH. In some trials, use of GP IIb/IIIa inhibitors are associated with some increased bleeding risk, and trials of these agents have generally excluded patients at high risk of bleeding (e.g., coagulopathy) (584, 587–589, 613–618, 620–626). Thus, recommendations about use of GP IIb/IIIa inhibitors are best construed as applying to those patients not at high risk of bleeding complications. Abciximab, double-bolus eptifibatide (180 mcg/kg bolus followed 10 minutes later by a second 180 mcg/kg bolus), and high-bolus dose tirofiban (25 mcg/kg) all result in a high degree of platelet inhibition (627–629), have been demonstrated to reduce ischemic complications in patients undergoing PCI (608, 609, 613, 615, 618–621), and appear to lead to comparable angiographic and clinical outcomes (630, 631).

Trials of GP IIb/IIIa inhibitors in the setting of STEMI and primary PCI were conducted in the era before routine stenting and DAPT. The results of these and more recent trials, as well as several meta-analyses, have yielded mixed results (584–590). Therefore, it is reasonable to administer GP IIb/IIIa inhibitors in patients with STEMI undergoing PCI, although these agents cannot be definitively recommended as routine therapy. These agents might provide more benefit in selective use, such as in patients with large anterior MI and/or large thrombus burden. Trials of precatheterization laboratory (e.g., ambulance or emergency room) administered GP IIb/IIIa inhibitors in patients with STEMI undergoing PCI, with or without fibrinolytic therapy, have generally shown no clinical benefit, and GP IIb/IIIa inhibitor use in this setting may be associated with an increased risk of bleeding (605–610, 612). Studies of intracoronary GP IIb/IIIa inhibitor administration (predominantly using abciximab) consist of several small RCTs, retrospective analyses, retrospective and prospective registries, cohort analyses, and case reports. Although most of these published studies have reported some benefit of intracoronary administration in terms of acute angiographic parameters, infarct size, left ventricle myocardial salvage, and composite clinical endpoints, several other studies have not detected any benefit with intracoronary administration (589, 591–604).

Trials of GP IIb/IIIa inhibitors in patients with UA/NSTEMI undergoing PCI demonstrated reduced ischemic outcomes, particularly in those with high-risk features such as positive biomarkers. Most trials were conducted in a prior PCI era and without $P2Y_{12}$ inhibitor pretreatment (613, 615, 618, 632, 633), although several trials have also demonstrated benefit in patients with high-risk features pretreated with clopidogrel (616, 619). In most older studies of stable patients undergoing balloon angioplasty or coronary stenting, treatment with GP IIb/IIIa inhibitors resulted in a reduction of composite ischemic events, primarily enzymatically defined MI (613–618, 620, 621, 634, 635). More contemporary trials of patients pretreated with a thienopyridine have not demonstrated any benefit with GP IIb/IIIa inhibitor therapy in patients with stable symptoms undergoing elective PCI (619, 622–624).

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TABLE 12. Dosing of Parenteral Anticoagulants During PCI

Drug	Patient Has Received Prior Anticoagulant Therapy	Patient Has Not Received Prior Anticoagulant Therapy
UFH	• IV GPI planned: additional UFH as needed (e.g., 2,000 to 5,000 U) to achieve an ACT of 200 to 250 s • No IV GPI planned: additional UFH as needed (e.g., 2,000 to 5,000 U) to achieve an ACT of 250 to 300 s for HemoTec, 300 to 350 s for Hemochron	• IV GPI planned: 50 to 70 U/kg bolus to achieve an ACT of 200 to 250 s • No IV GPI planned: 70 to 100 U/kg bolus to achieve target ACT of 250 to 300 s for HemoTec, 300 to 350 s for Hemochron
Enoxaparin	• For prior treatment with enoxaparin, if the last SC dose was administered 8 to 12 h earlier or if only 1 SC dose of enoxaparin has been administered, an IV dose of 0.3 mg/kg of enoxaparin should be given. • If the last SC dose was administered within the prior 8 h, no additional enoxaparin should be given.	0.5 to 0.75 mg/kg IV bolus
Bivalirudin	For patients who have received UFH, wait 30 min, then give 0.75 mg/kg IV bolus, then 1.75 mg/kg per h IV infusion.	0.75 mg/kg bolus, 1.75 mg/kg per h IV infusion
Fondaparinux	For prior treatment with fondaparinux, administer additional IV treatment with an anticoagulant possessing anti-IIa activity, taking into account whether GPI receptor antagonists have been administered.	N/A
Argatroban	200 mcg/kg IV bolus, then 15 mcg/kg per min IV infusion	350 mcg/kg bolus, then 15 mcg/kg per min IV infusion

ACT indicates activated clotting time; IV, intravenous; GPI, glycoprotein inhibitor; N/A, not applicable; PCI, percutaneous coronary intervention; SC, subcutaneous; and UFH, unfractionated heparin.

5.7.4. Anticoagulant Therapy

5.7.4.1. USE OF PARENTERAL ANTICOAGULANTS DURING PCI: RECOMMENDATION

CLASS I

1. An anticoagulant should be administered to patients undergoing PCI. *(Level of Evidence: C)*

Anticoagulant therapy prevents thrombus formation at the site of arterial injury, on the coronary guidewire, and in the catheters used for PCI (8). With rare exceptions (636), all PCI studies have used some form of anticoagulant. It is the consensus of the writing committee that PCI be performed with the use of some form of anticoagulant therapy. Suggested dosing regimens of parenteral agents used in PCI are given in Table 12. Recommendations for antiplatelet and antithrombin pharmacotherapy in PCI are given in Table 13.

5.7.4.2. UFH: RECOMMENDATION

CLASS I

1. Administration of IV UFH is useful in patients undergoing PCI. *(Level of Evidence: C)*

As the only anticoagulant available for PCI for many years, UFH became the standard of care by default (8). The dose of UFH for PCI has been based on empiricism and experience from RCTs. Suggested UFH dosing regimens are given in Table 12. When UFH is used during PCI, most cardiologists assess the degree of anticoagulation by measuring the activated clotting time. Although measurements are useful to show that an anti-IIa anticoagulant has been given, the value of the activated clotting time in current practice has been questioned. Although studies in the balloon angioplasty era did demonstrate a relationship between activated clotting time levels and ischemic complications (653–655), more recent analyses from the coronary stent era have not found a clear relationship between activated clotting time and outcomes (349, 656, 657). There may, however, be a modest relation between bleeding and activated clotting time levels (349, 657). In addition, not only are there differences between activated clotting time levels measured by Hemochron and HemoTec devices, but both devices have less than optimal precision (658). Thus, although traditional target activated clotting time levels are included in this document, the utility of measured activated clotting time levels in current practice should be considered uncertain.

Most cardiologists remove femoral sheaths when the activated clotting time falls to <150 to 180 seconds or when the activated partial thromboplastin time falls to <50 seconds. Full-dose anticoagulation is no longer used after successful PCI procedures. Almost all large clinical trials have enrolled patients who underwent transfemoral PCI, but recent small studies assessing the transradial approach have used similar doses of UFH (659) and similar activated clotting time target levels (660).

5.7.4.3. ENOXAPARIN: RECOMMENDATIONS

CLASS I

1. An additional dose of 0.3 mg/kg IV enoxaparin should be administered at the time of PCI to patients who have received fewer than 2 therapeutic

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TABLE 13. Recommendations for Antiplatelet and Antithrombin Pharmacotherapy at the Time of PCI

	COR	LOE	References	Relevant Caveats/Comments
Oral antiplatelet agents				
Aspirin	I	B	(301–304, 560–563)	N/A
$P2Y_{12}$ inhibitors	I	A	(564–568)	• A loading dose of a $P2Y_{12}$ inhibitor should be given to patients undergoing PCI with stenting.
• Clopidogrel	I	B	(564–566)	• 600-mg loading dose now recommended.
• Prasugrel	I	B	(567)	• Contraindicated in patients with prior TIA/CVA: ***Class III: Harm; LOE: B.*** • Generally not recommended in patients >75 y of age (Section 5.7.2). • Consideration of using a lower maintenance dose in patients weighing <60 kg suggested by FDA (Section 5.7.2).
• Ticagrelor	I	B	(568)	• Issues of patient compliance may be especially important.
GP IIb/IIIa inhibitors (abciximab, double-bolus eptifibatide, high-bolus dose tirofiban)				
• No clopidogrel pretreatment	STEMI: IIa	A	(584–590)	• UA/NSTEMI recommendation applies to those with high-risk features. • GPI use in STEMI may be most appropriate in those with large anterior MI and/or large thrombus burden. • IC abciximab administration in STEMI: ***Class IIb; LOE: B.*** • Precatheterization laboratory GPI administration in STEMI: ***Class III: No Benefit; LOE: B.*** • Recommendations apply to those not at high risk for bleeding complications.
	UA/NSTEMI: I	A	(613–618)	
	SIHD: IIa	B	(619–621)	
• Clopidogrel pretreatment	STEMI: IIa	C	(584–590)	
	UA/NSTEMI: IIa	B	(616, 619)	
	SIHD: IIb	B	(619, 622–624)	
Antithrombin agents				
UFH	I	C	N/A	• Dosing based on whether or not GPI was administered.
Bivalirudin	I	B	(625, 637–645)	• Lower bleeding rates associated with bivalirudin are mitigated when used concomitantly with a GPI.
Enoxaparin	IIb	B	(646–650)	• Recommendations apply to administration of IV enoxaparin at the time of PCI for those who have not received prior antithrombin therapy or who have received "upstream" SC enoxaparin therapy for UA/NSTEMI. • An additional dose of 0.3 mg/kg IV enoxaparin should be administered at the time of PCI to patients who have received <2 therapeutic SC doses (e.g., 1 mg/kg) or received the last SC enoxaparin dose 8 to 12 h before PCI: ***Class I; LOE: B.*** • Patients treated with SC enoxaparin within 12 h of PCI should not receive additional treatment with UFH during PCI ("stacking"): ***Class III: Harm; LOE: B.***
Anti-Xa inhibitors				
Fondaparinux	III: Harm	C	(651, 652)	• PCI should not be performed with fondaparinux as the sole antithrombin agent in patients treated with upstream fondaparinux. An additional anticoagulant with anti-IIa activity should be administered.

ACT indicates activated clotting time; COR, class of recommendation; CVA, cerebrovascular accident; FDA, U.S. Food and Drug Administration; GP, glycoprotein; GPI, glycoprotein IIb/IIIa inhibitor; IC, intracoronary; IV, intravenous; LOE, level of evidence; MI, myocardial infarction; N/A, not applicable; PCI, percutaneous coronary intervention; SC, subcutaneous; SIHD, stable ischemic heart disease; STEMI, ST-elevation myocardial infarction; TIA, transient ischemic attack; UA/NSTEMI, unstable angina/non-ST-elevation myocardial infarction; and UFH, unfractionated heparin.

subcutaneous doses (e.g., 1 mg/kg) or received the last subcutaneous enoxaparin dose 8 to 12 hours before PCI (649, 661–664). *(Level of Evidence: B)*

CLASS IIb

1. Performance of PCI with enoxaparin may be reasonable in patients either treated with "upstream" subcutaneous enoxaparin for UA/ NSTEMI or who have not received prior antithrombin therapy and are administered IV enoxaparin at the time of PCI (646–650). *(Level of Evidence: B)*

CLASS III: HARM

1. UFH should not be given to patients already receiving therapeutic subcutaneous enoxaparin (649, 665). *(Level of Evidence: B)*

Trials of enoxaparin relevant to PCI include both studies in which patients with UA/NSTEMI were started on upstream subcutaneous enoxaparin therapy that was continued up to the time of PCI and trials in which patients who had received no prior antithrombin therapy were treated with IV enoxaparin at the time of PCI (646–650, 661–663, 666). In the SYNERGY

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(Superior Yield of the New strategy of Enoxaparin, Revascularization and Glycoprotein IIb/IIIa Inhibitors) trial, there was an increased incidence of bleeding in those treated with upstream enoxaparin, later attributed at least in part to the fact that some patients being treated with enoxaparin were also administered UFH at the time of PCI (so-called "stacking") (649, 665). Almost all patients undergoing elective PCI who are administered enoxaparin (0.5 mg/kg IV) will have a peak anti-Xa level > 0.5 IU/mL (647). Most clinical studies have used a regimen of 0.5 to 0.75 mg IV (667). Several studies have used this regimen in elective patients and those with STEMI (646). Patients who have received multiple doses of subcutaneously administered enoxaparin who undergo PCI within 8 hours of the last subcutaneous dose generally have adequate degrees ofanticoagulation to undergo PCI, but the degree of anticoagulation may diminish in the 8- to 12-hour period after the last subcutaneous dose. In such patients, as well as in patients who have received only 1 subcutaneous dose of enoxaparin, the addition of enoxaparin (0.3 mg/kg IV) at the time of PCI provides an additional degree of anticoagulation and has become standard practice (648, 661–664). Patients who undergo PCI >12 hours after the last subcutaneous dose are usually treated with full-dose de novo anticoagulation using an established regimen (e.g., full-dose UFH or bivalirudin).

5.7.4.4. BIVALIRUDIN AND ARGATROBAN: RECOMMENDATIONS

CLASS I

1. For patients undergoing PCI, bivalirudin is useful as an anticoagulant with or without prior treatment with UFH (625, 637–645). *(Level of Evidence: B)*
2. For patients with heparin-induced thrombocytopenia, it is recommended that bivalirudin or argatroban be used to replace UFH (668, 669). *(Level of Evidence: B)*

Bivalirudin is being increasingly used in clinical practice (670) as evidence emerges from clinical trials across the spectrum of CAD (638–644). In individual trials and meta-analyses, the use of bivalirudin has been associated with reduced bleeding compared with UFH plus a GP IIb/IIIa inhibitor, although concerns about ischemic events have emerged in individual studies (625, 637–645). Longer-term follow-up of the major bivalirudin trials, however, suggests that small or nominal increases in ischemic events have not translated into long-term consequences and that treatment at or before the time of PCI with clopidogrel may mitigate any increased early ischemic risk (637–645). Thus, a treatment strategy of bivalirudin compared with heparin (or enoxaparin) plus GP IIb/IIIa inhibitor appears to lower the risk of bleeding complications. The lower bleeding rates associated with bivalirudin (compared with UFH plus a GP IIb/IIIa inhibitor) are mitigated when used concomitantly with a GP IIb/IIIa inhibitor (639). A strategy of use of provisional GP IIb/IIIa inhibitor in patients treated with bivalirudin is widely accepted (639, 643, 644).

In patients with heparin-induced thrombocytopenia (671, 672), a direct-thrombin inhibitor (argatroban) has been approved as an alternative parenteral anticoagulant to be used during PCI (668). The use of bivalirudin for heparin-induced thrombocytopenia has been reported as well (669).

5.7.4.5. FONDAPARINUX: RECOMMENDATION

CLASS III: HARM

1. Fondaparinux should not be used as the sole anticoagulant to support PCI. An additional anticoagulant with anti-IIa activity should be administered because of the risk of catheter thrombosis (651, 652). *(Level of Evidence: C)*

Fondaparinux, a pentasaccharide, is an indirect factor Xa inhibitor but has no effect on thrombin. On the basis of reports of catheter thrombosis when fondaparinux is used alone during primary PCI (651, 652), the writing committee recommends that an anticoagulant with anti-IIa activity be used in patients undergoing PCI (651, 652). One study suggested that clinical outcomes were better when fondaparinux was replaced during PCI by a standard dose of UFH (85 U/kg, 60 U/kg with GP IIb/IIIa inhibitors) rather than by a low dose (50 U/kg) (673).

5.7.5. No-Reflow Pharmacological Therapies: Recommendation

CLASS IIa

1. Administration of an intracoronary vasodilator (adenosine, calcium channel blocker, or nitroprusside) is reasonable to treat PCI-related no-reflow that occurs during primary or elective PCI (674–689). *(Level of Evidence: B)*

See Online Data Supplement 25 for additional data regarding no-reflow therapies.

No-reflow is a broad term used to describe 2 distinct entities. The first is "interventional no-reflow" attributed to vasospasm and downstream embolization of debris dislodged during PCI, usually in the setting of atherectomy, thrombus, or degenerated SVGs. The second entity is suboptimal reperfusion of an infarct artery, attributed to endothelial injury in addition to embolization and vasospasm. Angiographic no-reflow is the most obvious sequela of the same

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pathophysiology that produces abnormal TIMI frame counts and TIMI blush scores, so these measures are often used interchangeably. The principal clinical sequela of no-reflow is myonecrosis. Efforts to prevent no-reflow overlap with strategies to reduce MI size and prevent periprocedural MI.

In the setting of MI, several drugs have been shown to reduce the incidence of no-reflow. Evidence for a beneficial effect on no-reflow exists for abciximab, adenosine, nicorandil, and nitroprusside (674, 675, 680, 682, 683, 685, 687, 688, 690). However, their adoption into clinical practice has depended on their effect on hard clinical endpoints such as infarct size and mortality. These benefits, and consequentially the use of these agents, have been limited.

For interventional no-reflow, several therapies have proven effective after no-reflow has started. These include adenosine, calcium channel blockers, and nitroprusside (676, 678, 679, 681, 684, 686, 689, 691). There are fewer data to support the use of epinephrine (692). No-reflow after rotational atherectomy was less common with nicorandil compared with verapamil infusions in 3 studies (693–695), and an infusion of nicorandil/adenosine during rotational atherectomy prevented no-reflow in 98% of patients (677). Trials of pre-PCI intracoronary verapamil, nicardipine, and adenosine have reported them to be safe but have not demonstrated reductions in post-PCI no-reflow (696–698). Mechanical devices to prevent interventional and myocardial infarct reperfusion no-reflow are also covered in Section 5.5.5.

5.8. PCI in Specific Anatomic Situations

5.8.1. CTOs: Recommendation

CLASS IIa

1. PCI of a CTO in patients with appropriate clinical indications and suitable anatomy is reasonable when performed by operators with appropriate expertise (699–703). *(Level of Evidence: B)*

See Online Data Supplements 26 to 28 for additional data regarding CTOs.

Approximately one third of patients with suspected CAD who undergo coronary angiography have $\geq$ 1 CTO (defined as occlusion of a duration >3 months) (704). Although stress-induced ischemia can be elicited in the majority of patients with CTO despite the presence of collaterals (706, 707), only 8% to 15% of these patients undergo PCI (708, 709). The disparity between the frequency of CTOs and percutaneous treatment underscores not only the technical and procedural complexities of this lesion subtype but also the clinical uncertainties regarding which patients benefit from CTO revascularization. Studies suggest that patients who undergo successful, rather than failed, recanalization of CTOs fare better in terms of symptom status and need for CABG (699), as well as LV function (710). However, the impact of successful CTO recanalization on long-term survival remains unsettled (701, 711, 712). The decision to try PCI for a CTO (versus continued medical therapy or surgical revascularization) requires an individualized risk-benefit analysis encompassing clinical, angiographic, and technical considerations. Consultation with a cardiothoracic surgeon and use of the Heart Team approach in cases of CTO in which a large territory is subtended and/or multivessel CAD is present are frequently done.

From a technical perspective, successful recanalization of CTOs has steadily increased over the years because of adoption of dedicated wires, novel techniques, and increased operator experience (702). In patients who undergo successful CTO recanalization, use of DES significantly reduces the need for repeated target-vessel revascularization, compared with BMS and balloon angioplasty, without compromising safety (703, 713–719).

5.8.2. SVGs: Recommendations

CLASS I

1. EPDs should be used during SVG PCI when technically feasible (532–535). *(Level of Evidence: B)*

CLASS III: NO BENEFIT

1. Platelet GP IIb/IIIa inhibitors are not beneficial as adjunctive therapy during SVG PCI (212, 571, 720, 721). *(Level of Evidence: B)*

CLASS III: HARM

1. PCI is not recommended for chronic SVG occlusions (722–724). *(Level of Evidence: C)*

See Online Data Supplement 29 for additional data regarding SVG.

Adverse cardiac event rates are doubled after SVG PCI compared with native-artery PCI (536). A distal balloon occlusion EPD decreased the 30-day composite outcome of death, MI, emergency CABG, or target-lesion revascularization (9.6% versus 16.5%) in the only RCT comparing embolic protection with no embolic protection (532). Subsequent noninferiority comparisons have demonstrated similar benefit with proximal occlusion and distal filter EPDs, with benefit limited to reduction in periprocedural MI (534, 535). PCI in chronic SVG occlusion is associated with low success rates, high complication rates, and poor long-term patency rates (722, 723). Restenosis and target-vessel revascularization rates are lower with DES compared with BMS, although mortality and stent thrombosis rates are similar (725). The use of covered stents is

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limited to the treatment of the uncommon complication of SVG perforation. Balloon angioplasty for distal SVG anastomotic stenoses has low restenosis rates (724), so stenting is commonly reserved at this location for suboptimal balloon angioplasty results or restenosis. Routine GP IIb/IIIa inhibitor therapy has not proven beneficial in SVG PCI (720). Fibrinolytic therapy is no longer used for thrombus-containing lesions, but rheolytic or manual aspiration thrombectomy is sometimes employed.

5.8.3. Bifurcation Lesions: Recommendations

CLASS I

1. Provisional side-branch stenting should be the initial approach in patients with bifurcation lesions when the side branch is not large and has only mild or moderate focal disease at the ostium (726–729). *(Level of Evidence: A)*

CLASS IIa

1. It is reasonable to use elective double stenting in patients with complex bifurcation morphology involving a large side branch where the risk of side-branch occlusion is high and the likelihood of successful side-branch reaccess is low (730–733). *(Level of Evidence: B)*

Side-branch occlusion or severe stenosis after stenting the main artery in coronary bifurcation PCI occurs in 8% to 80% of unselected patients (732, 734). The frequency of side-branch occlusion is related to complex bifurcation morphology (severe and/or long side-branch ostial stenosis, large plaque burden in the side-branch ostium, and/or unfavorable side-branch angulation) (732, 735, 736). Side-branch occlusion after PCI is associated with Q-wave and non-Q-wave MI (734, 735). Therefore, preservation of physiologic flow in the side branch after PCI is important (736). There are 2 bifurcation PCI strategies: provisional stenting (stenting the main vessel with additional balloon angioplasty or stenting of the side branch only in the case of an unsatisfactory result) and elective double stenting of the main vessel and the side branch. When there is an unsatisfactory result in the side branch from the provisional stent in the main branch, sometimes balloon angioplasty alone in the side branch will improve the result and stenting the side branch is not necessary. Some experts have suggested that using the side-branch balloon alone will distort the main branch stent and thus this always needs to be a kissing balloon inflation.

In patients with low-risk bifurcation lesions (minimal or moderate ostial side-branch disease [<50% diameter stenosis] of focal length [5 to 6 mm]), provisional stenting yields similar clinical outcome to elective double stenting, with lower incidence of periprocedural biomarker elevation (726–729). Conversely, in patients with high-risk bifurcations, elective double stenting is associated with a trend toward higher angiographic success rates, lower in-hospital MACE, and better long-term patency of the side branch compared with provisional stenting (193). Culotte, Crush, and T-stent techniques have been studied in RCTs (726–729, 737). Use of DES yields better outcomes than BMS (738), and sirolimus-eluting stents yield better outcomes than paclitaxel-eluting stents (739–742). Clinical evidence supports the use of final kissing balloon inflation after elective double stenting (743).

5.8.4. Aorto-Ostial Stenoses: Recommendations

CLASS IIa

1. IVUS is reasonable for the assessment of angiographically indeterminant left main CAD (744, 745). *(Level of Evidence: B)*
2. Use of DES is reasonable when PCI is indicated in patients with an aorto-ostial stenosis (746, 747). *(Level of Evidence: B)*

Aorto-ostial stenoses of native coronary arteries (left main coronary artery and right coronary artery) are most commonly caused by atherosclerosis, but they can also occur in patients with congenital malformations, radiation exposure, vasculitides, and aortic valve replacement. The angiographic diagnosis of aorto-ostial disease is not always straightforward, especially in the ostial left main coronary artery, where eccentricity and angulation can be mistaken for stenosis (490, 748). Aorto-ostial disease can be evaluated with IVUS (744, 745); FFR (with IV adenosine) has also been used (484, 749). The treatment of aorto-ostial stenoses with balloon angioplasty has been associated with lower procedural success rates, more frequent in-hospital complications, and a greater likelihood of late restenosis (750). Although atherectomy devices (directional atherectomy, rotational atherectomy, and excimer laser angioplasty) have improved acute angiographic results over balloon angioplasty, restenosis has remained a limitation (751). In patients with aorto-ostial stenoses undergoing PCI, use of DES has been shown to reduce restenosis compared with BMS (176, 746, 752).

5.8.5. Calcified Lesions: Recommendation

CLASS IIa

1. Rotational atherectomy is reasonable for fibrotic or heavily calcified lesions that might not be crossed by a balloon catheter or adequately dilated before stent implantation (514, 515, 520). *(Level of Evidence: C)*

The presence of coronary calcification is a marker for significant CAD and increased long-term mortality

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(753). Calcified coronary lesions are not a homogenous entity, and their response to PCI varies according to severity of calcification. Severely calcified lesions respond poorly to balloon angioplasty (230, 754), and when stents are implanted in such lesions, an incomplete and asymmetrical stent expansion occurs in the majority of cases (755). Attempts to remedy the underexpanded stents with aggressive high-pressure balloon dilatation may result in coronary artery rupture (756). All the published prospective RCTs that evaluated the various catheter-based coronary interventional devices excluded patients with severely calcified lesions. Therefore, the evidence base for best PCI practices in patients with severely calcified lesions comes from nonrandomized single-arm studies. Among the various adjunct devices that are used to facilitate PCI in severely calcified lesions, only rotational atherectomy has been shown to have potential utility (514, 757). Although rotational atherectomy increases the chances of angiographic success in severely calcified lesions, its use as a stand-alone device has not led to a reduction in restenosis (520, 521, 758). Several retrospective studies have shown that in patients with severely calcified lesions, the use of rotational atherectomy before implantation of BMS (514)or DES(515)is safe. Intermediate-term patency is more favorable with DES than BMS (759).

5.9. PCI in Specific Patient Populations

Several specific patient subsets with higher risks for PCI, and at times higher absolute clinical benefit, have traditionally been underrepresented in RCTs and are described below.

5.9.1. Elderly. The elderly constitute a growing proportion of patients considered for PCI (760). In 1 series examining trends over a 25-year period, the proportion of patients undergoing PCI who were 75 to 84 years of age doubled, and those >85 years of age increased 5-fold (761). Age is one of the strongest predictors of mortality after PCI (762), and elderly patients present with a substantially higher clinical risk profile (760). Nonetheless, the angiographic success rates and clinical benefits of PCI in elderly patients are similar to younger patients (763). In fact, the absolute benefit is typically greater because of higher absolute risk of adverse outcomes in these patients (764). However, increased risks of complications such as major bleeding and stroke mandate careful consideration of the benefits and risks of PCI in elderly patients (373).

5.9.2. Diabetes. Patients with diabetes represent approximately one third of patients undergoing PCI in the United States. Restenosis, which had been a major limitation of PCI, is significantly reduced in patients with diabetes treated with DES compared with BMS (471). However, there are no definitive data from RCTs supporting different clinical outcomes for different types of DES (765), with a recent meta-analysis of 35 RCTs involving 3,852 patients with diabetes unable to find major differences between patients receiving sirolimus-eluting stents or paclitaxel-eluting stents (472). Numerous analyses and clinical studies have evaluated how the presence of diabetes may impact the clinical outcome of patients undergoing PCI and decisions about PCI or CABG (14, 116, 163, 164, 186). These studies and the approach to revascularization decisions in diabetes are addressed in Section 4.

Diabetes is an important risk factor for the development of contrast-induced AKI. Strategies to reduce the risk of contrast-induced AKI in patients with diabetes are discussed in Section 4.4.

5.9.3. Women. Cardiovascular disease is the leading cause of death in women in the United States and Europe (766), and an estimated 35% of PCIs in the United States are performed in women (767, 768). Women undergoing PCI usually have more risk factors (including hypertension, advanced age, elevated cholesterol, and more significant and diffuse CAD) compared with men (769). Women with STEMI are also less likely to receive early medical treatments and experience longer delays to reperfusion therapy (770, 771). In subgroup analyses of clinical trials, use of DES appears to be similarly efficacious in women and men (772).

5.9.4. CKD: Recommendation

CLASS I

1. In patients undergoing PCI, the glomerular filtration rate should be estimated and the dosage of renally cleared medications should be adjusted (298–300). *(Level of Evidence: B)*

CKD is an independent risk factor for the development and progression of CAD (773, 774), and is also associated with worse prognosis after MI or PCI (369, 775). A glomerular filtration rate of <60 mL/min per 1.73 m^2 of body surface area should be considered abnormal. Patients with CKD undergoing PCI have a higher risk ofcomplications, including bleeding (776), AKI, and death (236, 777), but CKD is not a strong predictor of restenosis after BMS or DES (778). Strategies to reduce the risk of contrast-induced AKI in patients with CKD are discussed in Section 4.4. Platelet dysfunction and overdosing of antiplatelet and antithrombin drugs (350) in patients with CKD contribute to the increased risk of bleeding. The Cockcroft-Gault formula is commonly used as a surrogate marker for estimating creatinine clearance, which in turn estimates glomerular filtration rate (298, 299, 779, 780).

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Medications that require dosage adjustments in patients with CKD include eptifibatide, tirofiban, bivalirudin, enoxaparin, and fondaparinux (781).

5.9.5. Cardiac Allografts. Cardiac allograft vasculopathy is a major cause of death in cardiac transplant recipients after their first year of survival (782). In general, revascularization for cardiac allograft vasculopathy with PCI is only palliative, with no evidence supporting benefit in regard to long-term survival or avoidance of retransplantation. The restenosis rate after PCI in patients with cardiac allograft vasculopathy is high, although stent implantation reduces early and midterm reste-nosis compared with balloon angioplasty. DES have been shown to have a tendency to lower restenosis rates compared with BMS (783, 784). Thus, many clinicians perform stenting with DES or BMS in cardiac transplant patients with discrete lesions who have an abnormal stress test or symptoms suggestive of myocardial ischemia.

5.10. Periprocedural MI Assessment: Recommendations

CLASS I

1. In patients who have signs or symptoms suggestive of MI during or after PCI or in asymptomatic patients with significant *persistent* angiographic complications (e.g., large side-branch occlusion, flow-limiting dissection, no-reflow phenomenon, or coronary thrombosis), creatinine kinase-MB and troponin I or T should be measured. *(Level of Evidence: C)*

CLASS IIb

1. Routine measurement of cardiac biomarkers (creatinine kinase-MB and/or troponin I or T) in all patients after PCI may be reasonable. *(Level of Evidence: C)*

Major events leading to ischemia or MI after PCI include acute closure, embolization and no-reflow, side-branch occlusion, and acute stent thrombosis. Issues surrounding the routine assessment of cardiac biomarkers after PCI are complex, especially given that the definition of PCI-related MI has evolved over the years and most events are asymptomatic. The most recent consensus definition of MI considers troponin elevations of 3 times the upper limit of normal as a PCI-related MI in patients with normal baseline levels; this is further classified as a type 4a MI (240). This definition is supported by studies with delayed-enhancement MRI confirming that there is irreversible injury in the myocardium associated with biomarker elevations and that the size of this injury correlates with the degree of elevation (785). Furthermore, a meta-analysis of 15 observational studies found that troponin elevations at any level were linked with worse in-hospital and long-term outcomes; elevations >3 times the upper limit of normal predicted even worse outcomes (242). Other observational data, however, have raised concerns about whether the relationship is causal (786, 787). A recent study found creatinine kinase-MB to correlate better with MRI-detected MI than troponin level (788). Definitions of PCI-related MI are being reevaluated by the Task Force for the Redefinition of Myocardial Infarction. Although there may be value for individual operators and hospitals to routinely measure cardiac biomarkers to track rates of PCI-related MI, at present there are not compelling data to recommend this for all PCI procedures.

5.11. Vascular Closure Devices: Recommendations

CLASS I

1. Patients considered for vascular closure devices should undergo a femoral angiogram to ensure their anatomic suitability for deployment. *(Level of Evidence: C)*

CLASS IIa

1. The use of vascular closure devices is reasonable for the purposes of achieving faster hemostasis and earlier ambulation compared with the use of manual compression (257, 789–791). *(Level of Evidence: B)*

CLASS III: NO BENEFIT

1. The routine use of vascular closure devices is not recommended for the purpose of decreasing vascular complications, including bleeding (256, 257, 789–792). *(Level of Evidence: B)*

See Online Data Supplement 30 for additional data regarding vascular closure devices.

Vascular (arteriotomy) closure devices have been extensively reviewed (790), most recently in a 2010 AHA scientific statement (257), which issued several formal recommendations. The results of 4 meta-analyses have found that vascular closure devices decrease time to hemostasis compared with manual compression but do not decrease vascular complications, bleeding complications, or the need for blood transfusions (256, 789, 791, 793). Future studies of vascular closure devices need to be randomized, include "high-risk" patients and "high-risk" anatomy, use blinded endpoint adjudication as much as possible, use well-defined and comprehensive complication endpoints, and be adequately powered to

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detect clinically important endpoints, particularly bleeding and vascular complications.

6. POSTPROCEDURAL CONSIDERATIONS

Postprocedural considerations in patients undergoing PCI are discussed below and summarized in Table 14. Some recommendations and text regarding DAPT in Section 5.7.2 are intentionally repeated in this section for reader ease of use.

T14

6.1. Postprocedural Antiplatelet Therapy: Recommendations

CLASS I

1. After PCI, use of aspirin should be continued indefinitely (560–563). *(Level of Evidence: A)*
2. The duration of $P2Y_{12}$ inhibitor therapy after stent implantation should generally be as follows:
   a. In patients receiving a stent (BMS or DES) during PCI for ACS, $P2Y_{12}$ inhibitor therapy should be given for at least 12 months. Options include clopidogrel 75 mg daily (570), prasugrel 10 mg daily (567), and ticagrelor 90 mg twice daily (568). *(Level of Evidence: B)*
   b. In patients receiving DES for a non-ACS indication, clopidogrel 75 mg daily should be given for at least 12 months if the patient is not at high risk of bleeding (208, 212, 571). *(Level of Evidence: B)*
   c. In patients receiving BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 month and ideally up to 12 months (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks) (572). *(Level of Evidence: B)*
3. Patients should be counseled on the importance of compliance with DAPT and that therapy should not be discontinued before discussion with their cardiologist (208). *(Level of Evidence: C)*

CLASS IIa

1. After PCI, it is reasonable to use aspirin 81 mg per day in preference to higher maintenance doses (302, 573–576). *(Level of Evidence: B)*
2. If the risk of morbidity from bleeding outweighs the anticipated benefit afforded by a recommended duration of $P2Y_{12}$ inhibitor therapy after stent implantation, earlier discontinuation (e.g., <12 months) of $P2Y_{12}$ inhibitor therapy is reasonable. *(Level of Evidence: C)*

CLASS IIb

1. Continuation of clopidogrel, prasugrel, or ticagrelor beyond 12 months may be considered in patients undergoing placement of DES (567, 568). *(Level of Evidence: C)*

Continued treatment with the combination of aspirin and a $P2Y_{12}$ inhibitor antagonist after PCI appears to reduce MACE (570, 572). On the basis of RCT protocols, secondary prevention measures, and expert consensus opinion, aspirin 81 mg daily should be given indefinitely after PCI.

Likewise, $P2Y_{12}$ inhibitors should be given for a minimum of1 month after BMS (minimum 2 weeks for patients at significant increased risk of bleeding) (580) and for 12 months after DES and ideally in all patients who are not at high risk of bleeding.

The 2009 STEMI/PCI guidelines update (10) listed the recommendation "if the risk of morbidity because of bleeding outweighs the anticipated benefit afforded by thienopyridine therapy, earlier discontinuation *should be considered*" as a Class I recommendation, although the language used, in part, was consistent with a Class IIa recommendation. To clarify the intent ofthe recommendation, as well as to acknowledge the inherent difficulties in weighing bleeding and stent thrombosis risks, the recommendation is designated a Class IIa recommendation, using the phrase "earlier discontinuation *is reasonable*." Recommendations regarding $P2Y_12$ inhibitor discontinuation before elective or urgent CABG are provided in the "2011 ACCF/AHA Guideline for Coronary Artery Bypass Graft Surgery" (824).

6.1.1. PPIs and Antiplatelet Therapy: Recommendations

CLASS I

1. PPIs should be used in patients with a history of prior gastrointestinal (GI) bleeding who require DAPT (794). *(Level of Evidence: C)*

CLASS IIa

1. Use of PPIs is reasonable in patients with an increased risk of GI bleeding (e.g., advanced age, concomitant use of warfarin, steroids, nonsteroidal anti-inflammatory drugs, *Helicobacter pylori* infection) who require DAPT (794). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. Routine use of a PPI is not recommended for patients at low risk of GI bleeding, who have much less potential to benefit from prophylactic therapy (794). *(Level of Evidence: C)*

See Online Data Supplement 31 for additional data regarding the clopidogrel—PPI interaction.

PPIs are often prescribed prophylactically when clopi-dogrel is started to prevent GI complications such

TABLE 14. Postprocedural Recommendations for Patients Undergoing PCI

Recommendations		COR	LOE	References
Aspirin				
After PCI, use of aspirin should be continued indefinitely.		I	A	(560–563)
After PCI, it is reasonable to use aspirin 81 mg/d in preference to higher maintenance doses.		IIa	B	(302,573–576)
$P2Y_{12}$ inhibitors				
In patients receiving a stent (BMS or DES) during PCI for ACS, $P2Y_{12}$ inhibitor therapy should be given for at least 12 mo. Options include clopidogrel 75 mg/d, prasugrel 10 mg/d, and ticagrelor 90 mg twice daily.		I	B	(567,568,570)
In patients receiving DES for a non-ACS indication, clopidogrel 75 mg/d should be given for at least 12 mo if patients are not at high risk of bleeding.		I	B	(208,212,571)
In patients receiving BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 mo and ideally up to 12 mo (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 wk).		I	B	(572)
Patients should be counseled on the importance of compliance with DAPT and that therapy should not be discontinued before discussion with their cardiologist.		I	C	(208)
PPIs should be used in patients with a history of prior GI bleeding who require DAPT.		I	C	(794)
If the risk of morbidity from bleeding outweighs the anticipated benefit afforded by a recommended duration of $P2Y_{12}$ inhibitor therapy after stent implantation, earlier discontinuation (e.g., <12 mo) of $P2Y_{12}$ inhibitor therapy is reasonable.		IIa	C	N/A
Use of PPIs is reasonable in patients with an increased risk of GI bleeding (e.g., advanced age, concomitant use of warfarin, steroids, NSAIDs, *Helicobacter pylori* infection) who require DAPT.		IIa	C	(794)
Continuation of clopidogrel, prasugrel, or ticagrelor beyond 12 mo may be considered in patients undergoing placement of DES.		IIb	C	N/A
Routine use of a PPI is not recommended for patients at low risk of GI bleeding, who have much less potential to benefit from prophylactic therapy.		III: No Benefit	C	(794)
Exercise testing				
For patients entering a formal cardiac rehabilitation program after PCI, treadmill exercise testing is reasonable.		IIa	C	(567,568)
Routine periodic stress testing of asymptomatic patients after PCI without specific clinical indications should not be performed.		III: No Benefit	C	(795)
Cardiac rehabilitation				
Medically supervised exercise programs (cardiac rehabilitation) should be recommended to patients after PCI, particularly for patients at moderate to high risk, for whom supervised exercise training is warranted.		I	A	(796–804)
Secondary prevention (recommendations included from the 2011 AHA/ACCF Secondary Prevention and Risk Reduction Therapy Guideline) (805)				
Lipid management with lifestyle modification and lipid-lowering pharmacotherapy	Lifestyle modification	I	B	(806,807)
	Statin therapy	I	A	(344,806,808–810,810a)
	Statin therapy which lowers LDL cholesterol to <100 mg/dL and achieves at least a 30% lowering of LDL cholesterol	I	C	(344,806,808–810,810a)
	Statin therapy which lowers LDL cholesterol to <70 mg/dL in very high-risk* patients	IIa	B	(345,808–810,810a,811,812)
Blood pressure control (with a blood pressure goal of <140/90 mm Hg)	Lifestyle modification	I	B	(813–817)
	Pharmacotherapy	I	A	(813,818,819)
Diabetes management (e.g., lifestyle modification and pharmacotherapy) coordinated with the patient's primary care physician and/or endocrinologist		I	C	N/A
Complete smoking cessation		I	A	(820–823)

*Presence of established cardiovascular disease plus 1) multiple major risk factors (especially diabetes), 2) severe and poorly controlled risk factors (especially continued cigarette smoking), 3) multiple risk factors of the metabolic syndrome (especially high triglycerides >200 mg/dL plus non-HDL cholesterol ≥130 mg/dL with low HDL cholesterol [<40 mg/dL]), and 4) acute coronary syndromes.

ACS indicates acute coronary syndromes; BMS, bare-metal stent(s); COR, class of recommendation; DAPT, dual antiplatelet therapy; DES, drug-eluting stent(s); GI, gastrointestinal; HDL, high-density lipoprotein; LDL, low-density lipoprotein; LOE, level of evidence; N/A, not applicable; NSAID, nonsteroidal anti-inflammatory drug; PCI, percutaneous coronary intervention; and PPI, proton pump inhibitor.

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as ulceration and bleeding due to DAPT (825). There is pharmacodynamic evidence that omeprazole interferes with clopidogrel metabolism (826, 827), but there is no clear evidence implicating other PPIs. However, even with omeprazole, there are no convincing data supporting an important clinical drug-drug interaction (826). The FDA communication about an ongoing safety review of clopidogrel advises that healthcare providers avoid the use of clopidogrel in patients with impaired *CYP2C19* function due to known genetic variation or drugs that inhibit *CYP2C19* activity. The FDA notes that there is no evidence that other drugs that reduce stomach acid, such as histamine-2 receptor antagonists (except cimetidine) or antacids, interfere with clopidogrel responsiveness. The COGENT (Clopidogrel and the Optimization of Gastrointestinal Events) trial randomized patients with DAPT to clopidogrel and omeprazole or clopidogrel and placebo, and while there was no difference in cardiovascular events between the 2 groups, GI events were halved in those randomized to omeprazole (828). It is reasonable to carefully evaluate the indication for PPI therapy in patients treated with clopidogrel, based on the presence or absence of the risk factors discussed above (794). The need for GI protection increases with the number of risk factors for bleeding. Prior upper GI bleeding is the strongest and most consistent risk factor for GI bleeding on antiplatelet therapy. Patients with ACS and prior upper GI bleeding are at substantial cardiovascular risk, so DAPT with concomitant use of a PPI may provide the optimal balance of risk and benefit. It should be noted that PPIs, by decreasing adverse GI effects related to clopidogrel, might decrease patients' discontinuation of clopidogrel. In patients in whom there is a clear indication for PPI therapy, some clinicians may choose to use a PPI other than omeprazole.

6.1.2. Clopidogrel Genetic Testing: Recommendations

CLASS IIb

1. Genetic testing might be considered to identify whether a patient at high risk for poor clinical outcomes is predisposed to inadequate platelet inhibition with clopidogrel (829). *(Level of Evidence: C)*
2. When a patient predisposed to inadequate platelet inhibition with clopidogrel is identified by genetic testing, treatment with an alternate $P2Y_{12}$ inhibitor (e.g., prasugrel or ticagrelor) might be considered (829). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. The routine clinical use of genetic testing to screen patients treated with clopidogrel who are undergoing PCI is not recommended (829). *(Level of Evidence: C)*

On March 12, 2010, the FDA approved a new label for clopidogrel with a "boxed warning" about the diminished effectiveness of clopidogrel in patients with impaired ability to convert the drug into its active metabolite (829). Patients with decreased *CYP2C19* function because of genetic polymorphisms metabolize clopidogrel poorly and have higher rates of cardiovascular events after ACS and PCI than patients with normal *CYP2C19* function. The warning also notes that tests are available to identify patients with genetic polymorphisms and that alternative treatment strategies should be considered for patients who are poor metabolizers. The clopidogrel boxed warning leaves the issue of whether to perform *CYP2C19* testing up to the individual physician. It does not specifically require genetic testing or other changes in evaluation or treatment and does not imply that there are solid evidence-based reasons for such actions. Rather, it serves to inform clinicians of genetic variations in response to clopidogrel and to emphasize that clinicians should use this knowledge to make decisions about how to treat individual patients. At the present time, the evidence base is insufficient to recommend routine genetic testing in patients undergoing PCI. There may be a potential role for genetic testing for patients undergoing elective high-risk PCI procedures (e.g., unprotected left main, bifurcating left main, or last patent coronary artery).

6.1.3. Platelet Function Testing: Recommendations

CLASS IIb

1. Platelet function testing may be considered in patients at high risk for poor clinical outcomes (829). *(Level of Evidence: C)*
2. In patients treated with clopidogrel with high platelet reactivity, alternative agents, such as prasugrel or ticagrelor, might be considered (829). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. The routine clinical use of platelet function testing to screen patients treated with clopidogrel who are undergoing PCI is not recommended (829). *(Level of Evidence: C)*

Platelet function testing to tailor antiplatelet therapy has received considerable interest. The GRAVITAS (Gauging Responsiveness With A VerifyNow Assay-Impact On Thrombosis And Safety) trial and several other ongoing trials test the concept that tailoring antiplatelet therapy based on platelet responsiveness assessed in an ex vivo $P2Y_{12}$ assay will improve cardiovascular outcomes (830). In GRAVITAS, treatment with high-dose clopidogrel for 6 months in patients with high platelet reactivity on standard-dose

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clopidogrel was not beneficial. At the present time, the evidence base is insufficient to recommend routine platelet function testing. The results of 2 ongoing trials (DANTE [Dual Antiplatelet Therapy Tailored on the Extent of Platelet Inhibition] and ARCTIC [Double Randomization of a Monitoring Adjusted Antiplatelet Treatment Versus a Common Antiplatelet Treatment for DES Implantation, and Interruption Versus Continuation of Double Antiplate-let Therapy, One Year After Stenting]) will provide further information on the issue (www.clinicaltrials.gov).

6.2. Stent Thrombosis

The majority of stent thrombosis occurs early (0 to 30 days after PCI). In broad clinical practice, the expected rate of early stent thrombosis is <1%, and beyond 30 days it is 0.2% to 0.6% per year (210, 831). Acute stent thrombosis often presents as STEMI, and emergency revascularization is indicated. Acute stent thrombosis is associated with mortality rates of 20% to 45% (832). Survivors are also at risk of recurrent stent thrombosis (833).

Mechanical and pharmacological factors are the most frequent cause of acute stent thrombosis. After the usual measures to restore flow in the infarct-related artery, it is important to consider the etiology of stent thrombosis as it pertains to further therapy and avoidance of recurrence. IVUS may identify factors such as an undersized stent, incomplete stent apposition, residual stenosis, or dissection and can guide subsequent treatment. The most common cause of acute stent thrombosis is nonadherence to DAPT; however, resistance to aspirin or thienopyridines and pro-thrombotic states such as congenital or acquired thrombophilic states (malignancy) are additional risk factors (834, 835).

Given the poor prognosis of stent thrombosis and the uncertainties surrounding treatment, the importance of prevention must be emphasized. This includes ensuring compliance with DAPT and adequate stent sizing and expansion (836).

6.3. Restenosis: Recommendations

CLASS I

1. Patients who develop clinical restenosis after balloon angioplasty should be treated with BMS or DES if anatomic factors are appropriate and if the patient is able to comply with and tolerate DAPT (837). *(Level of Evidence: B)*
2. Patients who develop clinical restenosis after BMS should be treated with DES if anatomic factors are appropriate and the patient is able to comply with and tolerate DAPT (838–840). *(Level of Evidence: A)*

CLASS IIa

1. IVUS is reasonable to determine the mechanism of stent restenosis (495). *(Level of Evidence: C)*

CLASS IIb

1. Patients who develop clinical restenosis after DES may be considered for repeat PCI with balloon angioplasty, BMS, or DES containing the same drug or an alternative antiproliferative drug if anatomic factors are appropriate and the patient is able to comply with and tolerate DAPT (495). *(Level of Evidence: C)*

6.3.1. Background and Incidence. After balloon angioplasty, mechanisms contributing to restenosis include smooth muscle cell migration and proliferation, platelet deposition, thrombus formation, elastic recoil, and negative arterial remodeling. Stents block elastic recoil and negative remodeling, and the predominant mechanism for restenosis after stent implantation is neointimal hyperplasia. Restenosis rates vary, depending on whether angiographic restenosis (defined as >50% diameter stenosis at follow-up angiography) or clinical restenosis (symptomatic and requiring target-lesion revascularization or target-vessel revascularization) is measured, as well as on patient characteristics, coronary anatomy considerations, and device type (balloon angioplasty, BMS, or DES). The incidence of angiographic restenosis rates for uncomplicated lesions treated in RCTs ranges from 32% to 42% after balloon angioplasty (463, 464) and from 16% to 32% after BMS (463, 464), and is generally <10% after DES (454, 841). Less than half of patients with angiographic restenosis present with symptomatic, clinically relevant restenosis at 1-year follow-up, and a pooled analysis of 6,186 patients from 6 trials of BMS showed target-lesion revascularization was performed in 12% and target-vessel revascularization in 14% at 1 year (842, 843). Patients with clinical restenosis typically present with recurrent exertional angina, but 5% to 10% of patients present with acute MI and 25% with UA (844, 845).

Factors associated with an increased risk of restenosis in various models include clinical setting (STEMI, ACS, daily angina), patient characteristics (diabetes, age <55 to 60 years, prior PCI, male sex, multivessel CAD), lesion location (unprotected left main, SVG), and procedural characteristics (minimum stent diameter ≤2.5 mm, total stent length ≥40 mm) (778, 846).

PCI strategies for treating restenosis after balloon angioplasty, BMS, and DES are reviewed in the following sections. In addition to repeat PCI, intensified medical therapy or CABG are often also reasonable strategies, dependent on initial treatment (e.g., balloon

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angioplasty, BMS), pattern of restenosis, likelihood of recurrent restenosis, ability to intensify medical therapy, suitability for CABG, and patient preference. Repeat PCI with BMS or DES is not appropriate if the patient is not able to comply with and tolerate DAPT.

6.3.2. Restenosis After Balloon Angioplasty. For clinical restenosis after balloon angioplasty, stent implantation is superior to repeat balloon angioplasty or atheroablation devices. The REST (REstenosis STent) study showed that target-lesion revascularization rates were 10% for stent-treated patients and 27% for balloon-treated patients (p=0.001) (837).

6.3.3. Restenosis After BMS. In-stent restenosis is classified according to these angiographic characteristics: Pattern I includes focal lesions $\leq$10 mm in length; Pattern II is in-stent restenosis >10 mm within the stent; Pattern III includes in-stent restenosis >10 mm extending outside the stent; and Pattern IV is totally occluded in-stent restenosis (847). Treatment of in-stent restenosis with balloon angioplasty, repeat BMS, or atheroablation devices for Patterns I to IV resulted in 1-year target-lesion revascularization rates of 19%, 35%, 50%, and 83%, respectively. For clinical restenosis after BMS, repeat stenting with DES is preferred. Studies have demonstrated lower recurrent restenosis rates with DES compared with BMS or vascular brachytherapy (495, 838–840).

6.3.4. Restenosis After DES. Clinical restenosis after placement of DES is becoming increasingly common due to the large numbers of patients who have been treated with DES. The predominant angiographic pattern for DES in-stent restenosis is focal ($\leq$10 mm in length). Several biologic, mechanical, and technical factors may contribute to DES in-stent restenosis, including drug resistance, hypersensitivity, stent underexpansion, stent strut fracture, nonuniform stent strut coverage, gap in stent coverage, and residual uncovered atherosclerotic lesion. IVUS might be considered to determine the cause for in-stent restenosis and help guide treatment strategy. Interventionists may treat focal DES restenosis with balloon angioplasty and treat nonfocal DES restenosis with BMS, CABG, or repeat DES with the same or an alternative antiproliferative drug (848, 849). Small, observational cohort studies have demonstrated angiographic restenosis rates of 25% to 30% with repeat DES either with the same or an alternative drug (495, 849, 850). There are no RCTs, and the most appropriate treatment of restenosis of DES remains unknown.

6.4. Clinical Follow-Up

At the time of discharge, patients are instructed to contact their physician or seek immediate medical attention if symptoms recur. Most physicians will give the patient instructions on return to work and timing of return to full activities. The importance of strict compliance with aspirin and $P2Y_{12}$ inhibitor therapy is ideally emphasized to the patient at the time of discharge and during follow-up visits.

Secondary prevention measures after PCI are an essential part of long-term therapy, reducing both future morbidity and mortality associated with CAD, and are discussed in Section 6.5. A follow-up visit after PCI is usually scheduled to assess the patient's clinical status, the patient's compliance with secondary prevention therapies, and the success of secondary prevention measures (e.g., blood pressure control, low-density lipoprotein levels, smoking cessation). Routine, periodic stress testing of asymptomatic patients is not considered part of standard patient follow-up.

6.4.1. Exercise Testing: Recommendations

CLASS IIa

1. In patients entering a formal cardiac rehabilitation program after PCI, treadmill exercise testing is reasonable. *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. Routine periodic stress testing of asymptomatic patients after PCI without specific clinical indications should not be performed (795). *(Level of Evidence: C)*

Treadmill exercise testing before cardiac rehabilitation provides information about peak exercise capacity and heart rate, helping to stratify patients for the level of supervision during training, and seems reasonable for this purpose (851); nuclear imaging to assess ischemia in this context usually adds little.

The role of exercise testing to evaluate restenosis is much less certain. Although the presence of symptoms may not be a reliable means of detecting restenosis, there is no evidence that the detection of silent restenosis leads to improved outcome (852, 853). Routine testing of all patients after PCI will also lead to many false-positive tests, particularly in the era of DES. As restenosis rates decline from 30% to 10%, the false-positive rate of stress imaging increases from 37% to 77% (854). A recent analysis of a national health insurance claims database and accompanying editorial find that stress testing after PCI is likely overused and rarely leads to repeat revascularization (855, 856). In summary, there is no proven benefit or indication for routine periodic stress testing in patients after PCI, and, thus, it is not indicated (8, 851). In cases in which there is a clear clinical indication for stress testing in a patient after PCI, exercise ECG alone is an insensitive predictor of restenosis (857, 858); therefore, stress

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imaging is the preferred stress test (8). In cases of recurrent angina after PCI in which the pretest likelihood of restenosis is high and repeat revascularization based on symptoms is likely indicated, most practitioners will proceed directly to cardiac catheterization rather than first obtain stress imaging.

6.4.2. Activity and Return to Work. The timing of return to physical activity depends on the presenting condition as well as previous functional status. For STEMI, for example, daily walking is encouraged immediately, and driving can begin within 1 week after uncomplicated MI if allowed by local motor vehicle laws (859). Sexual activity usually can be resumed within days, provided exercise tolerance is adequate, normally assessed by the ability to climb a flight of stairs (859). Similar recommendations have been issued for UA/NSTEMI (860). Patients with UA who have undergone successful revascularization and are otherwise doing well may return to physical activity on an accelerated schedule, usually within a few days (860).

Return to work is more complex. Return to work rates after MI range from 63% to 94% and are confounded by factors such as job satisfaction, financial stability, and company policies (861). The physical demands and degree of stress of a particular job require that recommendations be individualized. In the PAMI-2 (Primary Angioplasty in Myocardial Infarction) trial, patients were encouraged to return to work 2 weeks after primary PCI for STEMI, and no adverse events were reported (862). In the RITA (Randomized Intervention Treatment of Angina) trial, revascularization with PCI led to earlier return to work compared with CABG, and subsequent employment rates were associated with relief of angina (105). Many practitioners use graded exercise treadmill testing to determine the safety of activity and return to work by measuring the metabolic equivalent of task (MET) level achieved and comparing that level to energy levels required to perform different activities (863).

6.4.3. Cardiac Rehabilitation: Recommendation

CLASS I

1. Medically supervised exercise programs (cardiac rehabilitation) should be recommended to patients after PCI, particularly for moderate- to high-risk patients for whom supervised exercise training is warranted (796–804). *(Level of Evidence: A)*

Participation in cardiac rehabilitation is associated with significant reductions in all-cause mortality (OR: 0.80, 95% CI: 0.68 to 0.93) and cardiac mortality (796, 797). Reports from community-based surveys, which in general enroll older and higher-risk patients than clinical trials, have confirmed that participation in comprehensive rehabilitation is independently associated with a reduction in recurrent MI and reduced mortality (799). Cardiac rehabilitation is also associated with improvements in exercise tolerance, cardiac symptoms, lipid levels, cigarette smoking cessation rates (in conjunction with a smoking cessation program), stress levels, improved medical regimen compliance, and improved psychosocial well-being (800). Cardiac rehabilitation is cost-effective as well (864). Physician referral may be the most powerful predictor of patient participation in a cardiac rehabilitation program (865).

6.5. Secondary Prevention

The treatment of the patient does not end with PCI; secondary prevention measures are a critical component of patient management. Important secondary prevention measures were presented in detail in the "2006 AHA/ACC Guidelines for Secondary Prevention for Patients With Coronary and Other Atherosclerotic Vascular Disease" (562) and have recently been updated in the "AHA/ACCF Secondary Prevention and Risk Reduction Therapy for Patients With Coronary and Other Atherosclerotic Vascular Disease: 2011 Update" (805). The reader is referred to this document for detailed discussions of secondary prevention. Among the important recommendations are the following:

- Lipid management with lifestyle modification *(Class I; Level of Evidence: B)* (805–807) and statin therapy are recommended. *(Level of Evidence: A)* (344, 806, 808–810, 810a) An adequate statin dose should be employed which reduces low-density lipoprotein cholesterol to <100 mg/dL AND achieves at least a 30% lowering of low-density lipoprotein cholesterol. *(Class I; Level of Evidence: C)* (806–810, 810a) It is reasonable to treat patients with statin therapy which lowers low-density lipoprotein cholesterol to <70 mg/dL in very high-risk* patients. *(Class IIa; Level of Evidence: C)* (345,808–810,810a,811,812) Patients who have triglycerides ≥200 mg/dL should be treated with statins to lower non-high-density lipoprotein cholesterol to <130 mg/dL. *(Class I; Level of Evidence: B)* (344, 809, 810, 866) In patients who are very high risk* and have triglycerides ≥200 mg/dL, a non-high-density lipoprotein cholesterol goal of <100 mg/dL is reasonable. *(Class IIa; Level of Evidence: C)* (344, 809, 810, 866).

*Presence of established cardiovascular disease plus 1) multiple major risk factors (especially diabetes), 2) severe and poorly controlled risk factors (especially continued cigarette smoking), 3) multiple risk factors of the metabolic syndrome (especially high triglycerides ≥200 mg/dL plus non-high-density lipoprotein cholesterol ≥130 mg/dL with low high-density lipoprotein cholesterol [40 mg/dL]), and 4) acute coronary syndromes.

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- Blood pressure control with lifestyle modification *(Class I; Level of Evidence: B)* (813–817) and pharmacotherapy *(Class I; Level of Evidence: A)* (805, 813, 818, 819), with the goal of blood pressure <140/90 mm Hg.
- Diabetes management (e.g., lifestyle modification and pharmacotherapy), coordinated with the patient's primary care physician and/or endocrinologist. *(Class I; Level of Evidence: C)* (805)
- Advising patients on the need for complete smoking cessation. *(Class I; Level of Evidence: A)* (805, 820–823)

7. QUALITY AND PERFORMANCE CONSIDERATIONS

7.1. Quality and Performance: Recommendations

CLASS I

1. Every PCI program should operate a quality-improvement program that routinely 1) reviews quality and outcomes of the entire program; 2) reviews results of individual operators; 3) includes risk adjustment; 4) provides peer review of difficult or complicated cases; and 5) performs random case reviews. *(Level of Evidence: C)*
2. Every PCI program should participate in a regional or national PCI registry for the purpose of benchmarking its outcomes against current national norms. *(Level of Evidence: C)*

PCI quality and performance considerations are defined by attributes related to structure, processes, and risk-adjusted outcomes. Structural attributes include elements such as equipment, supplies, staffing, institutional and operator-level volumes, and the availability of electronic medical records. Processes include strategies for the appropriate patient, protocols for pre- and postprocedural care, appropriate procedural execution and management of complications, and participation in databases and registries for benchmarking performance of the program and individual operator. Risk-adjusted outcomes are the end result of these structures and processes of care, and when available are more reliable measures of quality than the institutional and individual operator volumes discussed in Section 7.4.

PCI process and outcomes assessments can be used for internal quality-improvement efforts and public reporting. Public reporting of institutional risk-adjusted outcomes is becoming more common. Although operator-level outcomes can be assessed and risk adjusted, the results are much less reliable due to lack of statistical power resulting from lower volumes. Any public reporting must use statistical methods that meet the high criteria established by the AHA Work Group (867).

7.2. Training

The cognitive knowledge and technical skill required to perform PCI continue to grow. Details on the training required for interventional cardiology are found in the most recent ACCF Core Cardiology Training Statement (868).

7.3. Certification and Maintenance of Certification: Recommendation

CLASS IIa

1. It is reasonable for all physicians who perform PCI to participate in the American Board of Internal Medicine interventional cardiology board certification and maintenance of certification program. *(Level of Evidence: C)*

The American Board of Internal Medicine established interventional cardiology board certification in 1999 as an "added qualification" to the cardiovascular disease board certification. Since 1990 all certificates from the American Board of Internal Medicine are time limited for a 10-year period and require all diplomats to participate in maintenance of certification to maintain their board-certified status. Maintenance of certification in interventional cardiology requires physicians to document a minimum of 150 interventional cases over the 2 years before expiration of the current certification, complete self-assessment modules of their medical knowledge, participate in practice-based quality-improvement activities, and pass a secure, knowledge-based examination (869–871). For those who cannot meet the case volume requirement, an alternative option is to submit a log of 25 consecutive cases including patient characteristics and procedural outcomes. The maintenance of certification process is likely to change, as the American Board of Internal Medicine intends to evolve maintenance of certification from an episodic event that occurs once every 10 years to a more continuous process of continuous professional development.

7.4. Operator and Institutional Competency and Volume: Recommendations

CLASS I

1. Elective/urgent PCI should be performed by operators with an acceptable annual volume (≥75 procedures) at high-volume centers (>400 procedures) with on-site cardiac surgery (872, 873). *(Level of Evidence: C)*

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2. Elective/urgent PCI should be performed by operators and institutions whose current risk-adjusted outcomes statistics are comparable to those reported in contemporary national data registries. *(Level of Evidence: C)*
3. Primary PCI for STEMI should be performed by experienced operators who perform more than 75 elective PCI procedures per year and, ideally, at least 11 PCI procedures for STEMI per year. Ideally, these procedures should be performed in institutions that perform more than 400 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year (872, 874–877). *(Level of Evidence: C)*

CLASS IIa

1. It is reasonable that operators with acceptable volume (≥75 PCI procedures per year) perform elective/urgent PCI at low-volume centers (200 to 400 PCI procedures per year) with on-site cardiac surgery (872). *(Level of Evidence: C)*
2. It is reasonable that low-volume operators (<75 PCI procedures per year) perform elective/urgent PCI at high-volume centers (>400 PCI procedures per year) with on-site cardiac surgery. Ideally, operators with an annual procedure volume of fewer than 75 procedures per year should only work at institutions with an activity level of more than 600 procedures per year. Operators who perform fewer than 75 procedures per year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume of at least 150 procedures per year. *(Level of Evidence: C)*

CLASS IIb

1. The benefit of primary PCI for STEMI patients eligible for fibrinolysis when performed by an operator who performs fewer than 75 procedures per year (<11 PCIs for STEMI per year) is not well established. *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. It is not recommended that elective/urgent PCI be performed by low-volume operators (<75 procedures per year) at low-volume centers (200 to 400 procedures per year) with or without on-site cardiac surgery. An institution with a volume of fewer than 200 procedures per year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer this service (872). *(Level of Evidence: C)*

Older observational evidence supported a volume-outcome relationship in PCI at both the institutional and operator level (873). However, this relationship is complicated and may be inconsistent across low-volume institutions or operators. More recent data on primary PCI suggest that operator experience may modify the volume-outcome relationship at the institutional level (876, 878). Risk-adjusted outcomes remain preferable to institutional and individual operator volumes as quality measures.

Operator and hospital volume recommendations have been carried over from the 2005 PCI guideline. However, the writing committee recognizes that these volume recommendations are controversial. In addition, after extensive review of all relevant data, the writing committee believes that the LOE in support of all the above recommendations is best categorized as LOE C rather than LOE B as it has been in prior guidelines for some recommendations. We encourage the ACCF/AHA/ACP Clinical Competence and Training writing group for PCI and other expert writing groups to review this issue so that new recommendations can be considered by the next PCI guideline writing committee.

7.5. Participation in ACC NCDR or National Quality Database

Assessment of PCI quality and outcomes is important both at the level of the entire program and at the level of the individual physician. This requires collection of clinical and procedural data for PCI that allows regular comparison of risk-adjusted outcomes and complications with national benchmarks. The ACC NCDR CathPCI Registry is an example of a national registry to fulfill the goals of assessing and benchmarking quality and outcomes.

8. FUTURE CHALLENGES

Although this latest guideline reflects significant advancements in the field of PCI, there remain future challenges to the formulation and updating of guidelines for PCI. The proliferation of studies comparing the many newer drugs and devices with older therapies (or other newer therapies), often using different or novel study endpoints, endpoint definitions, and noninferiority designs, pose increasing challenges to objectively evaluating newer therapies and generating recommendations for their use. Numerous potential advances in the field of PCI, including intracoronary stem cell infusions for chronic and acute ischemic heart disease, designer drugs, novel intracoronary imaging technologies such as optical coherence tomography and virtual histology, new stent composition and designs (e.g., drug-eluting, biodegradable, bifurcation), and drug-eluting balloons were considered for formal evaluation by the current writing committee, but it was thought that

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there were insufficient data at present to formulate any formal recommendations on these topics. These and other emerging technologies and treatments will need to be addressed in future PCI guidelines.

Finally, with this proliferation of new technology, the amount of data generated in the evaluation of these potential therapeutic advances will grow dramatically, adding significant challenges to future guideline generations. Of note, the Web site www.clinicaltrials.gov currently lists several hundred PCI-related clinical trials.

Staff

American College of Cardiology Foundation

David R. Holmes, Jr., MD, FACC, President

John C. Lewin, MD, Chief Executive Officer

Janet Wright, MD, FACC, Senior Vice President, Science and Quality

Charlene May, Senior Director, Science and Clinical Policy

Erin A. Barrett, MPS, Senior Specialist, Science and Clinical Policy

American College of Cardiology Foundation/ American Heart Association

Lisa Bradfield, CAE, Director, Science and Clinical Policy

Sue Keller, BSN, MPH, Senior Specialist, Evidence-Based Medicine

Jesse M. Welsh, Specialist, Science and Clinical Policy

Debjani Mukherjee, MPH, Associate Director, Evidence-Based Medicine

American Heart Association

Ralph L. Sacco, MS, MD, FAAN, FAHA, President

Nancy Brown, Chief Executive Officer

Rose Marie Robertson, MD, FAHA, Chief Science Officer

Gayle R. Whitman, PhD, RN, FAHA, FAAN, Senior Vice President, Office of Science Operations

Mark D. Stewart, MPH, Science and Medicine Advisor, Office of Science and Medicine

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APPENDIX 1. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—2011 ACCF/AHA/SCAI GUIDELINE FOR PERCUTANEOUS CORONARY INTERVENTION

Committee Member	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness	Voting Recusals by Section Number*
Glenn N. Levine *(Chair)*	Baylor College of Medicine—Professor of Medicine; Director, Cardiac Care Unit	None	None	None	None	None	None	None
Eric R. Bates *(Vice Chair)*	University of Michigan—Professor of Medicine	• Bristol-Myers Squibb • Daiichi-Sankyo • Datascope • Eli Lilly • Merck • Sanofi-aventis	None	None	None	None	None	5.7.2 5.7.3 5.7.4.1 5.7.4.2 5.7.4.3 5.7.4.4 5.7.4.5 6.1 6.1.2 6.1.3
James C. Blankenship *(Vice Chair)*	Geisinger Medical Center—Director of Cardiology and Cardiac Catheterization Laboratories	None	None	None	• Abiomed • AstraZeneca • Boston Scientific • Conor Medsystems • Kai Pharmaceutical • Schering-Plough	None	None	2.1 2.2 2.3 2.9.7 2.11 5.2.4 5.3 5.4.1 5.4.2 5.8.4 6.3
Steven R. Bailey	University of Texas Medical Center—Professor of Medicine and Radiology	• Volcano	None	None	• Boston Scientific	None	None 5.4.2	5.4.1
John A. Bittl	Munroe Heart—Interventional Cardiologist	None	None	None	None	None	None	None
Bojan Cercek	Cedars-Sinai Medical Center—Director, Coronary Care Unit	None	None	None	None	None	None	None
Charles E. Chambers	Penn State Milton S. Hershey Medical Center—Professor of Medicine and Radiology	None	None	None	None	None	None	None
Stephen G. Ellis	Cleveland Clinic Foundation—Section Head, Invasive and Interventional Cardiology	• Abbott Vascular • Boston Scientific • Cordis • Daiichi-Sankyo • Eli Lilly	None	None	• Abbott Vascular	None	None	2.2 2.11 5.7.2 6.1
Robert A. Guyton	Emory Clinic, Inc.—Professor and Chief, Division of Cardiothoracic Surgery	None	None	None	• Edwards Lifesciences	None	None	2.1 2.2 2.3 2.9.7 2.11 5.2.4 5.3 5.5.5 6.2 6.3
Steven M. Hollenberg	Cooper University Hospital—Director, Coronary Care Unit	• Eisai	None	None	None	None	None	5.7.4.3
Umesh N. Khot	CV Research Innovations, LLC—President/CEO	None	None	• Merck†	None	None	None	4.6 5.7.3

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APPENDIX 1. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—2011 ACCF/AHA/SCAI GUIDELINE FOR PERCUTANEOUS CORONARY INTERVENTION (continued)

Committee Member	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness	Voting Recusals by Section Number*
Richard A. Lange	University of Texas Health Science Center at San Antonio—Professor of Medicine	None	None	None	None	None	None	None
Laura Mauri	Brigham and Women's Hospital— Associate Professor of Medicine, Harvard Medical School	• Abbott	None	None	• Lutonix	• Abbott	• Defendant, Conor, interpretation of clinical trial results, 2010	2.9.7
		• Conor Medsystems (Johnson & Johnson)				• Abiomed • Boston Scientific • Bristol-Myers Squibb		5.2.3 5.3 5.4.2 5.5.1
		• Cordis • Medtronic				• Conor Medsystems		5.5.2 5.5.4
						• Cordis • Daiichi-Sankyo • Eli Lilly • Medtronic Cardiovascular • Sanofi-aventis		5.5.5 5.6 5.7.2 5.7.3 5.8.2 5.8.4 5.8.5 5.11 6.1 6.1.2 6.1.3 6.2
Roxana Mehran	Columbia University Medical Center— Associate Professor of Medicine; Director, Data Coordinating Analysis Center	• Abbott Vascular • Abiomed • AlphaMedical • AstraZeneca • Bracco • BMS/sanofi-aventis • DataScope • Eli Lilly/ Daichii-Sankyo • Guerbet • The Medicines Company • Medtronic Vascular • St. Jude	None	None	None	None	None	4.7 5.1 5.2.4 5.3 5.4.1 5.4.2 5.5.1 5.5.2 5.6 5.7.2 5.7.3 5.7.4.1 5.7.4.2 5.7.4.3 5.7.4.4 5.7.4.5 5.8.3 5.8.4 5.11 6.1 6.1.1 6.1.2 6.1.3

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Committee Member	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness	Voting Recusals by Section Number*
Issam D. Moussa	Mayo Clinic—Professor of Medicine; Chair, Division of Cardiovascular Diseases	None	None	None	None	None	None	None
Debabrata Mukherjee	Texas Tech University—Chief, Cardiovascular Medicine	None	None	None	None	None	None	None
Brahmajee K. Nallamothu	University of Michigan—Assistant Professor of Medicine	None	None	None	None	None	None	None
Henry H. Ting	Mayo Clinic—Professor of Medicine; Assistant Dean for Quality	None	None	None	None	None	None	None

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APPENDIX 2. REVIEWER RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—2011 ACCF/AHA/SCAI GUIDELINE FOR PERCUTANEOUS CORONARY INTERVENTION

Peer Reviewer	Representation	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Deepak L. Bhatt	Official Reviewer—AHA	None	None	None	• AstraZeneca* • Bristol-Myers Squibb • Eisai* • Eli Lilly • Ethicon* • The Medicines Company* • PLx Pharma† • Sanofi-aventis*	None	None
Mauricio G. Cohen	Official Reviewer—AHA	• AstraZeneca* • Momenta Pharma • Xoma	• Terumo Medical	None	• Invitrox*	None	None
John P. Erwin III	Official Reviewer— ACCF/AHA Task Force on Performance Measures	None	None	None	None	None	None
Kirk Garratt	Official Reviewer—SCAI	• Boston Scientific • Cordis/Johnson & Johnson • The Medicines Company	• Boston Scientific • BMS/sanofi-aventis* • Daiichi-Sankyo/Eli Lilly* • Medtronic • The Medicines Company	• Abbott Vascular • Boston Scientific	None	None	None
Steven L. Goldberg	Official Reviewer—SCAI	• AGA	• Bristol-Myers Squibb • Sanofi-aventis	None	None	None	• Plaintiff, patient litigation, 2010
Alice K. Jacobs	Official Reviewer—ACCF/AHA Task Force on Practice Guidelines	None	None	• Wyeth*	• Abbott Vascular* • Abiomed* • Accumetrics* • Cardiovascular Research Foundation (DSMB)† • Harvard Clinical Research Institute† • TIMI Study Group (DSMB)†	None	None
G. B. John Mancini	Official Reviewer—ACCF Board of Governors	• GlaxoSmithKline • Merck • Pfizer • Sanofi-aventis	None	None	• Merck*	None	None
W. Douglas Weaver	Official Reviewer— ACCF Board of Trustees	None	None	None	• Boehringher Ingelheim (DSMB) • Boston Scientific (DSMB) • Duke Clinical Research Institute (Johnson & Johnson/Schering Plough)* • GlaxoSmithKline • NHLBI (DSMB) • TIMI Study Group (Johnson & Johnson/ Bayer—DSMB)		
Thomas M. Bashore	Content Reviewer	None	None	None	None	None	None
Christopher E. Buller	Content Reviewer	• Abbott Vascular • Toshiba Medical	None	None	• Novartis • Regado Biosciences	None	None
James A. Burke	Content Reviewer— ACCF Interventional Scientific Council	None	None	None	None	None	None

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APPENDIX 2. REVIEWER RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—2011 ACCF/AHA/SCAI GUIDELINE FOR PERCUTANEOUS CORONARY INTERVENTION (continued)

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ACCF indicates American College of Cardiology Foundation; AHA, American Heart Association; DSMB, data safety and monitoring board; NHLBI, National Heart, Lung, and Blood Institute; NIH, National Institutes of Health; SCAI, Society for Cardiovascular Angiography and Interventions; and TIMI, Thrombolysis In Myocardial Infarction.

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APPENDIX 3. ABBREVIATION LIST

ACS = acute coronary syndromes
AKI = acute kidney injury
BMS = bare-metal stent(s)
CABG = coronary artery bypass graft surgery
CAD = coronary artery disease
CKD = chronic kidney disease
CTO = chronic total occlusion
DAPT = dual antiplatelet therapy
DES = drug-eluting stent(s)
ECG = electrocardiogram
EF = ejection fraction
EPD = embolic protection device
FDA = U.S. Food and Drug Administration
FFR = fractional flow reserve
GDMT = guideline-directed medical therapy
GI = gastrointestinal
GP = glycoprotein
IABP = intra-aortic balloon pump
IV = intravenous
IVUS = intravascular ultrasound
LAD = left anterior descending
LIMA = left internal mammary artery
LV = left ventricular
LVEF = left ventricular ejection fraction
MACE = major adverse cardiac event
MI = myocardial infarction
MRI = magnetic resonance imaging
NCDR = National Cardiovascular Data Registry
PCI = percutaneous coronary intervention
PPI = proton pump inhibitor
RCT = randomized controlled trial
SIHD = stable ischemic heart disease
STEMI = ST-elevation myocardial infarction
SVG = saphenous vein graft
TIMI = Thrombolysis In Myocardial Infarction
TMR = transmyocardial laser revascularization
UA/NSTEMI = unstable angina/non-ST-elevation myocardial infarction
UFH = unfractionated heparin

APPENDIX 4. ADDITIONAL TABLES/FIGURES

APPENDIX 4A. The NCDR CathPCI Risk Score System

Variable	Scoring Response Categories				Risk Score Calculation	
					Total Points	Risk of In-Patient Mortality (%)
Age	<60	≥60, <70	≥70, <80	≥80	0	0.0
	0	4	8	14	5	0.1
Cardiogenic shock	No	Yes			10	0.1
	0	25			15	0.2
Prior CHF	No	Yes			20	0.3
	0	5			25	0.6
Peripheral vascular disease	No	Yes			30	1.1
	0	5			35	2.0
Chronic lung disease	No	Yes			40	3.6
	0	4			45	6.3
GFR	<30	30-60	60-90	>90	50	10.9
	18	10	6	0	55	18.3
NYHA functional class IV	No	Yes			60	29.0
	0	4			65	42.7
PCI status (STEMI)	Elective	Urgent	Emergent	Salvage	70	57.6
	12	15	20	38	75	71.2
PCI status (no STEMI)	Elective	Urgent	Emergent	Salvage	80	81.0
	0	8	20	42	85	89.2
					90	93.8
					95	96.5
					100	98.0

CathPCI indicates catheterization percutaneous coronary intervention; CHF, congestive heart failure; GFR, glomerular filtration rate; NCDR, National Cardiovascular Data Registry; NYHA, New York Heart Association; and STEMI, ST-elevation myocardial infarction. Reproduced with permission from Peterson et al. (236).

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APPENDIX 4B. The SCAI Lesion Classification System

Type I lesions (highest success expected, lowest risk)
1. Does not meet criteria for C lesion
2. Patent

Type II lesions
1. Meets any of these criteria for ACC/AHA C lesion
   - Diffuse (>2 cm length)
   - Excessive tortuosity of proximal segment
   - Extremely angulated segments, >90°
   - Inability to protect major side branches
   - Degenerated vein grafts with friable lesions
2. Patent

Type III lesions
1. Does not meet criteria for C lesion
2. Occluded

Type IV lesions
1. Meets any of these criteria for ACC/AHA C lesion
   - Diffuse (>2 cm length)
   - Excessive tortuosity of proximal segment
   - Extremely angulated segments, >90°
   - Inability to protect major side branches
   - Degenerated vein grafts with friable lesions
   - Occluded for >3 mo
2. Occluded

ACC indicates American College of Cardiology; AHA, American Heart Association; and SCAI, Society for Cardiovascular Angiography and Interventions. Reprinted with permission from Krone et al. (879).

APPENDIX 4C. Strategies to Reduce Radiation Exposure to Patient and Operator

Precautions to minimize exposure to patient and operator
- Use radiation only when imaging is necessary to support clinical care
- Minimize use of cine
- Minimize use of steep angles of x-ray beam
- Minimize use of magnification modes
- Minimize frame rate of fluoroscopy and cine
- Keep the image receptor close to the patient
- Utilize collimation to the fullest extent possible
- Monitor radiation dose in real time to assess patient risk-benefit during procedure

Precautions to specifically minimize exposure to operator
- Use and maintain appropriate protective garments
- Maximize distance of operator from x-ray source and patient
- Keep above-table and below-table shields in optimal position at all times
- Keep all body parts out of field of view at all times

Precautions to specifically minimize exposure to patient
- Keep table height as high as comfortably possible for operator
- Vary imaging beam angle to minimize exposure to any single skin area
- Keep patient's extremities out of beam

APPENDIX 4D. Patient Care Consideration Based on Procedural Radiation Dose

$K_{a,r}$*	P_{KA}†	FT‡	Action
>5 Gray	>500 Gray cm^2	>60 min	Physician charts documentation about why exposure at this level occurred, documents whether multiple skin entry angles were used, assesses risk, educates patient about potential for skin injury, and arranges for appropriate follow-up within 30 d. Phone calls may be sufficient with an office visit arranged if issues/questions arise or a potential tissue injury is suspected.
≥10 Gray			Physician contacts radiation safety officer/medical physicist. The radiation safety officer/medical physicist should perform a detailed analysis of PSD. Document a) FOV, b) skin entrance port number, c) known geometry, with a "rough" geometric setup required. Educate patient about the potential for skin injury and document this in chart. Schedule an office visit in 2 to 4 wk.
PSD§ >15 Gray			If calculated PSD is indeed >15 Gray, the physician and/or radiation safety officer/medical physicist should contact hospital risk management within 24 h. Report the event to the Joint Commission and as needed to the appropriate State Department of Health.

*$K_{a,r}$ is total air kerma at reference point
†P_{KA} is air kerma-area product
‡FT is total fluoroscopy time, does not include cine
§PSD is peak skin dose, which requires calculations made by a qualified physicist.
FOV indicates field of view; and FT, fluoroscopy time.
Adapted with permission from Chambers et al. (317).

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APPENDIX 4E. General Considerations in Deciding Between Early Invasive Strategy and Initial Conservative Strategy

Early Invasive Strategy Generally Preferred	Initial Conservative Strategy Generally Preferred or Reasonable
• Recurrent angina or ischemia at rest or with low-level activities despite intensive medical therapy	• Low-risk score (e.g., GRACE, TIMI)
• Elevated cardiac biomarkers (TnT or TnI)	• Absence of high-risk features
• New or presumably new ST-segment depression	• High risk for catheterization-related complications
• Signs or symptoms of heart failure	• Patient not a candidate for revascularization (with either PCI or CABG)
• Hemodynamic instability	• Patient prefers conservative therapy
• High-risk score (e.g., GRACE, TIMI)	
• Sustained ventricular tachycardia	
• PCI within 6 mo	
• Prior CABG	
• Diabetes mellitus	
• Mild to moderate renal dysfunction	
• Reduced LV function (LVEF <40%)	

CABG indicates coronary artery bypass graft surgery; GRACE, Global Registry of Acute Coronary Events; LV, left ventricular; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; TIMI, Thrombolysis In Myocardial Infarction; TnI, troponin I; and TnT, troponin T.

APPENDIX 4F. Agents for Procedural Sedation and Analgesia

Drug	Clinical Effects	Dose	Onset	Duration	Comments
Midazolam	Sedation, anxiolysis. No analgesia.	Initial 0.5 to 1 mg IV, then titrated.	2 to 3 min	45 to 60 min	Reduce dose when used in combination with opioids. May produce paradoxical excitement. Reversible with flumazenil.
Fentanyl	Analgesia	50 mcg IV. May repeat every 3 min, titrate to effect.	3 to 5 min	30 to 60 min	Reduce dosing when combined with benzodiazepines. Reversible with naloxone.
Etomidate	Sedation, anxiolysis. No analgesia.	Sedation: 0.1 mg/kg IV; repeat if inadequate response.	<1 min	5 to 15 min	Respiratory depression may occur; institutional guidelines vary about administration to nonintubated patients by nonanesthesiologists. May cause myoclonus, nausea, and vomiting. Adrenocortical suppression occurs but is rarely of clinical significance. Not reversible.
Propofol	Sedation, anxiolysis. No analgesia.	Load 1 mg/kg IV; may administer additional 0.5 mg/ kg doses as needed to enhance or prolong sedation.	<1 min	5 to 15 min	Frequent hypotension and respiratory depression; institutional guidelines vary concerning administration to nonintubated patients by nonanesthesiologists. Avoid with egg or soy allergies. Not reversible.
Reversal Agents					
Naloxone	Opioid reversal	0.4 to 2 mg IV	2 min	20 to 40 min	If shorter acting than reversed drug, serial doses may be required.
Flumazenil	Benzodiazepine reversal	0.2 mg IV. May repeat every 1 min up to 1 mg.	1 to 2 min	30 to 60 min	If shorter acting than reversed drug, serial doses may be required. Do not use in patients receiving long-term benzodiazepines, cyclosporine, isoniazid, lithium, propoxyphene, theophylline, or tricyclic antidepressants.

IV indicates intravenous.

Executive Summary

Catheterization and Cardiovascular Interventions 69:471–478 (2007)

EXECUTIVE SUMMARY

The Current Status and Future Direction of Percutaneous Coronary Intervention Without On-Site Surgical Backup: An Expert Consensus Document from the Society for Cardiovascular Angiography and Interventions

Gregory J. Dehmer,[1]* MD, James Blankenship,[2] MD, Thomas P. Wharton Jr.,[3] MD, Ashok Seth,[4] MD, MBBS, DSc, Douglass A. Morrison,[5] MD, PhD, Carlo DiMario,[6] MD, David Muller,[7] MD, Mirle Kellett,[8] MD, and Barry F. Uretsky,[9] MD

*The full-length version of this article can be found on the **Catheterization and Cardiovascular Interventions** website (http://www.mrw.interscience.wiley.com/suppmat/1522-1946/suppmat/index.html) and on the SCAI website at www.scai.org.*

PREAMBLE

The Society for Cardiovascular Angiography and Interventions (SCAI) coauthored and cosponsored with the American College of Cardiology (ACC) and the American Heart Association (AHA) the percutaneous coronary intervention (PCI) guidelines update, released in November 2005 [1]. This guideline update continued to designate elective PCI without on-site surgery as a Class III indication, and primary PCI for ST-segment elevation myocardial infarction (STEMI) as a class IIb indication in the absence of on-site surgery. The performance of PCI without on-site surgical backup is currently the subject of debate. Although providing the highest quality of care and best outcomes to patients should always be the primary goal, debate on this topic has the potential to supersede quality of patient care issues. Within this context, SCAI developed this Expert Consensus document to determine the current status of PCI without on-site surgery not only in the United States, but globally, and make recommendations regarding the performance of PCI in this circumstance. The focus of this document is to provide a structure that provides the highest quality care to patients undergoing PCI in any circumstance.

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[1]Texas A&M School of Medicine, Scott & White Clinic, Temple, Texas
[2]Geisinger Medical Center, Danville, Pennsylvania
[3]Exeter Hospital and Exeter Cardiovascular Associates, Exeter, New Hampshire
[4]Max Devki Devi Heart & Vascular Institute, Saket, New Delhi, India
[5]Yakima Heart Center, Yakima, Washington
[6]Royal Brompton Hospital, London, United Kingdom
[7]St. Vincent's Hospital, Melbourne, Australia
[8]Maine Medical Center, Portland, Maine
[9]Sparks Health System, Fort Smith, Arkansas
See Appendix Table

Endorsed by the following societies: Asian Pacific Society of Interventional Cardiology, Belgian Working Group of Interventional Cardiology, Brazilian Society for Interventional Cardiology, British Cardiovascular Intervention Society, Working Group on Interventional Cardiology of the Bulgarian Cardiology Society, Cardiac Society of Australia and New Zealand, Egyptian Society of Cardiology Working Group on Interventional Cardiology, Interventional Council of the Cardiological Society of India, Italian Society of Interventional Cardiology, Working Group on Interventional Cardiology of the Latvian Society of Cardiology, Polish Working Group on Interventional Cardiology of the Polish Cardiology Society, Sociedad Venezolana de Cardiología Intervencionista (Venezuelan Society of Interventional Cardiology).

*Correspondence to: Gregory J. Dehmer, MD, FSCAI, Professor of Medicine, Texas A&M School of Medicine, Director, Cardiology Division, Scott & White Clinic, 2401 South 31st Street, Temple, Texas 76508. E-mail: president@scai.org

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BACKGROUND

Over the past 20 years, the use and indications for PCI have greatly expanded. It is now well-recognized that PCI is safer and the need for urgent coronary artery bypass graft (CABG) surgery greatly reduced [2]. Primary PCI, when available, has eclipsed fibrinolytic therapy for reperfusion in the treatment of STEMI [3], but is adversely affected by time delays in initiating the PCI procedure [4]. Studies examining patient transport to PCI hospitals have shown suboptimal initial door-to-balloon times, especially in the United States [5]. Efforts to provide primary PCI services locally at community hospitals without on-site cardiac surgery have developed and demonstrate outcomes comparable to facilities that have on-site cardiac surgery [6]. Because it is difficult to sustain a PCI program solely on STEMI patients, elective PCIs are also being performed at facilities without on-site surgery [7], enhancing the debate regarding PCI without on-site surgery.

PREVALENCE AND TRENDS OF PCI WITHOUT ON-SITE SURGERY

Data on the prevalence of PCI performed without on-site surgical backup in the United States are not easily found and are changing rapidly. Data gathered from several sources and believed accurate as of July 2006 indicate primary PCI programs without on-site surgical backup exist in all but 10 states (Alaska, Arkansas, Delaware, Georgia, Mississippi, North Dakota, Rhode Island, South Dakota, Vermont, and Wyoming) plus the District of Columbia. Facilities performing both primary and elective PCI without on-site surgery currently exist in 28 states. A large (n = 18,000) randomized trial of elective PCI without on-site surgery (The Atlantic Cardiovascular Patient Outcomes Research Team Elective Angioplasty Study) is currently enrolling patients and includes facilities in several states where elective PCI without on-site backup has been prohibited.

The exact number of patients receiving PCI at facilities without on-site surgery is unknown. Data from facilities reporting to the CathPCI Registry™ of the ACC-National Cardiovascular Data Registry (ACC-NCDR®) show an increase in the number of both primary and elective PCIs performed without on-site surgical backup [8]. In 2005, 75 of the 463 facilities reporting to the ACC-NCDR were performing PCI without on-site surgical backup.

PCI without on-site surgical backup is being performed in 35 of 39 (90%) countries responding to requests for information and appears to be increasing. For example, 7% of PCI procedures performed in the United Kingdom in 1996 were at facilities without on-site cardiac surgery. By 2004, this increased to 15% with 26% of the PCI centers in the United Kingdom operating without on-site cardiac surgery.

EXISTING GUIDELINES AND COMPETENCY DOCUMENTS

ACC/AHA/SCAI Guidelines

In the 2005 update of this guideline, primary PCI without on-site surgical backup remained a Class IIb indication, and elective PCI without on-site surgery remained a Class III indication. Many other programmatic recommendations were made [1].

European Society of Cardiology Guidelines

In contrast to the ACC/AHA/SCAI guidelines, the 2005 European Society of Cardiology (ESC) guidelines do not comment on PCI without on-site cardiac surgery or issues related to institutional or operator competency [9].

British Cardiac Society and British Cardiovascular Intervention Society Guidelines

The British Cardiac Society and British Cardiovascular Intervention Society (BCIS) guideline, published in 2005, acknowledges and approves PCI without on-site surgical backup and emphasizes a common standard applied across facilities with and without on-site surgical backup so as to avoid two levels of service provision [10].

German Guidelines

The only German guidelines found were published in 1987 [11] and thus may not be relevant today. However, there is substantial evidence that PCI without on-site surgical backup is widely performed in Germany.

The Cardiac Society of Australia and New Zealand Guidelines

Policy statements on support facilities and on the performance of coronary angiography and PCI at rural sites in Australia and New Zealand were published (online) in 2003 and 2005, respectively [12,13]. The Cardiac Society of Australia and New Zealand (CSANZ) guidelines state that PCI is preferably performed in hospitals with on-site surgical support, but acknowledge that the requirements for on-site cardiac surgical facilities may be omitted in certain circumstances, and that appropriately trained individuals can perform coronary interventional procedures safely in hospitals without on-site surgical

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backup. Furthermore, these documents acknowledge that rural patients have reduced access to diagnostic angiography and interventional procedures and further state that providing these services as close to the patient's place of residence as possible facilitates equity of access, which should result in improved quality of care.

Spanish Society of Cardiology Guidelines

Published in 1999 [14], these guidelines are specific for PCI at hospitals without on-site cardiac surgery. PCI performance without on-site cardiac surgery is not prohibited, provided a program meets certain requirements.

Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista

Guidelines from the Brazilian Society of Cardiac Hemodynamics and Intervention (Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista) [15] were published in 2003. They use a scheme similar to the ACC/AHA/SCAI guidelines [1] and classify elective PCI without on-site surgical backup as Class III. Primary PCI for STEMI in the absence of on-site surgery is a Class IIa indication; their guidelines do not have a IIb category.

Belgian Working Group on Invasive Cardiology Guidelines

Published in 2003, these guidelines acknowledge the increasing safety and diminishing risk of PCI but conclude that "the current standard practice for elective PCI remains the presence of on-site surgical standby" [16].

PEER-REVIEWED LITERATURE OF PCI WITHOUT ON-SITE SURGERY

There are over 30 published papers or abstracts reporting PCI results without on-site surgical backup. All published data for both primary and elective PCI were derived from retrospective reviews or registries, and thus are subject to unintentional bias and other methodological concerns. These are summarized and referenced in the on-line version of this document. These studies span a time period from 1990 to 2006, and thus incorporate changing treatment paradigms, including fibrinolytic therapy before PCI, glycoprotein IIb/IIIa inhibitors, and coronary artery stents. The total patient number within some of these reports is not easily derived because the studies listed are expanding experiences within the same registry; thus, simple aggregation of outcome data is not appropriate or meaningful. The more recent reports show that both primary and elective PCI without on-site surgical backup are performed with a high success rate, low in-hospital mortality rate, and a low rate of urgent cardiac surgery.

BEST PRACTICES FOR PCI WITHOUT ON-SITE SURGERY

Although no randomized or controlled studies exist and despite the current ACC/AHA/SCAI guideline recommendation, PCI without on-site surgery is being performed in many states and is accepted in many countries throughout the world. Moreover, data from many countries, including the United States, indicate that the use of PCI without on-site surgery is growing [8]. The purpose of this document is neither to challenge the ACC/AHA/SCAI guideline recommendations nor to support PCI without on-site surgery backup. However, with the reality that PCI without on-site surgery is growing, it is both appropriate and necessary to define the best standards of practice such that facilities and physicians operate within the highest possible quality standards.

Qualifications of the Physician

Simply performing a high volume of cases does not guarantee technical expertise or sound judgment on the part of the physician. More important than a specific case volume threshold is the accurate assessment of complication rates and patient outcomes. Recommendations for physicians performing PCI at facilities without on-site surgery include the following:

a. Only operators with complication rates and outcomes equivalent or superior to national benchmarks should perform PCI procedures with or without on-site surgery. The operator also must actively participate in a facility's quality improvement program. In addition to involvement in local continuous quality improvement efforts, participation in a national data registry if available and appropriate continuing medical education is mandatory.
b. A proven record of satisfactory outcomes is of greater importance than simply meeting an arbitrary case volume requirement. However, operators must have sufficient prior experience to allow assessment of their judgment and quality. The initial operators at a facility without on-site backup should not begin performing PCI in such facilities until they have a lifetime experience of >500 PCIs as primary operator after completing fellowship. Interventional cardiologists joining those already engaged in PCI without on-site surgery with <500 cases of lifetime experience should be mentored and monitored by existing physicians until it is determined and certi-

TABLE I. Personnel and Facility Requirements for PCI Programs Without On-Site Surgical Backup

Experienced nursing and technical laboratory staff with training in interventional laboratories. Personnel must be comfortable treating acutely ill patients with hemodynamic and electrical instability.
On-call schedule with operation of laboratory 24 hr/day, 365 days/year[a].
Experienced coronary care unit nursing staff, comfortable with invasive hemodynamic monitoring, temporary pacemaker operation, and intraaortic balloon pump management. Personnel capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.
Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services (e.g., respiratory care, blood bank, etc.).
Written agreements for the emergency transfer of patients to a facility with cardiac surgery. Transport protocols should be developed and tested a minimum of twice per year.
Well-equipped and maintained cardiac catheterization laboratory with high-resolution digital imaging capability and intraaortic balloon pump equipment compatible with transport vehicles. The ability for the real-time transfer of images and hemodynamic data (via T-1 transmission line) as well as audio and video images to review terminals for consultation at the facility providing surgical backup support is ideal.
Appropriate inventory of interventional equipment, including guide catheters, balloons, and stents in multiple sizes, thrombectomy and distal protection devices, covered stents, temporary pacemakers, pericardiocentesis trays. Pressure wire device and intravascular ultrasound equipment are optimal but not mandatory. Rotational or other atherectomy devices should be used cautiously in these facilities due to the greater risk of perforation.
Meticulous clinical and angiographic selection criteria for PCI (Tables II and III).
Performance of primary PCI as the treatment of first choice for STEMI to ensure streamlined care paths and increased case volumes. Door-to-balloon times should be tracked and be $\leq$90 min. Outlier cases should be carefully reviewed for process improvement opportunities.
On-site rigorous data collection, outcomes analysis, benchmarking, quality improvement, and formalized periodic case review.
Participation in a national data registry where available, such as the American College of Cardiology-National Cardiovascular Data Registry® in the United States.

CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation acute myocardial infarction.
[a]Required for the United States facilities, but this may not be possible for all facilities world-wide.
Adapted from Ref. 6.

TABLE II. Recommendations for Primary PCI and Emergency Aortocoronary Bypass Surgery at Hospitals Without On-Site Cardiac Surgery

Avoid intervention in:
Patients with >50% stenosis of left main artery proximal to infarct-related lesion especially if the area in jeopardy is relatively small and the overall LV function is not severely impaired.
Long, calcified or severely angulated target lesions at high-risk for PCI failure with TIMI grade 3 flow present during initial diagnostic angiography.
Lesions in other than the infarct artery (unless they appeared to be flow-limiting in patients with hemodynamic instability or ongoing symptoms).
Lesions with TIMI grade 3 flow that are not amenable to stenting in patients with left main or three-vessel disease that will require coronary bypass surgery.
Culprit lesions in more distal branches jeopardizing only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention.
Transfer emergently for coronary bypass surgery patients with:
High-grade left main or three-vessel coronary disease with clinical or hemodynamic instability after successful or unsuccessful PCI of an occluded vessel and preferably with intra-aortic balloon pump support.
Failed or unstable PCI result and ongoing ischemia, with intra-aortic balloon pump support during transfer.

LV, left ventricular; PCI, percutaneous coronary intervention; TIMI, Thrombolysis in Myocardial Infarction.
Adapted from Ref. 6.

fied formally by that hospital that their skills and judgment are excellent and outcomes equivalent or superior to the national benchmarks.

c. Operators performing PCI without on-site surgery should perform $\geq$100 total PCIs per year, including $\geq$18 primary PCIs per year. These numbers exceed those currently recommended in the ACC/AHA/SCAI guidelines to reflect the opinion of this writing group that a greater experience level is appropriate for PCI in this setting.
d. In the United States, board certification in interventional cardiology by the American Board of Internal Medicine is strongly recommended for all physicians performing PCI.

Facilities and Support Personnel

It is essential that all support personnel have adequate education regarding the management of PCI patients before, during, and after the procedure. This knowledge should include potential procedural complications and their management and the drug therapies used in PCI patients (Table I).

Facilities performing both primary and elective procedures without on-site surgery should perform a minimum of 200 PCI/year. Programs with <200 PCI/year should be reviewed on an individual basis. They should remain open only if they are in geographically isolated or under-served areas and their performance metrics are equivalent to accepted benchmarks. We recommend that each country or state review this issue, and establish an absolute minimum annual case volume below which a PCI program must close under any circumstance. In the United States, this minimum should be 150 PCI/year for a program offering both primary and elective PCIs and this must include a minimum of 36 primary PCI/year. Programs offering only primary PCIs must perform a minimum of 36 primary PCIs/year to remain operational. At the present time in the United States, there is no justification for a PCI

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TABLE III. Recommendations for Patient and Lesion Selection and Backup Strategy for Nonemergent PCI at Hospitals Without On-site Cardiac Surgery and by Operators Performing ≥100 PCIs/Year

Patient Risk: expected clinical risk in case of occlusion caused by procedure.

High Patient Risk: Patients with any of the following:

- decompensated congestive heart failure (Killip Class 3) without evidence for active ischemia, recent CVA, advanced malignancy, known clotting disorders;
- left ventricular ejection fraction ≤25%;
- left main stenosis (≥50%) or three-vessel disease unprotected by prior bypass surgery (>70% stenoses in the proximal segment of all major epicardial coronary arteries);
- single target lesion that jeopardizes over 50% of remaining viable myocardium.

Lesion Risk: probability that procedure will cause acute vessel occlusion.

Increased Lesion Risk: lesions in open vessels with any of the following characteristics:

- diffuse disease (>2 cm in length) and excessive tortuosity of proximal segments;
- more than moderate calcification of a stenosis or proximal segment;
- location in an extremely angulated segment (>90°);
- inability to protect major side branches;
- degenerated older vein grafts with friable lesions;
- substantial thrombus in the vessel or at the lesion site;
- any other feature that may, in the operator's judgment, impede successful stent deployment.
- aggressive measures to open chronic total occlusions are also discouraged due to an increased risk of perforation.

Strategy for Surgical Backup Based on Lesion and Patient Risk:

High-Risk Patient with High-Risk Lesion should not undergo nonemergent PCI at a facility without on-site surgery.

High-Risk Patient with Not High-Risk Lesion: nonemergent patients with this profile may undergo PCI, but confirmation that a cardiac surgeon and operating room is immediately available is necessary.

Not High-Risk Patient with High-Risk Lesion requires no additional precautions.

Not High-Risk Patient with Not High-Risk Lesion requires no additional precautions. Best scenario for PCI without on-site surgery.

CVA, cerebrovascular accident; PCI, percutaneous coronary intervention. Adapted from Ref. 6.

TABLE IV. Requirements for Off-Site Surgical Backup

1. Interventional cardiologists establish a working relationship with cardiac surgeons at the receiving facility.
2. Cardiac surgeon must have privileges at the referring facility to allow review of treatment options as time allows.
3. Cardiac surgeons and receiving hospital agree to provide cardiac surgical backup for urgent cases at all hours and for elective cases at mutually agreed hours
4. Surgeon and receiving facility assure that patient will be accepted based on medical condition, capacity of surgeons to provide services at the time of request and availability of resources. If this cannot be assured before starting an elective procedure, the case should not be done at that time.
5. Interventional cardiologist must review with the surgeon the immediate needs and status of any patient transferred for urgent surgery.
6. Hospital administrations from both facilities endorse transfer agreement.
7. Transferring and receiving facility establish a rigorous protocol for the rapid transfer of patients, including the proper personnel with appropriate experience.
8. Transport provider is available to begin transport within 20 min of the request and provide vehicle/helicopter with necessary life-sustaining equipment, including IABP and monitoring capability.
9. Transferring physician obtains consent for surgery from patient or appropriate surrogate.
10. Initial informed consent for PCI discloses that procedure is being done without on-site surgical backup and acknowledges possibility of risks related to transfer. The consent process should include the risk of urgent surgery (~0.3%) and state that a written plan for transfer exists.
11. As part of the local continuous quality improvement program, a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of any improvement opportunities.

IABP, intraaortic balloon pump; PCI, percutaneous coronary intervention.

program without on-site surgery to perform only elective procedures or not provide availability to primary PCI 24 hr/day, but such a situation may exist in other countries and be appropriate. New programs should have 2 years to reach the absolute minimum volume, but after that programs failing to reach this volume for 2 consecutive years should not remain open under any circumstance.

Patient and Lesion Selection

Rigorous clinical and angiographic selection criteria are essential for programs performing PCI without on-site surgery. Since the clinical situation and risk-to-benefit ratio are different for primary versus elective PCI, different criteria and standards should apply (Table II). In elective PCI without on-site surgery, it is necessary to assess not only the likelihood of PCI failure, but also the potential patient risk if complications occur since it is possible to have a low-risk lesion in a high-risk patient and vice versa. It is important to consider both the patient and lesion risk when developing criteria for selection of appropriate patients for treatment in facilities without on-site surgery (Table III).

Requirements for Off-Site Surgery

A close alliance and cross-communication with cardiovascular surgeons with formalized agreements and periodically tested protocols for the emergency transfer of patients are essential (Table IV). Interventional cardiologists and cardiac surgeons must be actively involved in the program with attendance at regularly scheduled cardiac catheterization conferences and participation in risk management activities.

In hospitals with on-site surgery, it is no longer standard for a surgical suite to be held open awaiting the completion of a PCI. Because the need for urgent

surgery is so infrequent, there are no current data regarding the actual time required to transport a patient to the operating room and initiate cardiopulmonary bypass should the need arise. Should a patient undergoing PCI at a facility without on-site surgery develop a complication requiring urgent transfer for surgery, it is unclear whether or by how much the facility-to-facility transport would add an additional delay in the current practice environment where operating rooms are not held open at on-site facilities. Minimizing the time to the initiation of cardiopulmonary bypass is the goal in this situation and more likely is feasible with on-site cardiac surgery if that surgery is immediately available. There is no acknowledged goal with supporting data similar to a door-to-balloon time for the initiation of cardiopulmonary bypass in this situation, but this should always be accomplished as rapidly as possible, with the goal of <120 min. Operators at facilities without on-site surgical backup should activate the emergency transport system at the first clear signs of a complication even if they attempt to salvage the situation using percutaneous techniques.

Monitoring of Programs

Providing the highest quality PCI services to patients mandates the collection of outcome data and comparison of these data to established benchmarks. Regardless of the mechanism, all PCI programs, with or without on-site surgical backup, must collect appropriate outcome data and compare their data to state, national or their country's performance standards. Data submitted must be audited by an independent authority periodically to insure integrity of the entire process.

UNRESOLVED ISSUES AND FUTURE DIRECTIONS

PCI without on-site surgery is a polarizing and emotional issue for many individuals both within and external to the interventional community. Although debate has focused on whether facilities that offer PCI without on-site surgery should exist, a more meaningful approach would focus on the goal of providing the best possible care to patients who require PCI, regardless of the setting. Recent publications suggest this goal is not being consistently met. Data indicate that the number of coronary artery bypass operations is declining. This trend is likely to continue, resulting in the closing of smaller surgical programs and the coalescence of cardiac surgical services to more centralized locations. If cardiac surgery programs begin to shrink, it will become more difficult for all PCI facilities to have on-site cardiac surgery.

It is inappropriate to open PCI centers if they are not based on the health needs of the community. Opening a low-volume PCI program within the same geographic area and thereby converting a high-volume program at another facility to a low-volume program is not necessarily in the best interests of patients in the community. There is clearly a potential for unnecessary or inappropriate PCI program development in the same geographic area and this is strongly discouraged. However, the factors that define a geographic area are not consistent throughout the United States or other countries. The level and availability of emergency transport services, response times of emergency medical transport, immediate availability of qualified cath lab personnel, and coverage by interventional cardiologists must be considered.

Desires for personal or institutional financial gain, prestige, market share, or other similar motives should not be part of the decision process in determining the need for a PCI program. These considerations apply equally to those wishing to start a new PCI program without on-site backup and those wishing to protect existing programs with on-site backup. In the final analysis, every PCI procedure, regardless of where it is performed, should be of the highest possible quality. This means the PCI is done for appropriate clinical indications, by a skilled operator with documented satisfactory outcomes in a laboratory with appropriate equipment and personnel that has careful tracking of patient outcomes and corrective mechanisms in place to manage individual operator or laboratory outcome data that fall below national standards. Ensuring that all PCI programs meet appropriate performance metrics is likely to save more lives than requiring all PCI programs have on-site surgery.

RECOMMENDATIONS

1. PCI without on-site surgical backup is being performed with acceptable outcomes and risks in the United States and many other countries. The recommendations outlined in this document are made to ensure patient safety and quality outcomes in such a work environment. This is not an open endorsement of PCI without on-site surgery and we do not support the wide-spread use of PCI without on-site surgery especially in the United States, but acknowledge that this practice may be appropriate in some circumstances.
2. The decision to begin or operate a PCI program without on-site surgical backup should be based on the health needs of a local area, not on desires for personal or institutional financial gain, prestige, market share, or other similar motives. Rural communities may have different health care delivery needs than urban centers and this should be considered.

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3. It is the goal of SCAI to promote the highest possible program quality. Accordingly, PCI programs both with and without on-site surgical backup must evaluate their outcomes against their countries' benchmark for program performance or other acceptable standard.
4. Operators performing PCI without on-site surgery should perform $\geq$100 total PCIs per year, including $\geq$18 primary PCIs per year. The initial operators at a facility without on-site backup should not begin performing PCI in such facilities until they have a lifetime experience of >500 PCIs as primary operator after completing fellowship. Only operators with complication rates and outcomes equivalent or superior to national benchmarks should perform PCI procedures.
5. Independent program oversight should occur either within the context of a local facility's quality assurance program or through an independent government or external agency. Any program failing to perform adequately should close.
6. Further data collection and analysis should be done to more completely understand the role of PCI without on-site surgical backup as a strategy for the delivery of care.

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APPENDIX

TABLE SCAI Writing Committee for Expert Consensus Document Disclosures

Name	Do you perform elective PCIs in a hospital that has on-site surgical backup?	Do you have an ownership or other financial relationship with a hospital that performs elective PCIs and has on-site surgical backup?	Do you perform elective PCIs in a hospital that does not have on-site surgical backup?	Do you have an ownership or other financial relationship with a hospital that performs elective PCIs and does not have on-site surgical backup?	Comments
Dr. Gregory J. Dehmer	Yes	No	No	No	None
Dr. James Blankenship	Yes	No	No	No	None
Dr. Thomas P. Wharton, Jr.	Yes	No	Yes	No	None
Dr. Ashok Seth	Yes	No	No	No	None
Dr. Douglass A. Morrison	Yes	No	No	No	I perform PCI at one hospital with on-site surgery and primary PCI only at a different hospital without on-site surgery.
Dr. Carlo DiMario	Yes	No	No	No	
Dr. David Muller	Yes	No	No	No	I perform primary PCI at a hospital without on site surgery
Dr. Mirle Kellett	Yes	No	No	No	None
Dr. Barry F. Uretsky	Yes	No	No	No	None

PCI, percutaneous coronary intervention.

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ATTACHMENT VII

Signed Agreements Between Greenwich Hospital and Yale-New Haven Hospital

Yale-New Haven Heart and Vascular Center Cardiac Services at Greenwich Hospital

I. General Description of the Program

The Yale-New Haven Heart and Vascular Center (YNHHVC) has established and supported the development of cardiac services at Greenwich Hospital for the purpose of improving acute cardiac care to the residents of Connecticut and Westchester County, New York. The initial relationship was established with the implementation of the Primary Angioplasty program in 2005. The YNHHVC with Greenwich Hospital is seeking the development of an Elective Angioplasty program at Greenwich Hospital to be part of an expanded cardiac program at Greenwich Hospital to include advanced congestive heart failure and management and treatment of peripheral vascular disease. YNHHVC will provide cardiac specialists at Greenwich Hospital. The frequency of YNHHVC physicians' presence at Greenwich Hospital will be determined by patient demand, but the interventional cardiologists will be onsite to ensure 24-hour coverage, 365 days a year. The services will be operated under the license of Greenwich Hospital. The Elective Angioplasty program will be located on the Greenwich Hospital campus on Perryridge Road.

The YNHHVC will provide medical and clinical direction, education, training and management and oversight to ensure the delivery of the highest quality of care. A Medical Director and HVC Patient Services Director from YNHHVC will oversee the global aspects of the cardiac services at Greenwich Hospital. The Directors will work closely with Vice President of the YNHHVC as well as Greenwich Hospital's Director, Section of Cardiology and the Program Director for Cardiology and Medicine to ensure the smooth operation of all aspects of the Cardiac program including Elective Angioplasty.

Participation in the Elective Angioplasty program will be limited to experienced interventional cardiologists who meet or exceed the minimum volume standards put forth in the ACCF/AHA/SCAI guidelines as well as the more stringent guidelines from the SCAI Expert Consensus Document for Percutaneous Coronary Intervention without On-site Cardiac Surgery. All interventional cardiologists will also be required to fulfill all necessary educational and academic criteria to maintain a full-time appointment on the GH Department of Medicine, Section of Cardiology medical staff. Greenwich Hospital will participate in ACC benchmarking registry and D_2B benchmarking.

Responsibilities

YNHHVC is responsible for providing the clinical oversight to the proposed program and for providing training to GH staff. YNHHVC management is responsible for the overall management of the cardiac services at Greenwich Hospital, including the proposed Elective Angioplasty program. YNHHVC involvement provides integration with the YNHHVC to ensure one standard of care across the Yale New Haven Health System. Greenwich Hospital will retain appropriate authorities and responsibilities that are necessary for Greenwich Hospital to comply with Medicare requirements for provider-based status and state licensure. The expectation is that Greenwich Hospital will adhere to and complete same the Competency Based Orientation.

Patient Selection Guidelines

Elective PCI Patient Selection Criteria

Pre-catheterization:
Be undergoing diagnostic cardiac catheterization for suspected coronary artery disease
Be at least 18 years of age
Must not be pregnant

Post catheterization:
Coronary artery disease judged to be clinically and angiographically significant
Ability to perform PCI with equipment available at the local site
Procedure risk judged to be not high (See below)
No need for coronary artery by-pass surgery

High procedural risk criteria are:
PCI of unprotected left main coronary artery
PCI of left coronary circulation lesion in the presence of critical (greater than 70%) unprotected left main coronary artery lesion
Poor left ventricular function (EF less than 25%) and need to perform PCI in a vessel supplying significant myocardium
PCI of single lesion that jeopardizes greater than 50% of viable myocardium

II. Emergency Transfers/Referrals

Elective angioplasty patients from Greenwich Hospital requiring emergency cardiac surgery can be transferred to the nearest cardiac surgery facility or to Yale-New Haven Hospital or Bridgeport Hospital when travel time does not impose a safety risk for the patient. Y-Access will be utilized to ensure ready access.

VI. Joint Quality Assurance Reviews

The program will be consistent with the clinical standards established through the Yale New Haven Heart and Vascular Center. In addition to strict adherence to the American College of Cardiology/American Heart Association (ACCF/AHA/SCAI) guidelines for PCI the proposed program will strive to meet the more stringent guidelines from the SCAI Expert Consensus Document on PCI without On-site Surgical Backup.

YNHHVC will draw on its collective clinical resources and experience to ensure that all of the necessary standards, protocols, policies, procedures and quality assessments are in place prior to the initiation of the elective angioplasty program and that the program staff and physicians are fully educated on these standards and procedures.

Utilization and outcomes data will be tracked by YNHHVC and the Center for Outcomes Research and Evaluation (CORE) and provided to GH on a regular basis for ongoing quality improvement. Quality improvement plans will be developed. The Greenwich Hospital program will be fully integrated into YNHHVC quality improvement activities including monthly morbidity and mortality (M&M) conferences and quality indicators monitoring. The YNHHS Quality Council will also track the elective angioplasty program outcomes. This includes participation in national and state benchmarking projects. Expect participation D_2B quality review and full case review analysis for outliers.

VII. Joint Training

All technical and nursing staff from Greenwich Hospital's Cardiac Catheterization Laboratory participates in an education program consisting of didactic, "one-on-one" observational and hands-on training. Greenwich Hospital staff rotates through the cardiac catheterization laboratory at YNHH, as well as shadow experiences in ICU and CV floor.

Training includes but is not limited to familiarization with: angioplasty equipment (guide catheters, guide wires, and angioplasty catheters including balloons and stents); commonly used drugs, assessment and monitoring anticoagulation, use of intra-aortic balloon equipment, patient transfer and a number of items related to patient care before, during and after the procedure. Participation in HVC Operations Council with issues relevant to the Elective Angioplasty Program.

VIII. Implementation of Agreement

Implementation of the agreement is subject to the receipt of the CON approval from OHCA and an ongoing evaluation of quality and outcomes measures that have been identified by YNHHVC to the program.

The foregoing is agreed to this 27th day of January, 2012.

GREENWICH HOSPITAL

By:_____
Frank Corvino
President and Chief Executive Officer

YALE-NEW HAVEN HOSPITAL

By:_____
Richard D'Aquila
Chief Operating Officer

VIII. Implementation of Agreement

Implementation of the agreement is subject to the receipt of the CON approval from OHCA and an ongoing evaluation of quality and outcomes measures that have been identified by YNHHVC to the program.

The foregoing is agreed to this 27th day of January, 2012.

YALE-NEW HAVEN HOSPITAL

By: _____
Marna P. Borgstrom
President and Chief Executive Officer

VIII. Implementation of Agreement

Implementation of the agreement is subject to the receipt of the CON approval from OHCA and an ongoing evaluation of quality and outcomes measures that have been identified by YNHHVC to the program.

The foregoing is agreed to this 27th day of January, 2012.

YALE NEW HAVEN HEALTH SYSTEM

By: _____
Gayle Capozzalo
Executive Vice President

ATTACHMENT VIII

Greenwich Hospital's Historical
PAMI Volume by ZIP Code

Angioplasty by ZIP Code

ZIP Code	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012*
06484	1	0	0	0	0
06606	0	0	0	1	0
06759	0	0	0	1	0
06807	3	0	0	0	0
06824	0	1	0	0	0
06825	1	0	0	0	1
06830	9	4	5	8	3
06831	5	8	3	0	2
06850	1	0	1	0	0
06851	0	0	0	1	0
06854	1	0	0	0	0
06870	0	2	1	2	0
06878	0	0	1	2	0
06896	1	0	0	0	0
06902	2	1	2	2	1
06906	0	0	0	1	0
06907	2	0	0	1	0
07921	0	0	0	0	0
10003	0	0	0	1	0
10462	0	1	0	0	0
10528	1	1	1	0	0
10538	0	2	0	0	0
10543	1	3	1	3	1
10550	0	1	0	0	0
10573	7	8	10	5	4
10580	2	5	2	4	0
10591	0	1	0	0	0
10597	0	0	0	1	0
10604	0	0	1	0	0
10605	1	0	1	0	0
10707	1	0	0	0	0
10709	0	0	1	0	0
10801	1	0	0	0	0
10804	0	0	0	1	0
10974	0	0	0	1	0
11372	0	0	1	0	0
12533	0	1	0	0	0
12590	0	1	0	0	0
19810	0	0	0	0	1
22827	0	0	1	0	0
33446	0	0	0	1	0
44113	0	0	0	1	0
78148	0	0	0	0	1
78624	0	0	0	0	1
99998	0	0	0	1	0
Total	**40**	**40**	**32**	**38**	**15**

*Note: Actual Q1 volume; annualized volume would equal 60

Sources: CHIME and Greenwich Hospital Department of Cardiology

ATTACHMENT IX

Articles, Studies, Reports

- Atlantic Cardiovascular Patient Outcomes Research Team CPORT-E Trial Presentation
- American Heart Association/American Stroke Association CPORT-E Trial Summary
- 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention Presentation
- For PCI, No Surgeons Required – Study: Elective PCI No Longer Requires On-Site Surgical Backup, The Advisory Board Company, The Daily Briefing

CPORT-E Trial Presentation

Atlantic Cardiovascular Patient Outcomes Research Team

CPORT- E Trial

Randomized trial comparing medical, economic and quality of life outcomes of non-primary PCI at hospitals with and without on-site cardiac surgery

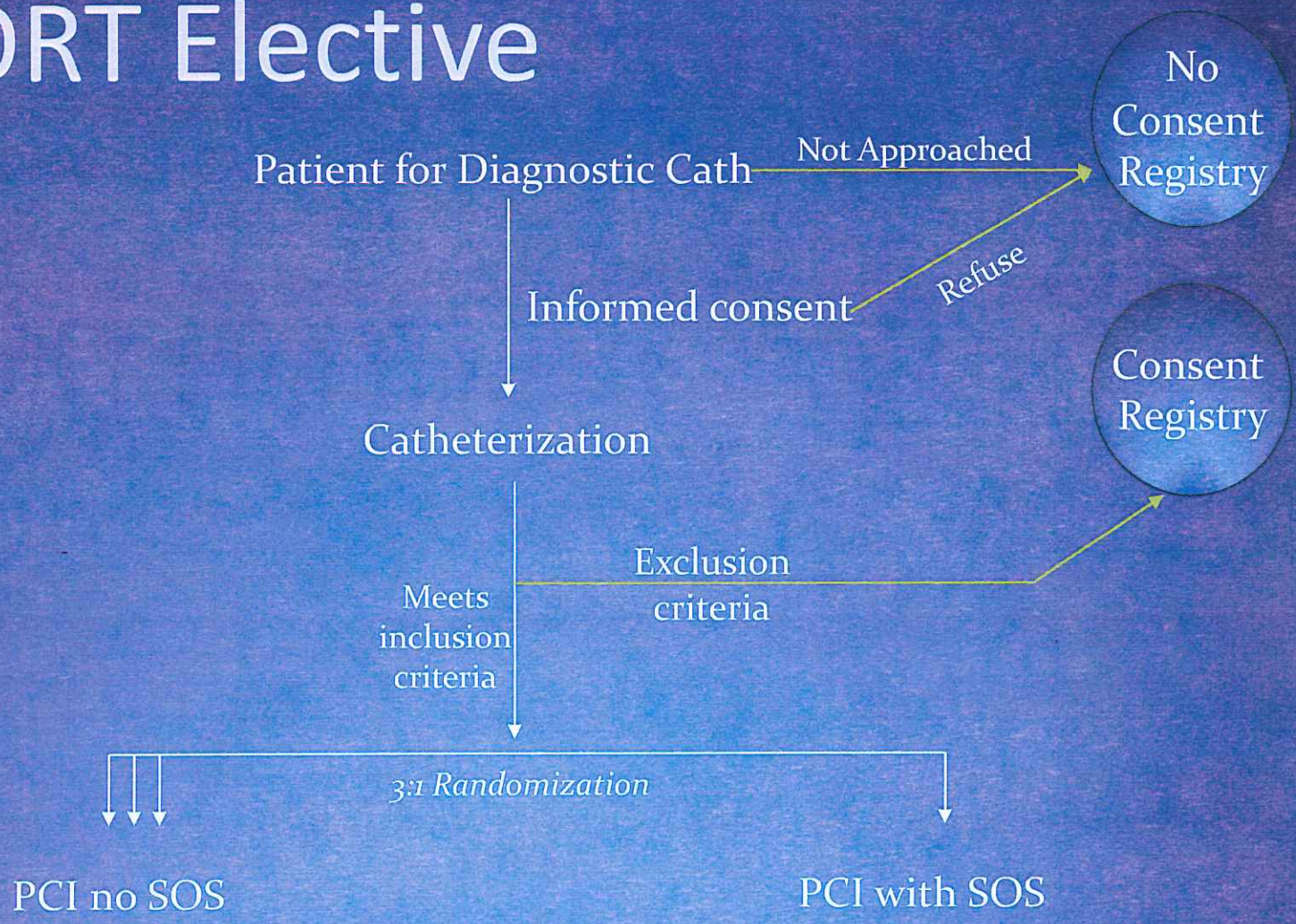
Atlantic C-PORT

Motivation for Trial

- Sustain primary PCI program at no-SOS hospitals
- Improve access to PCI services
- Reduce pressure to create additional cardiac surgery programs
- Need for research to inform healthcare policy decisions by state and national organizations

Atlantic C-PORT

C-PORT Elective



Analysis by intention-to-treat

Atlantic C-PORT

Study Endpoints

- Non-inferiority trial
- Primary Endpoints
  - **All-cause mortality at 6 weeks**
  - MACE at 9 months
    - All-cause mortality
    - Q-wave myocardial infarction
    - Target vessel revascularization
- *Assuming 6 week mortality to be 0.8%, a sample size of **18360** was selected to define a non-inferiority margin of 0.4% with a one-sided test for non-inferiority using α=0.05 and β=0.80 for both primary endpoints.*

Atlantic C-PORT

Inclusion and Exclusion Criteria

Patient

Inclusion

- Age ≥ 18 years
- Informed consent
- ≥ 50% stenosis
- All target lesions approachable at no-SOS hospital

Exclusion

- Unprotected LM
- EF < 20%
- MD-judged high risk

Devices

Inclusion

- Balloon, stent
- Distal protection
- Covered stent
- Cutting balloon - in-stent restenosis

Exclusion

- Atherectomy
- Cutting balloon- de novo lesion

Institution

Inclusion

- ≥ 200 PCI/year
- 24/7 Primary PCI
- Complete formal development program
- Interventionalist meets AHA/ACC competency

Atlantic C-PORT

Participating Centers

60 Centers

Center Annual PCI Procedure Volume

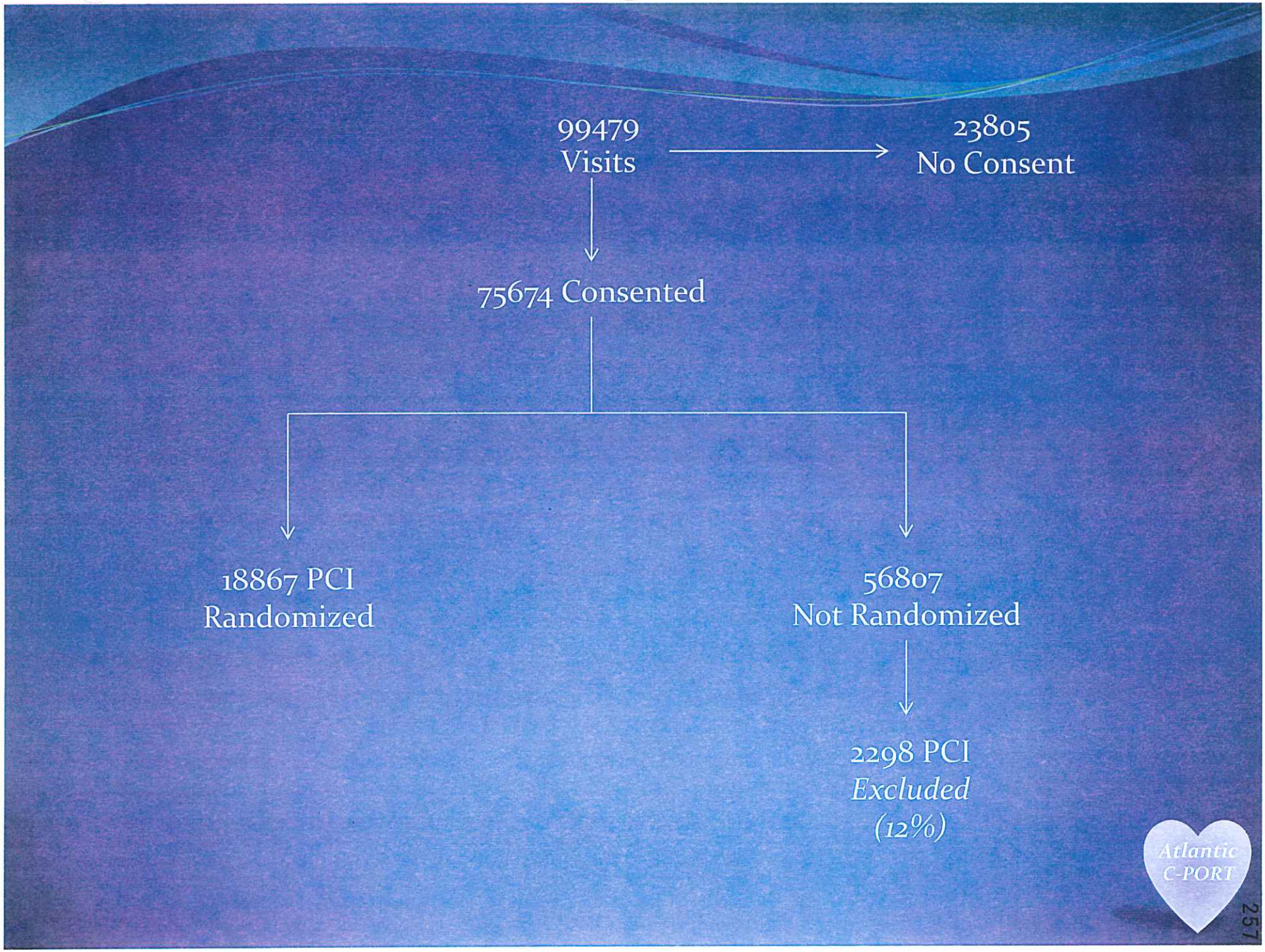
150 (99,216)

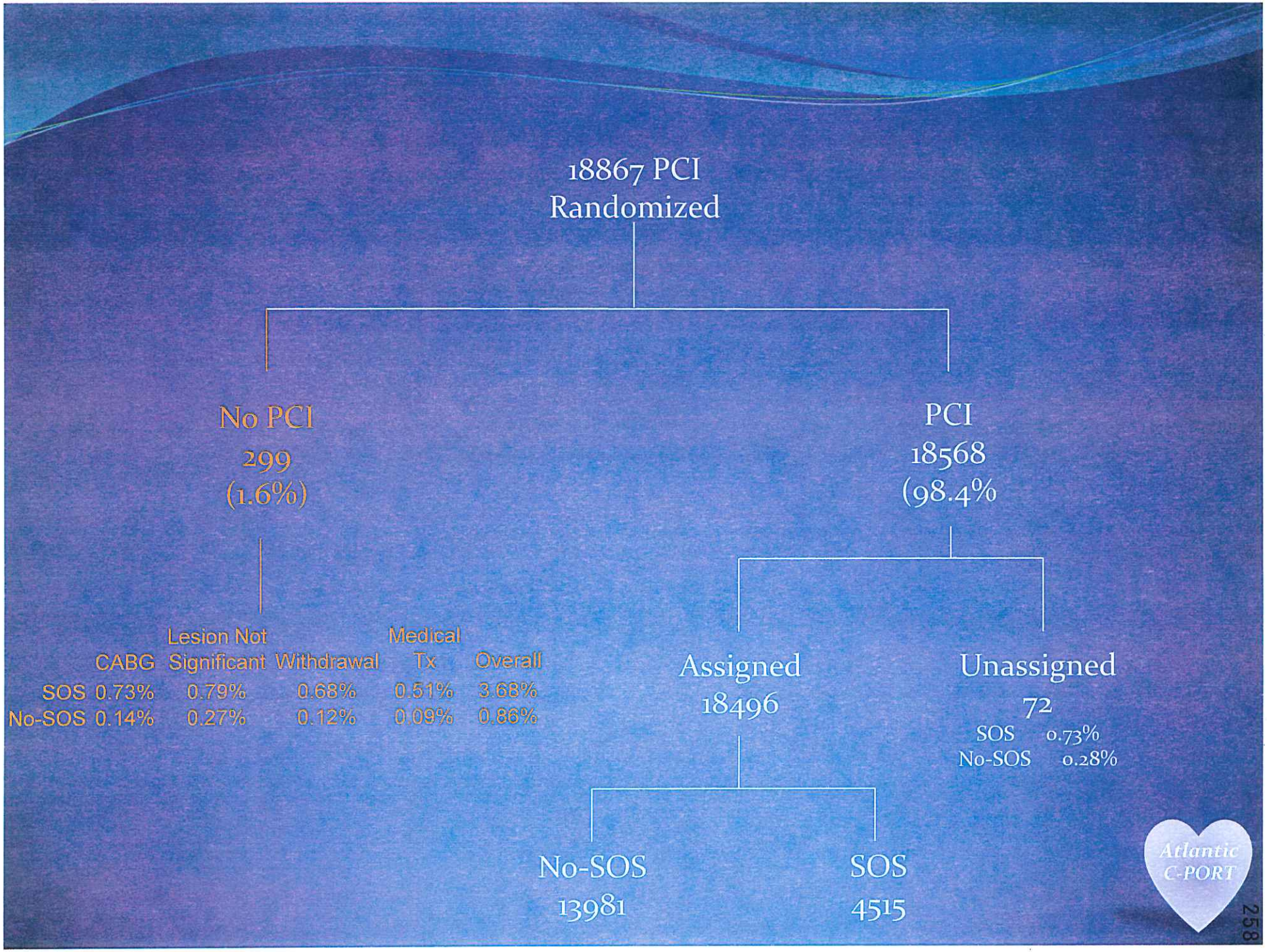
median (25th,75th percentile)

Median Participation Duration

2.2 years

Atlantic C-PORT


99479
Visits
23805
No Consent
75674 Consented
18867 PCI
Randomized
56807
Not Randomized
2298 PCI
Excluded
(12%)
Atlantic
C-PORT
257


18867 PCI
Randomized
No PCI
299
(1.6%)
PCI
18568
(98.4%
CABG
Lesion Not Significant
Withdrawal
Medical Tx
Overall
SOS 0.73% 0.79% 0.68% 0.51% 3.68%
No-SOS 0.14% 0.27% 0.12% 0.09% 0.86%
Assigned
18496
Unassigned
72
SOS 0.73%
No-SOS 0.28%
No-SOS
13981
SOS
4515
Atlantic
C-PORT

	No-SOS	SOS	p-value
Age (years) (mean+/-SD)	64+/-12	64+/-12	0.42
Male Gender (%)	64.0	63.2	0.37
Race/Ethnicity (%)			
Caucasian	79.1	80.2	0.33
Africa-American	11.8	11.3	
Hispanic	5.6	5.6	
Asian	2.1	1.9	
Hypertension (%)	84.6	85.3	0.29
Hypercholesterolemia (%)	82.2	82.2	0.95
Smoking (Current & Former) (%)	61.6	62.7	0.20
Diabetes (%)	39.0	39.7	0.41
Family History of CAD (%)	56.7	57.9	0.17
Heart Failure (%)	8.6	8.8	0.64
Prior MI (%)	42.5	43.3	0.35
Prior PCI (%)	31.9	30.4	0.06
Prior CABG (%)	13.1	13.5	0.47
Prior Stroke or PVD (%)	17.3	18.4	0.09
Creatinine (mg/dl)	1.15+/-0.88	1.15+/-0.87	0.63
GFR ml/min/1.73 m^2	76.5+/-34.1	76.3+/-27.1	0.63
BMI kg/m^2	32.7+/-21.9	33.2+/-24.5	0.22

Atlantic C-PORT

Presentation

Clinical Characteristics

	No-SOS (%)	SOS (%)
ACS	63.8	64.1
Stable	36.1	36.0

Procedure Status

	No-SOS (%)	SOS (%)
Elective	76.7	79.4
Urgent	22.9	20.1
Emergency	0.36	0.57

* $P < 0.001$

Atlantic C-PORT

Baseline Diagnostic Catheterization

	No-SOS (%)	SOS (%)	p-value
One vessel CAD	36.1	34.7	0.22
Two vessel CAD	35.9	37.2	
Three vessel CAD	28.0	28.0	
Left main disease	3.2	3.7	0.13
Graft disease	9.4	9.7	0.44
LV function (EF)	54.2 +/- 10.6	54.3 +/- 10.7	0.72

Totals add up to >100% because Left Main and Graft disease are in addition to disease in the three major circulations

Atlantic C-PORT

Procedure Characteristics

	No-SOS (%)	SOS (%)	P-Value
Staged	25.7	67.7	<0.0001
Lab Visits /Index PCI	1.28	1.73	<0.0001
Single Vessel PCI	79	78	
Multi-Vessel PCI	21	22	

Staged Index PCI
procedure requires one or more catheterization laboratory visit dates in addition to the diagnostic catheterization date

Atlantic C-PORT

PCI Success

	No-SOS (%)	SOS (%)
Complete Success	90.8	91.9*
Partial Success	5.7	5.5
Failure	3.4	2.5*

Patient Success
P=0.0096

	No-SOS (%)	SOS (%)
Success	93.4	94.1
Failure	6.6	5.9

Lesion Success
P=0.0474

PCI Success: ≤20% residual stenosis and TIMI 3 flow

Atlantic C-PORT

Mortality *6- Weeks*

	No-SOS (%)	SOS (%)	P-value
Death	0.91	0.93	0.94

The difference in 6 week mortality is -0.014% with a 90% confidence interval of -0.26% to 0.28%. The upper bound is <0.4%, so that the hypothesis of inferior 6 week mortality for the no-SOS hospitals is rejected at the one-sided P<0.05 level.

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Adverse Events - *6-Weeks*

	No-SOS (%)	SOS (%)	P-value
Death	0.91	0.93	0.94
Bleeding	3.41	3.00	0.18
Vascular repair	0.38	0.40	0.86
Stroke	0.27	0.15	0.16
Renal Failure	0.50	0.37	0.28

Atlantic C-PORT

Unplanned Procedures

	No-SOS (%)	SOS (%)	P-value
CABG	0.48	0.68	0.10
Emergency CABG	0.10	0.22	0.05
Unplanned Cath	4.41	3.35	0.002
Unplanned PCI	2.11	1.32	0.001

Atlantic C-PORT

Summary

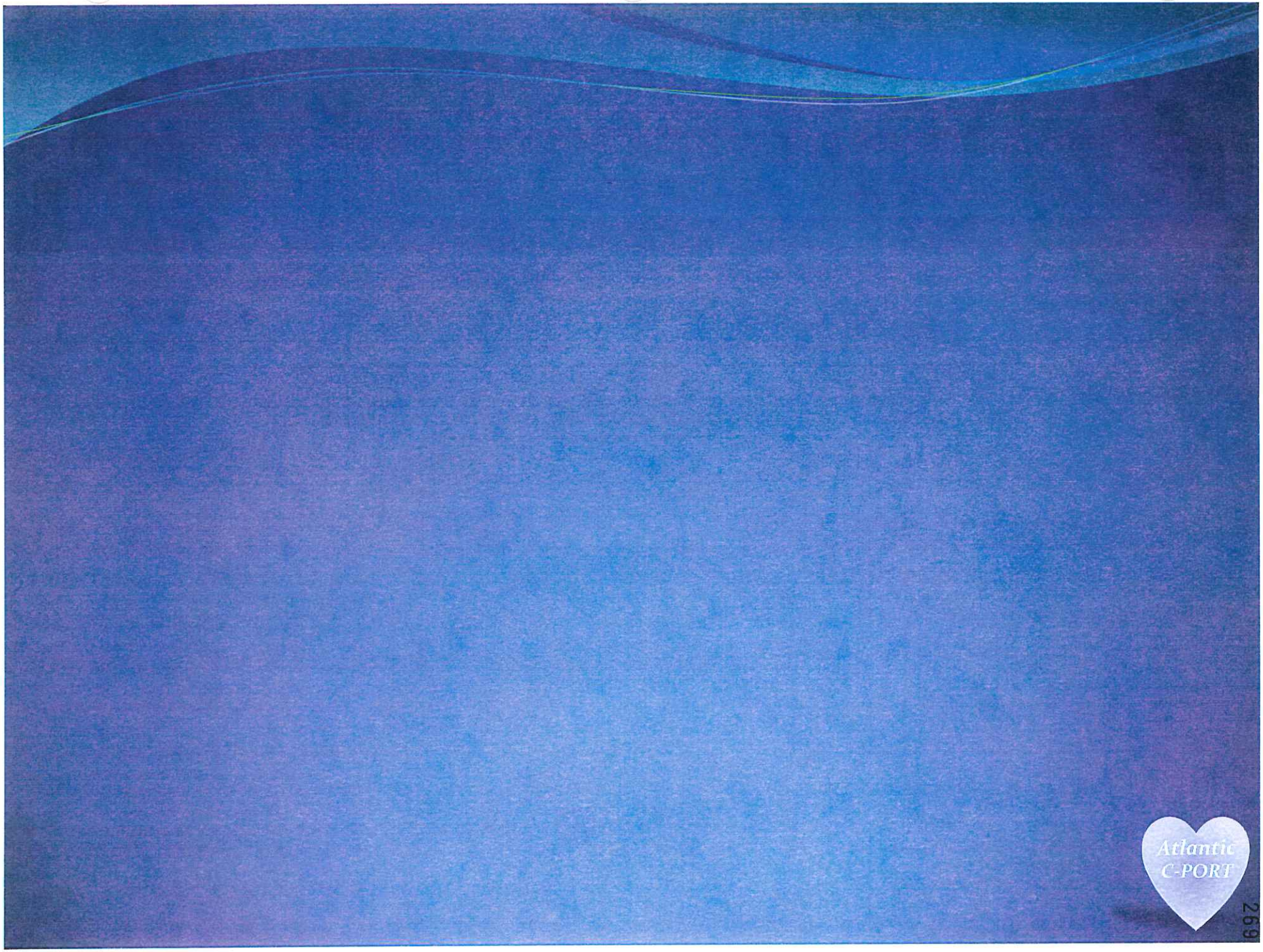
- **PCI success is greater than 90% in both groups but lower in patients randomized to hospitals without surgery on-site**
  (success rate difference of 1.1% on per patient basis; 0.7% on per lesion basis)
- **Number of cath lab visits required to complete the index PCI is greater in patients randomized to hospitals with surgery on-site**
  (1.3 versus 1.7 visits/patient)
- **Unplanned catheterization and PCI procedures are uncommon but occur more frequently in patients randomized to hospitals without surgery on-site**
  (4.4% no-SOS vs 3.4% SOS)
- **Emergency CABG procedures are rare, but occur more frequently in patients randomized to hospitals with surgery on-site**
  (0.1% no-SOS vs 0.2% SOS)
- **Mortality is similar in both groups**
  (0.91% no-SOS vs 0.93% SOS)
- **The incidence of bleeding, vascular repair, stroke and renal failure is similar in both groups**

Atlantic C-PORT

Conclusion

- In hospitals without on-site cardiac surgery that complete a formal PCI development program, adhere to C-PORT participation requirements, and whose outcomes are monitored, non-primary PCI is safe and associated with similar rates of adverse events including mortality.
- Long-term, quality outcome data are currently being collected on these study subjects and will be reported early in 2012.

Atlantic C-PORT


Atlantic
C-PORT

Summary

- **Angiographic Outcomes**
  - PCI Success > 90% in both groups but lower in hospitals without surgery on-site
    (success rate difference of 1.1% on per patient basis; 0.7% on per lesion basis)
  - Number of catheterization laboratory visits required to complete the index PCI is greater in patients randomized to hospitals with surgery on-site
    (1.3 versus 1.7 visits/patient)
- **Unplanned procedure outcomes**
  - Unplanned catheterization and PCI procedures were uncommon but occurred more frequently in patients randomized to hospitals without surgery on-site
    (4.4% no-SOS vs 3.4% SOS)
  - Emergency coronary CABG was rarely required, but was utilized more among patients at hospitals with surgery on-site
    (0.1% no-SOS vs 0.2% SOS)
- **Patient Outcomes**
  - Mortality is similar in both groups
    (0.91% no-SOS vs 0.93% SOS)
  - The incidence of bleeding, vascular repair, stroke and renal failure is similar in both groups

Atlantic C-PORT

Summary

	No SOS (%)	SOS (%)	Relative Difference	Absolute Difference
PCI Success	90.8	91.9	1.2 %	204
Number procedures / index PCI	1.3	1.7	30 %	5570
Unplanned cath or PCI	4.4	3.4	29 %	184
Unplanned emergency CABG	0.10	0.22	50 %	22
Mortality	.91	.93	3.2 %	4
Bleeding	3.4	3	13 %	76

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Summary - 1

- Historical, angiographic and clinical characteristics of study subjects are similar at hospitals with and without on-site surgery
- Acute coronary syndrome is the most frequent clinical presentation in both groups
- Fewer procedures are classified as "elective" at hospitals without surgery on-site
- PCI success rate differs by less than 1% in the two groups, but is statistically lower at hospitals without on-site surgery
- In patients assigned to hospitals with on-site surgery there are more staged procedures and more catheterization laboratory visits are required to complete the index PCI.

Atlantic C-PORT

Summary - 2

- Six weeks after index PCI
  - Mortality is similar at hospitals with and without SOS
  - Incidence of bleeding, renal failure and stroke are similar at hospitals with and without SOS
  - Unplanned CABG, particularly emergency CABG, are more frequent at hospitals with SOS
  - Unplanned catheterization and PCI procedures are more frequent in patient assigned to no-SOS hospitals

Atlantic C-PORT

Catheterization Laboratory Visits

	No-SOS	SOS
Diagnositic Cath Visits	14023	4545
Visits to Complete Index PCI	17964	7855
Visits/PCI	1.28	1.73
Unplanned Visits	618	152
Total	18302	8007
Visits/PCI	1.31	1.76

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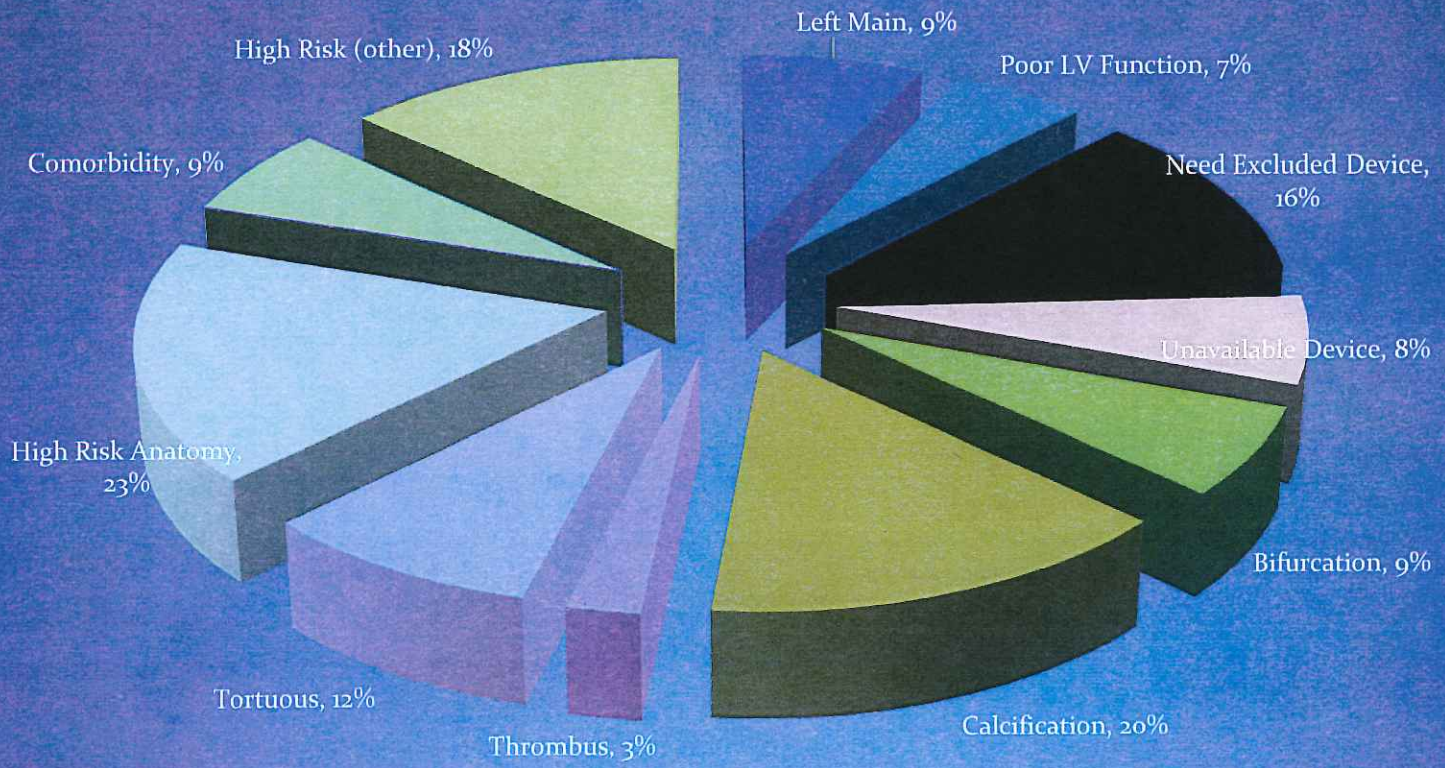
Reason No PCI – consented, not randomized



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Consented But Not Randomized

PCI at alternate site

Exclusion Criteria		
Need Excluded Device	368	16%
Left Main	218	9%
Poor LV Function	161	7%
High Risk		
High Risk Anatomy	537	23%
Calcification	452	20%
High Risk (other)	410	18%
Tortuous	270	12%
Co-morbidity	200	9%
Bifurcation	197	9%
Thrombus	70	3%

Total > 100 % because of multiple reasons for some patients

Atlantic C-PORT

PCI Success

	No-SOS (%)	SOS (%)	Off-Site* (%)	On-Site* (%)
Success	94.3	95.2	95	94
Partial Success or Failure	5.7	4.8		

PCI Success: ≤50% residual stenosis and TIMI 3 flow

** Kutcher MA et al. J Am Coll Cardiol, 2009, 54:16-24*

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	No-SOS	SOS	Off-Site*	On-Site*
Age (years) (mean+/-SD)	64+/-12	64+/-12	64.2	64 ± 12
Male Gender (%)	64.0	63.2	65	66
Race/Ethnicity (%)				
Caucasian	79.1	80.2		
Africa-American	11.8	11.3		
Hispanic	5.6	5.6		
Asian	2.1	1.9		
Hypertension (%)	84.6	85.3	76	77
Hypercholesterolemia (%)	82.2	82.2	71	76
Smoking (Current & Former) (%)	61.6	62.7		
Diabetes (%)	39.0	39.7	32	33
Family History of CAD (%)	56.7	57.9		
Heart Failure (%)	8.6	8.8	11	11
Prior MI (%)	42.5	43.3	29	31
Prior PCI (%)	31.9	30.4	36	37
Prior CABG (%)	13.1	13.5	14	21
Prior Stroke or PVD (%)	17.3	18.4		
Creatinine (mg/dl)	1.15+/-0.88	1.15+/-0.87		
GFR ml/min/1.73 m^2	76.5+/-34.1	76.3+/-27.1		
BMI kg/m^2	32.7+/-21.9	33.2+/-24.5		

** Kutcher MA et al. J Am Coll Cardiol, 2009, 54:16-24*

Atlantic C-PORT

Adverse Events - *6-Weeks*

	No-SOS (%)	SOS (%)	Off-Site* (%)	On-Site* (%)
Death	0.91	0.93	0.8	0.8
Bleeding	3.41	3.00	2.3	2
Vascular repair	0.38	0.40	0.8	1.1
Stroke	0.27	0.15		
Renal Failure	0.50	0.37		

** Kutcher MA et al. J Am Coll Cardiol, 2009, 54:16-24*

Atlantic C-PORT

Unplanned Procedures

	No-SOS (%)	SOS (%)	Off-Site* (%)	On-Site* (%)
CABG	0.48	0.68		
Emergency CABG	0.10	0.22	0.3	0.4
Unplanned Cath	4.41	3.35		
Unplanned PCI	2.11	1.32		

*Kutcher MA et al. J Am Coll Cardiol, 2009, 54:16-24

Atlantic C-PORT

Disclosure

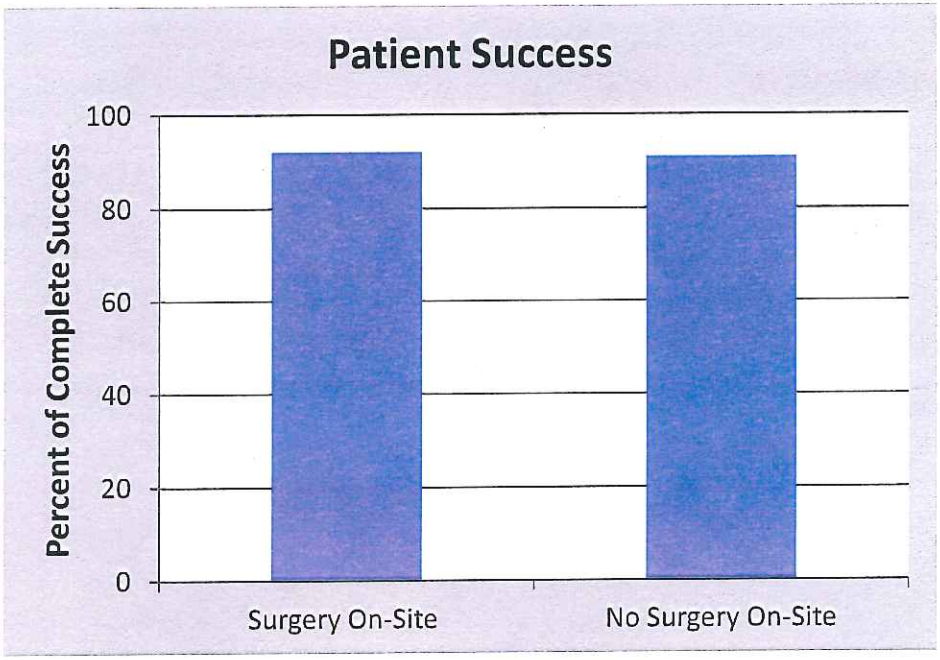
- Participating sites supported study infrastructure and personnel at
  - Johns Hopkins – Clinical Coordinating Center
  - Duke – Economics and Quality of Life
  - Clinical Trials and Survey Corporation – Data Analysis

AHA/ASA CPORT-E Trial Summary

CPORT-E Trial

Background: Comparison of the safety and quality outcomes of PCI performed at hospitals with and without on-site cardiac surgery.

Purpose: To determine whether the safety and benefits of angioplasty are the same at hospitals with or without surgery backup. The study is designed to show that there is no detectable difference between the safety and benefits of the procedure at the two types of hospital. Cost is also compared.



Methods: Interventional , randomized, safety/efficacy study, parallel assignment, open label, non-inferiority, health services research (n=18,867 randomized)

Primary Endpoints: Mortality at 6 weeks and MACE = death + MI + TVR at 9 months

Secondary Endpoints: Include emergency CABG; MI; TVR & subsequent TVR; HF & class; Angina & class; stroke; MACE; angiographic complications & success; please see complete listing at clinicaltrials.gov

Results: Mortality and incidence of bleed, vascular repair, stroke and renal failure was comparable in both groups.

Conclusion: Patients who had non-emergency artery-opening angioplasty or stent implantation at hospitals without cardiac surgery capabilities fared as well as those in hospitals that did. Outcomes at 9 months post procedure will be reported next year.

Presented by: T. Aversano, AHA Scientific Sessions , 2011, Orlando

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2011 ACCF/AHA/SCAI
Guideline Presentation

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions

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Citation

This slide set was adapted from the 2011 ACCF/AHA /SCAI Guideline for Percutaneous Coronary Intervention. Published on November 7th ahead of print, available at: http://circ.ahajournals.org/lookup/doi/10.1161/CIR.0b013e31823ba622

The full-text guidelines are also available on the following Web sites:
ACC (www.cardiosource.org), AHA (my.americanheart.org), and SCAI (www.scai.org)

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Special Thanks To

Slide Set Editor

Glenn N. Levine, MD, FACC, FAHA

The PCI Guideline Writing Committee Members

Glenn N. Levine, MD, FACC, FAHA, *Chair*
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James C. Blankenship, MD, FACC, FSCAI, *Vice Chair*

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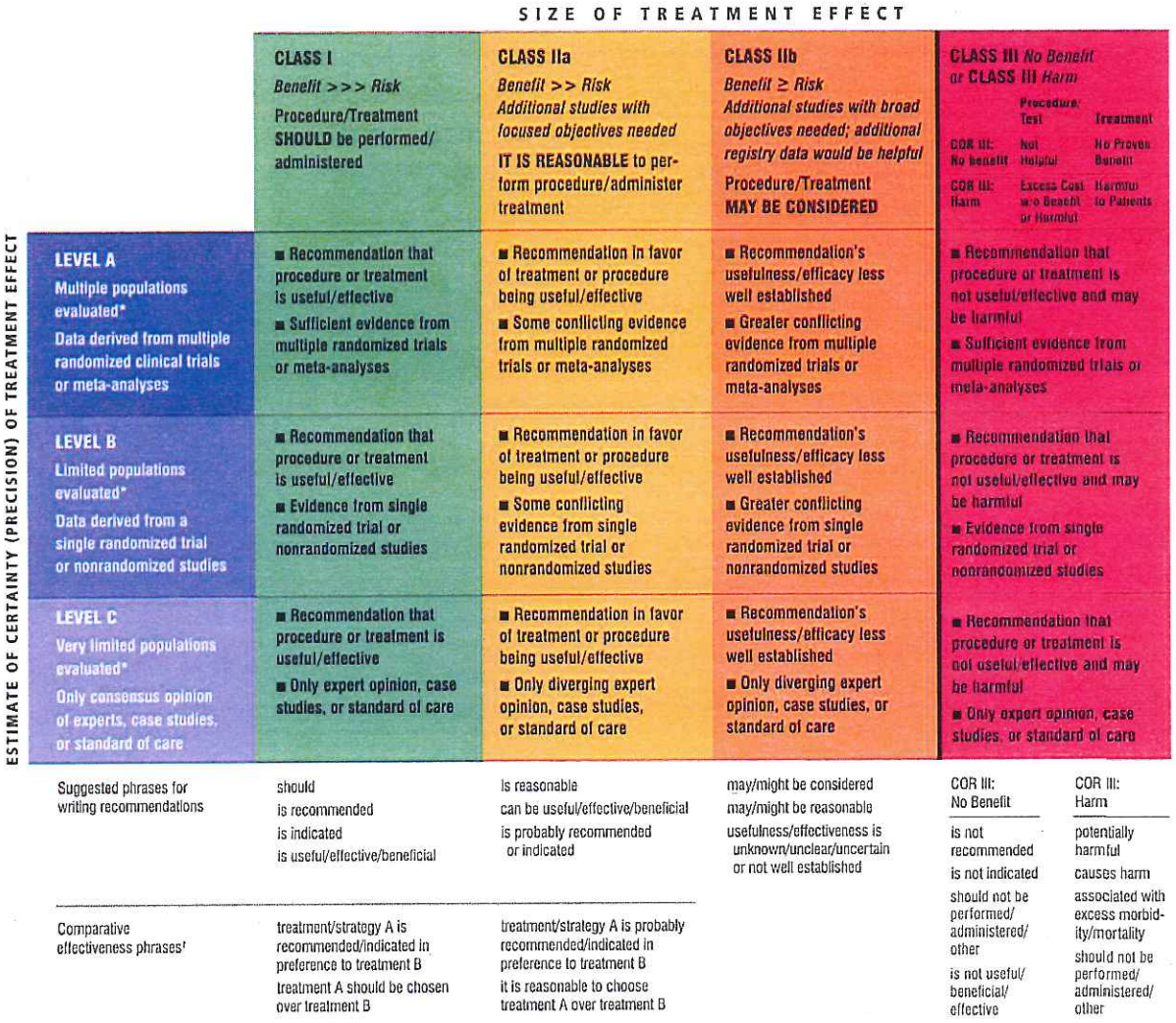
Classification of Recommendations and Levels of Evidence



SIZE OF TREATMENT EFFECT

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT

	CLASS I *Benefit >>> Risk* Procedure/Treatment **SHOULD** be performed/ administered	CLASS IIa *Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	CLASS IIb *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	CLASS III *No Benefit* or CLASS III *Harm* Procedure/ Test / Treatment COR III: No benefit — Not Helpful — No Proven Benefit COR III: Harm — Excess Cost w/o Benefit or Harmful — Harmful to Patients
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care
Suggested phrases for writing recommendations	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR III: No Benefit: is not recommended; is not indicated; should not be performed/ administered/ other; is not useful/ beneficial/ effective COR III: Harm: potentially harmful; causes harm; associated with excess morbidity/mortality; should not be performed/ administered/ other
Comparative effectiveness phrases†	treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B		

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

*Data available from clinical trials or registries about the usefulness/ efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

†For comparative effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

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Introduction

The PCI guideline reflects the growth of knowledge in the field and parallels the many advances and innovations in the field of interventional cardiology, including primary PCI, BMS and DES, IVUS and physiologic assessments of stenosis, and newer antiplatelet and anticoagulant therapies. This guideline addresses ethical aspects of PCI, vascular access considerations, CAD revascularization, including hybrid revascularization, revascularization before noncardiac surgery, optical coherence tomography, advanced hemodynamic support devices, no-reflow therapies, and vascular closure devices.

Most of this document is organized according to "patient flow," consisting of preprocedural considerations, procedural considerations, and postprocedural considerations.

The STEMI, PCI, and CABG guidelines were written concurrently, with additional collaboration with the SIHD guideline writing committee, allowing for greater collaboration on topics such as PCI in STEMI and revascularization strategies in patients with CAD.

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CAD Revascularization

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Heart Team Approach to Revascularization Decisions

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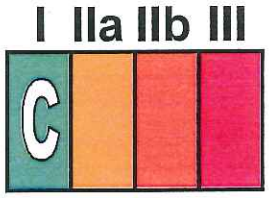
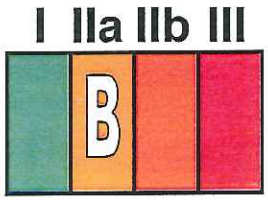
Heart Team Approach to Revascularization Decisions



A Heart Team approach to revascularization is recommended in patients with unprotected left main or complex CAD.



Calculation of the STS and SYNTAX scores is reasonable in patients with unprotected left main and complex CAD.

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Revascularization to Improve Survival

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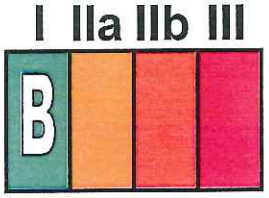
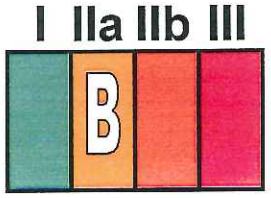
Revascularization to Improve Survival: Left Main CAD Revascularization



CABG to improve survival is recommended for patients with significant (≥50% diameter stenosis) left main CAD.



PCI to improve survival is reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of a good long-term outcome (e.g., a low SYNTAX score [≤22], ostial or trunk left main CAD); and 2) clinical characteristics that predict a significantly increased risk of adverse surgical outcomes (e.g., STS-predicted risk of operative mortality ≥5%).

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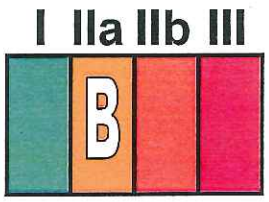
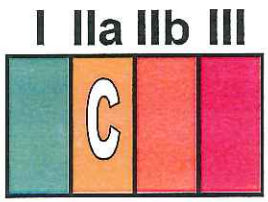
Revascularization to Improve Survival: Left Main CAD Revascularization (cont.)



PCI to improve survival is reasonable in patients with UA/NSTEMI when an unprotected left main coronary artery is the culprit lesion and the patient is not a candidate for CABG.



PCI to improve survival is reasonable in patients with acute STEMI when an unprotected left main coronary artery is the culprit lesion, distal coronary flow is TIMI (Thrombolysis In Myocardial Infarction) grade <3, and PCI can be performed more rapidly and safely than CABG.

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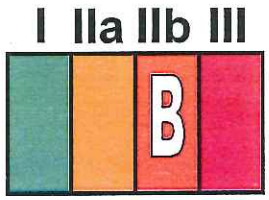
Revascularization to Improve Survival: Left Main CAD Revascularization (cont.)



PCI to improve survival may be reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low to intermediate risk of PCI procedural complications and an intermediate to high likelihood of good long-term outcome (e.g., low-intermediate SYNTAX score of <33, bifurcation left main CAD); and 2) clinical characteristics that predict an increased risk of adverse surgical outcomes (e.g., moderate-severe chronic obstructive pulmonary disease, disability from previous stroke, or previous cardiac surgery; STS-predicted risk of operative mortality >2%).

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Revascularization to Improve Survival: Left Main CAD Revascularization (cont.)



Harm

PCI to improve survival should not be performed in stable patients with significant (≥50% diameter stenosis) unprotected left main CAD who have unfavorable anatomy for PCI and who are good candidates for CABG.

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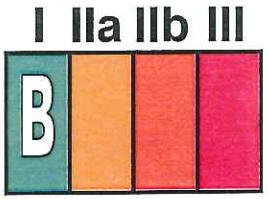
Revascularization to Improve Survival: Non-Left Main CAD Revascularization



CABG to improve survival is beneficial in patients with significant (≥70% diameter) stenoses in 3 major coronary arteries (with or without involvement of the proximal LAD artery) or in the proximal LAD plus 1 other major coronary artery.

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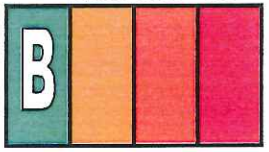
Revascularization to Improve Survival: Non-Left Main CAD Revascularization (cont.)

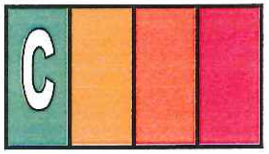
CABG

I IIa IIb III



PCI

I IIa IIb III



CABG or PCI to improve survival is beneficial in survivors of sudden cardiac death with presumed ischemia-mediated ventricular tachycardia caused by a significant (≥70% diameter) stenosis in a major coronary artery.

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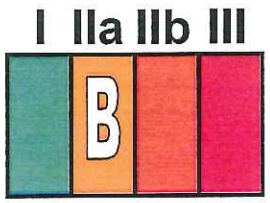
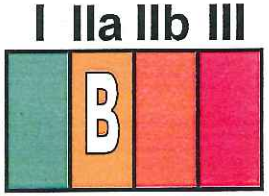
Revascularization to Improve Survival: Non-Left Main CAD Revascularization (cont.)



CABG to improve survival is reasonable in patients with significant (≥70% diameter) stenoses in 2 major coronary arteries with severe or extensive myocardial ischemia (e.g., high-risk criteria on stress testing, abnormal intracoronary hemodynamic evaluation, or >20% perfusion defect by myocardial perfusion stress imaging) or target vessels supplying a large area of viable myocardium.



CABG to improve survival is reasonable in patients with mild-moderate left ventricular systolic dysfunction (ejection fraction 35% to 50%) and significant (≥70% diameter stenosis) multivessel CAD or proximal LAD coronary artery stenosis, when viable myocardium is present in the region of intended revascularization.

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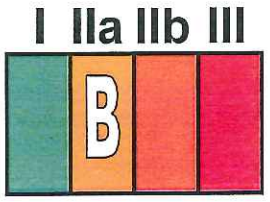
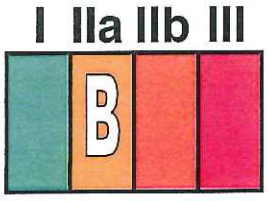
Revascularization to Improve Survival: Non-Left Main CAD Revascularization (cont.)



CABG with a LIMA graft to improve survival is reasonable in patients with a significant (≥70% diameter) stenosis in the proximal LAD artery and evidence of extensive ischemia.



It is reasonable to choose CABG over PCI to improve survival in patients with complex 3-vessel CAD (e.g., SYNTAX score >22) with or without involvement of the proximal LAD artery who are good candidates for CABG.

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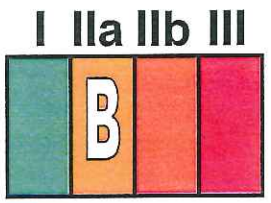
Revascularization to Improve Survival: Non-Left Main CAD Revascularization (cont.)



CABG is probably recommended in preference to PCI to improve survival in patients with multivessel CAD and diabetes mellitus, particularly if a LIMA graft can be anastomosed to the LAD artery.



The usefulness of CABG to improve survival is uncertain in patients with significant (≥70%) stenoses in 2 major coronary arteries not involving the proximal LAD artery and without extensive ischemia.

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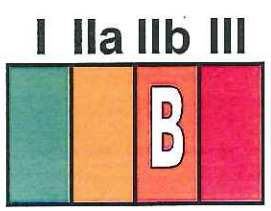
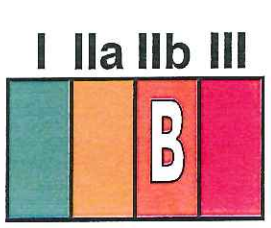
Revascularization to Improve Survival: Non-Left Main CAD Revascularization (cont.)



The usefulness of PCI to improve survival is uncertain in patients with 2- or 3-vessel CAD (with or without involvement of the proximal LAD artery) or 1-vessel proximal LAD disease.



CABG might be considered with the primary or sole intent of improving survival in patients with SIHD with severe LV systolic dysfunction (EF<35%) whether or not viable myocardium is present.



The usefulness of CABG or PCI to improve survival is uncertain in patients with previous CABG and extensive anterior wall ischemia on noninvasive testing.

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Revascularization to Improve Survival: Non-Left Main CAD Revascularization (cont.)



Harm

CABG or PCI should not be performed with the primary or sole intent to improve survival in patients with SIHD with 1 or more coronary stenoses that are not anatomically or functionally significant (e.g., <70% diameter non–left main coronary artery stenosis, fractional flow reserve >0.80, no or only mild ischemia on noninvasive testing), involve only the left circumflex or right coronary artery, or subtend only a small area of viable myocardium.

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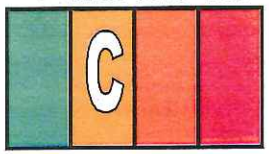
Revascularization to Improve Symptoms



CABG or PCI to improve symptoms is beneficial in patients with 1 or more significant (≥70% diameter) coronary artery stenoses amenable to revascularization and unacceptable angina despite GDMT.



CABG or PCI to improve symptoms is reasonable in patients with 1 or more significant (≥70% diameter) coronary artery stenoses and unacceptable angina for whom GDMT cannot be implemented because of medication contraindications, adverse effects, or patient preferences.

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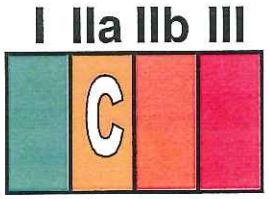
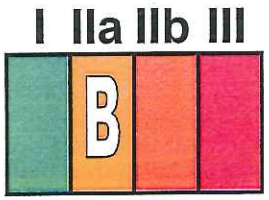
Revascularization to Improve Symptoms (cont.)



PCI to improve symptoms is reasonable in patients with previous CABG, 1 or more significant (≥70% diameter) coronary artery stenoses associated with ischemia, and unacceptable angina despite GDMT.



It is reasonable to choose CABG over PCI to improve symptoms in patients with complex 3-vessel CAD (e.g., SYNTAX score >22), with or without involvement of the proximal LAD artery who are good candidates for CABG.

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Revascularization to Improve Symptoms (cont.)



CABG to improve symptoms might be reasonable for patients with previous CABG, 1 or more significant (≥70% diameter) coronary artery stenoses not amenable to PCI, and unacceptable angina despite GDMT.



Transmyocardial laser revascularization performed as an adjunct to CABG to improve symptoms may be reasonable in patients with viable ischemic myocardium that is perfused by arteries that are not amenable to grafting.

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Revascularization to Improve Symptoms (cont.)



Harm

CABG or PCI to improve symptoms should not be performed in patients who do not meet anatomic (≥50% left main or ≥70% non–left main stenosis) or physiologic (e.g., abnormal fractional flow reserve) criteria for revascularization.

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Dual Antiplatelet Therapy Compliance and Stent Thrombosis

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Dual Antiplatelet Therapy Compliance and Stent Thrombosis



Harm

PCI with coronary stenting (BMS or DES) should not be performed if the patient is not likely to be able to tolerate and comply with DAPT for the appropriate duration of treatment based on the type of stent implanted.

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Hybrid Coronary Revascularization

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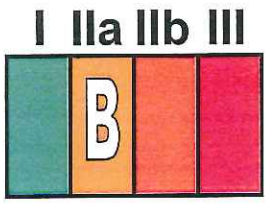
Hybrid Coronary Revascularization



Hybrid coronary revascularization (defined as the planned combination of LIMA-to-LAD artery grafting and PCI of ≥1 non-LAD coronary arteries) is reasonable in patients with 1 or more of the following:

a. Limitations to traditional CABG, such as a heavily calcified proximal aorta or poor target vessels for CABG (but amenable to PCI);

b. Lack of suitable graft conduits;

c. Unfavorable LAD artery for PCI (i.e., excessive vessel tortuosity or chronic total occlusion).

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Hybrid Coronary Revascularization (cont.)



Hybrid coronary revascularization (defined as the planned combination of LIMA-to-LAD artery grafting and PCI of ≥1 non-LAD coronary arteries) may be reasonable as an alternative to multivessel PCI or CABG in an attempt to improve the overall risk-benefit ratio of the procedures.

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Preprocedural Considerations

Radiation Safety

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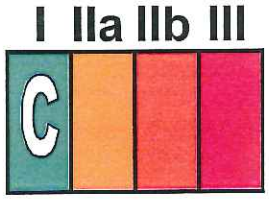
Radiation Safety



Cardiac catheterization laboratories should routinely record relevant available patient procedural radiation dose data (e.g., total air kerma at the international reference point [$K_{a,r}$], air kerma air product [P_{KA}], fluoroscopy time, number of cine images), and should define thresholds with corresponding follow-up protocols for patients who receive a high procedural radiation dose.

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Contrast-Induced Acute Kidney Injury

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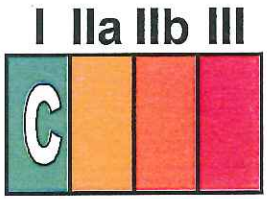
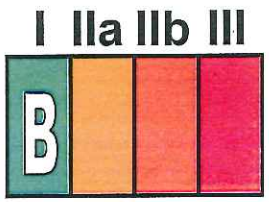
Contrast-Induced Acute Kidney Injury



Patients should be assessed for risk of contrast-induced AKI before PCI.



Patients undergoing cardiac catheterization with contrast media should receive adequate preparatory hydration.



In patients with CKD (Crcl <60 mL/min), the volume of contrast media should be minimized.

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Contrast-Induced Acute Kidney Injury (cont.)



No Benefit

Administration of N-acetyl-L-cysteine is not useful for the prevention of contrast-induced AKI.

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Preprocedural Considerations

Anaphylactoid Reactions

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Anaphylactoid Reactions



Patients with prior evidence of an anaphylactoid reaction to contrast media should receive appropriate steroid and antihistamine prophylaxis before repeat contrast administration.



No Benefit

In patients with a prior history of allergic reactions to shellfish or seafood, anaphylactoid prophylaxis for contrast reaction is not beneficial.

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Preprocedural Considerations

Statin Treatment

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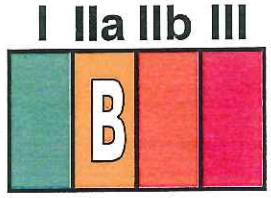
Statin Treatment

Statin-naive patients:



Administration of a high-dose statin is reasonable before PCI to reduce the risk of periprocedural MI.

Patients on chronic statin therapy:



Administration of a high-dose statin is reasonable before PCI to reduce the risk of periprocedural MI.

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Preprocedural Considerations

Bleeding Risk

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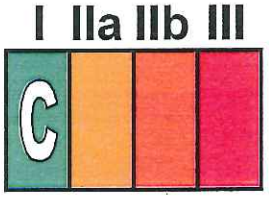
Bleeding Risk



All patients should be evaluated for risk of bleeding before PCI.

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PCI in Hospitals Without On-Site Surgical Backup

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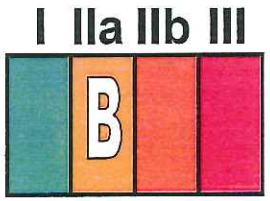
PCI in Hospitals Without On-Site Surgical Backup



Primary PCI is reasonable in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished.



Elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection.

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PCI in Hospitals Without On-Site Surgical Backup (cont.)



Harm

Primary or elective PCI should not be performed in hospitals without on-site cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without appropriate hemodynamic support capabilities for transfer.

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Procedural Considerations

Vascular Access

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Vascular Access



The use of radial artery access can be useful to decrease access site complications.

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PCI in Specific Clinical Situations

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PCI in Specific Clinical Situations: UA/NSTEMI



An early invasive strategy (i.e., diagnostic angiography with intent to perform revascularization) is indicated in UA/NSTEMI patients who have refractory angina or hemodynamic or electrical instability (without serious comorbidities or contraindications to such procedures).

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PCI in Specific Clinical Situations: UA/NSTEMI (cont.)



An early invasive strategy (i.e., diagnostic angiography with intent to perform revascularization) is indicated in initially stabilized UA/NSTEMI patients (without serious comorbidities or contraindications to such procedures) who have an elevated risk for clinical events.

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PCI in Specific Clinical Situations: UA/NSTEMI (cont.)



The selection of PCI or CABG as the means of revascularization in the patient with ACS should generally be based on the same considerations as those without ACS.

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PCI in Specific Clinical Situations: UA/NSTEMI (cont.)



No Benefit

An early invasive strategy (i.e., diagnostic angiography with intent to perform revascularization) is not recommended in patients with extensive comorbidities (e.g., liver or pulmonary failure, cancer) in whom

a. The risks of revascularization and comorbid conditions are likely to outweigh the benefits of revascularization,

b. There is a low likelihood of ACS despite acute chest pain, or

c. Consent to revascularization will not be granted regardless of the findings.

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PCI in Specific Clinical Situations: STEMI

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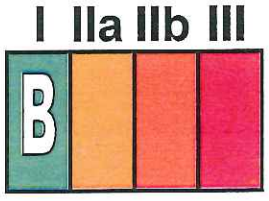
PCI in Specific Clinical Situations: STEMI–Coronary Angiography

Strategies in STEMI



A strategy of immediate coronary angiography with intent to perform PCI (or emergency CABG) in patients with STEMI is recommended for

a. Patients who are candidates for primary PCI.



b. Patients with severe heart failure or cardiogenic shock who are suitable candidates for revascularization.

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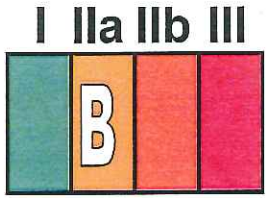
PCI in Specific Clinical Situations: STEMI–Coronary Angiography Strategies in STEMI (cont.)



A strategy of immediate coronary angiography (or transfer for immediate coronary angiography) with intent to perform PCI is reasonable for patients with STEMI, a moderate to large area of myocardium at risk, and evidence of failed fibrinolysis.

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PCI in Specific Clinical Situations: STEMI–
Coronary Angiography Strategies in STEMI (cont.)



A strategy of coronary angiography (or transfer for coronary angiography) 3 to 24 hours after initiating fibrinolytic therapy with intent to perform PCI is reasonable for hemodynamically stable patients with STEMI and evidence for successful fibrinolysis when angiography and revascularization can be performed as soon as logistically feasible in this time frame.

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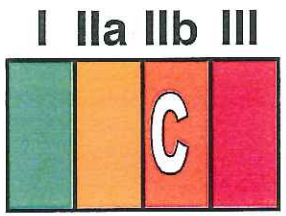
PCI in Specific Clinical Situations: STEMI–Coronary Angiography Strategies in STEMI (cont.)



A strategy of coronary angiography performed before hospital discharge might be reasonable in stable patients with STEMI who did not undergo cardiac catheterization within 24 hours of STEMI onset.

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PCI in Specific Clinical Situations: STEMI–Coronary Angiography Strategies in STEMI (cont.)



No Benefit

A strategy of coronary angiography with intent to perform PCI is not recommended in patients with STEMI in whom the risks of revascularization are likely to outweigh the benefits or when the patient or designee does not want invasive care.

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Procedural Considerations

PCI in Specific Clinical Situations: Primary PCI of the Infarct Artery

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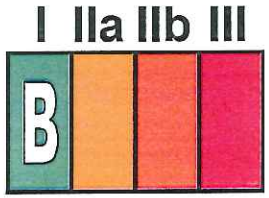
PCI in Specific Clinical Situations: STEMI–Primary PCI of the Infarct Artery



Primary PCI should be performed in patients within 12 hours of onset of STEMI.



Primary PCI should be performed in patients with STEMI presenting to a hospital with PCI capability within 90 minutes of first medical contact as a systems goal.

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PCI in Specific Clinical Situations: STEMI–Primary PCI of the Infarct Artery (cont.)



Primary PCI should be performed in patients with STEMI presenting to a hospital without PCI capability within 120 minutes of first medical contact as a systems goal.



Primary PCI should be performed in patients with STEMI who develop severe heart failure or cardiogenic shock and are suitable candidates for revascularization as soon as possible, irrespective of time delay.

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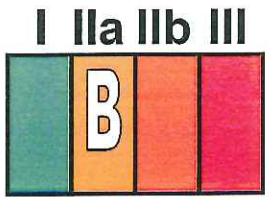
PCI in Specific Clinical Situations: STEMI–Primary PCI of the Infarct Artery (cont.)



Primary PCI should be performed as soon as possible in patients with STEMI and contraindications to fibrinolytic therapy with ischemic symptoms for <12 hours.



Primary PCI is reasonable in patients with STEMI if there is clinical and/or electrocardiographic evidence of ongoing ischemia between 12 and 24 hours after symptom onset.

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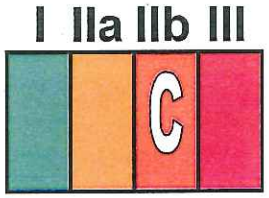
PCI in Specific Clinical Situations: STEMI–Primary PCI of the Infarct Artery (cont.)



Primary PCI might be considered in asymptomatic patients with STEMI and higher risk presenting between 12 and 24 hours after symptom onset.



Harm

PCI should not be performed in a noninfarct artery at the time of primary PCI in patients with STEMI without hemodynamic compromise.

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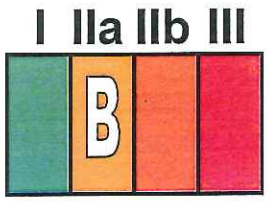
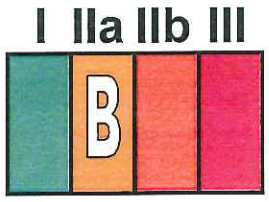
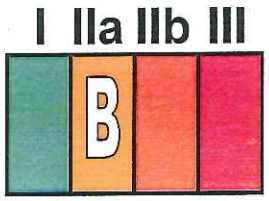
Delayed or Elective PCI in Patients with STEMI



PCI is reasonable in patients with STEMI and clinical evidence for fibrinolytic failure or infarct artery reocclusion.



PCI is reasonable in patients with STEMI and a patent infarct artery 3 to 24 hours after fibrinolytic therapy.



PCI is reasonable in patients with STEMI who demonstrate ischemia on noninvasive testing.

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Delayed or Elective PCI in Patients with STEMI



PCI of a hemodynamically significant stenosis in a patent infarct artery >24 hours after STEMI may be considered as part of an invasive strategy.



PCI of a totally occluded infarct artery >24 hours after STEMI should not be performed in asymptomatic patients with 1- or 2-vessel disease if patients are hemodynamically and electrically stable and do not have evidence of severe ischemia.

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PCI in Specific Clinical Situations: Cardiogenic Shock



PCI is recommended for patients with acute MI who develop cardiogenic shock and are suitable candidates.



A hemodynamic support device is recommended for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacologic therapy.

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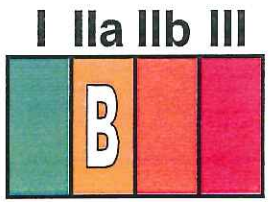
PCI in Specific Clinical Situations: Revascularization Before Noncardiac Surgery



For patients who require PCI and who are scheduled for elective noncardiac surgery in the subsequent 12 months, a strategy of balloon angioplasty, or BMS implantation followed by 4 to 6 weeks of DAPT, is reasonable.

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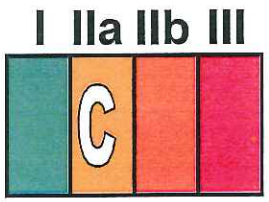
PCI in Specific Clinical Situations: Revascularization Before Noncardiac Surgery



For patients with a DES who must undergo urgent surgical procedures that mandate the discontinuation of DAPT, it is reasonable to continue aspirin if possible and restart the $P2Y_{12}$ inhibitor as soon as possible in the immediate postoperative period.

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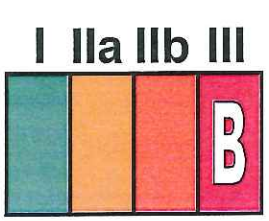
PCI in Specific Clinical Situations: Revascularization Before Noncardiac Surgery



Harm

Routine prophylactic coronary revascularization should not be performed in patients with stable CAD before noncardiac surgery.



Harm

Elective noncardiac surgery should not be performed in the 4 to 6 weeks after balloon angioplasty or BMS implantation or the 12 months after DES implantation in patients in whom the $P2Y_{12}$ inhibitor will need to be discontinued perioperatively.

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Procedural Considerations

Coronary Stents

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Coronary Stents



Before implantation of DES, the interventional cardiologist should discuss with the patient the need for and duration of DAPT and the ability of the patient to comply with and tolerate DAPT.



PCI/STEMI



UA/NSTEMI

DES is useful as an alternative to BMS to reduce the risk of restenosis in cases in which the risk of restenosis is increased and the patient is likely to be able to tolerate and comply with prolonged DAPT.

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Coronary Stents (cont.)



Balloon angioplasty or BMS should be used in patients with high bleeding risk, inability to comply with 12 months of DAPT, or with anticipated invasive or surgical procedures within the next 12 months during which time DAPT may be interrupted.

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Coronary Stents (cont.)



Harm

PCI with coronary stenting should not be performed if the patient is not likely to be able to tolerate and to comply with DAPT.



Harm

DES should not be implanted if the patient is not likely to be able to tolerate and comply with prolonged DAPT, or this cannot be determined prior to stent implantation.

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Adjunctive Diagnostic Devices

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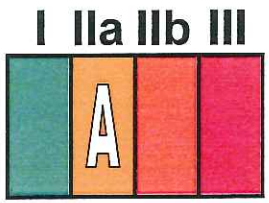
Fractional Flow Reserve



FFR is reasonable to assess angiographic intermediate coronary lesions (50% to 70% diameter stenosis) and can be useful in guiding revascularization decisions in patients with SIHD.

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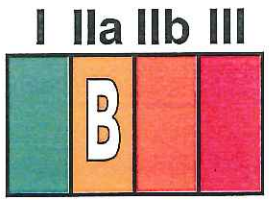
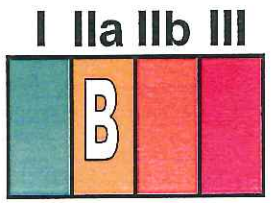
Intravascular Ultrasound



IVUS is reasonable for the assessment of angiographically indeterminate left main CAD.



IVUS and coronary angiography are reasonable 4 to 6 weeks and 1 year after transplantation to exclude donor CAD, to detect rapidly progressive cardiac allograft vasculopathy, and to provide prognostic information.

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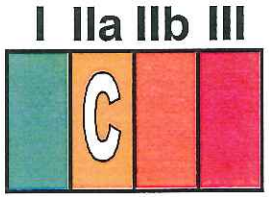
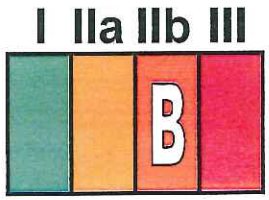
Intravascular Ultrasound (cont.)



IVUS is reasonable to determine the mechanism of stent restenosis.



IVUS may be reasonable for the assessment of non-left main coronary arteries with angiographically intermediate coronary stenoses (50% to 70% diameter stenosis).

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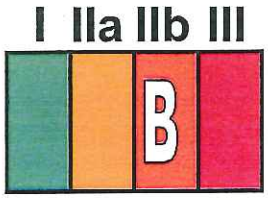
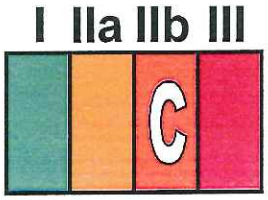
Intravascular Ultrasound (cont.)



IVUS may be considered for guidance of coronary stent implantation, particularly in cases of left main coronary artery stenting.



IVUS may be reasonable to determine the mechanism of stent thrombosis.



No Benefit

IVUS for routine lesion assessment is not recommended when revascularization with PCI or CABG is not being contemplated.

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Procedural Considerations

Adjunctive Therapeutic Devices

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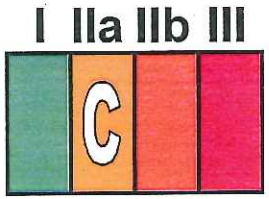
Coronary Atherectomy



Rotational atherectomy is reasonable for fibrotic or heavily calcified lesions that might not be crossed by a balloon catheter or adequately dilated before stent implantation.



No Benefit

Rotational atherectomy should not be performed routinely for de novo or in-stent restenosis.

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Thrombectomy



Aspiration thrombectomy is reasonable for patients undergoing primary PCI.

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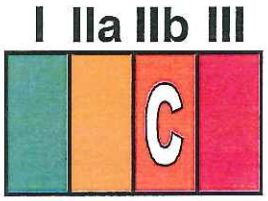
Laser Angioplasty



Laser angioplasty might be considered for fibrotic or moderately calcified lesions that cannot be crossed or dilated with conventional balloon angioplasty.



No Benefit

Laser angioplasty should not be used routinely during PCI.

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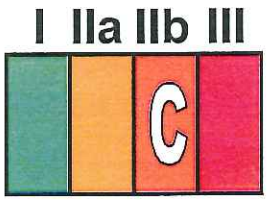
Cutting Balloon Angioplasty



Cutting balloon angioplasty might be considered to avoid slippage-induced coronary artery trauma during PCI for in-stent restenosis or for ostial lesions in side branches.



No Benefit

Cutting balloon angioplasty should not be performed routinely during PCI.

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Embolic Protection Devices



Cutting balloon angioplasty should not be performed routinely during PCI.

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Percutaneous Hemodynamic Support Devices

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Percutaneous Hemodynamic Support Devices



Elective insertion of an appropriate hemodynamic support device as an adjunct to PCI may be reasonable in carefully selected high-risk patients.

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Oral Antiplatelet Therapy



Patients already taking daily aspirin therapy should take 81 to 325 mg prior to PCI.



Patients not on aspirin therapy should be given nonenteric aspirin 325 mg prior to PCI.



After PCI, aspirin should be continued indefinitely.

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Oral Antiplatelet Therapy (cont.)



A loading dose of a $P2Y_{12}$ receptor inhibitor should be given to patients undergoing PCI with stenting. Options include:



a. Clopidogrel 600 mg (ACS and non-ACS patients).

b. Prasugrel 60 mg (ACS patients).

c. Ticagrelor 180 mg (ACS patients).

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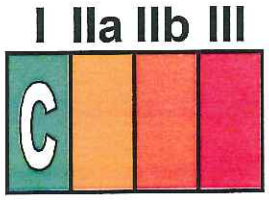
Oral Antiplatelet Therapy (cont.)



The loading dose of clopidogrel for patients undergoing PCI after fibrinolytic therapy should be 300 mg within 24 hours and 600 mg more than 24 hours after receiving fibrinolytic therapy.



Patients should be counseled on the need for and risks of DAPT before placement of intracoronary stents, especially a DES, and alternative therapies should be pursued if they are unwilling or unable to comply with the recommended duration of DAPT.

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Oral Antiplatelet Therapy (cont.)



The duration of $P2Y_{12}$ inhibitor therapy after stent implantation should generally be as follows:

a)In patients receiving a stent (BMS or DES) during PCI for ACS, $P2Y_{12}$ inhibitor therapy should be given for at least 12 months. Options include: clopidogrel 75 mg daily, prasugrel 10 mg daily, and ticagrelor 90 mg twice daily.

b) In patients receiving a DES for a non–ACS indication, clopidogrel 75 mg daily should be given for at least 12 months if patients are not at high risk of bleeding.

c)In patients receiving a BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 month and ideally up to 12 months (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks).

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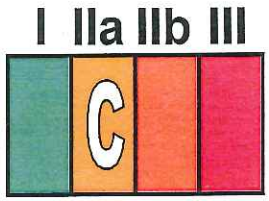
Oral Antiplatelet Therapy (cont.)



After PCI, it is reasonable to use 81 mg per day of aspirin in preference to higher maintenance doses.



If the risk of morbidity from bleeding outweighs the anticipated benefit afforded by a recommended duration of $P2Y_{12}$ inhibitor therapy after stent implantation, earlier discontinuation (e.g., <12 months) of $P2Y_{12}$ inhibitor therapy is reasonable.

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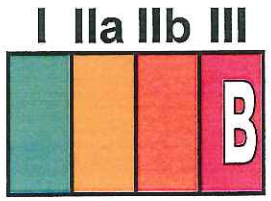
Oral Antiplatelet Therapy (cont.)



Continuation of DAPT beyond 12 months may be considered in patients undergoing DES implantation.



Harm

Prasugrel should not be administered in patients with a prior history of stroke or TIA.

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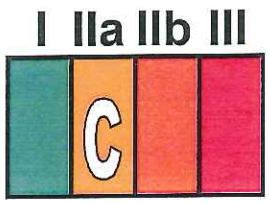
Intravenous Antiplatelet Therapy: STEMI

In patients undergoing primary PCI treated with UFH, it is reasonable to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban), whether or not pretreated with clopidogrel.



For GP IIb/IIIa inhibitor administration in patients not pretreated with clopidogrel.



For GP IIb/IIIa inhibitor administration in patients who are pretreated with clopidogrel.

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Intravenous Antiplatelet Therapy : STEMI (cont.)



In patients undergoing primary PCI with abciximab, it may be reasonable to administer intracoronary abciximab.

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Intravenous Antiplatelet Therapy: STEMI (cont.)



No Benefit

Routine precatheterization laboratory (e.g., ambulance or emergency room) administration of GP IIb/IIIa inhibitors as part of an upstream strategy for patients with STEMI undergoing PCI is not beneficial.

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Intravenous Antiplatelet Therapy : UA/NSTEMI



In UA/NSTEMI patients with high-risk features (e.g., elevated troponin level) not treated with bivalirudin and not adequately pretreated with clopidogrel, it is useful at the time of PCI to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban) in patients treated with UFH.

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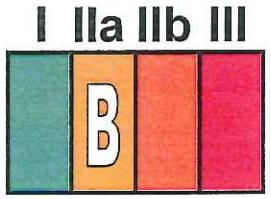
Intravenous Antiplatelet Therapy : UA/NSTEMI (cont.)



In UA/NSTEMI patients with high-risk features (e.g., elevated troponin level) treated with UFH and adequately pretreated with clopidogrel, it is reasonable at the time of PCI to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban).

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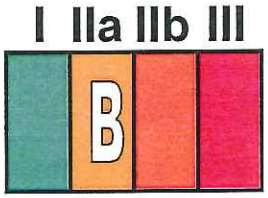
Intravenous Antiplatelet Therapy: SIHD



In patients undergoing elective PCI treated with UFH and not pretreated with clopidogrel, it is reasonable to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban).

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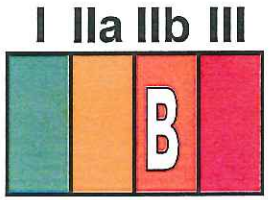
Intravenous Antiplatelet Therapy: SIHD (cont.)



In patients undergoing elective PCI with stent implantation treated with UFH and adequately pretreated with clopidogrel, it might be reasonable to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban).

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Antiocoagulant Therapy: Use of Parenteral Anticoagulants During PCI



An anticoagulant should be administered to patients undergoing PCI.

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Antiocoagulant Therapy: UFH



Administration of intravenous UFH is useful in patients undergoing PCI.

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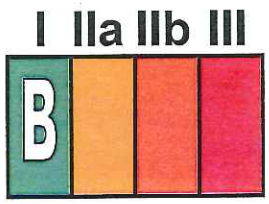
Anticoagulant Therapy: Enoxaparin



An additional dose of 0.3 mg/kg intravenous enoxaparin should be administered at the time of PCI to patients who have received <2 therapeutic subcutaneous doses (e.g., 1 mg/kg) or received the last subcutaneous enoxaparin dose 8 to12 hours prior to PCI.



Performance of PCI with enoxaparin may be reasonable in patients either treated with "upstream" subcutaneous enoxaparin for UA/NSTEMI or who have not received prior antithrombin therapy and are administered intravenous enoxaparin at the time of PCI.



UFH should not be given to patients already receiving therapeutic subcutaneous enoxaparin.

Harm

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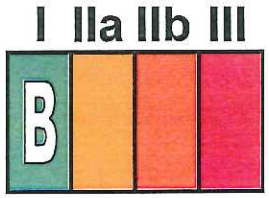
Antiocoagulant Therapy: Bivalirudin and Argatroban



For patients undergoing PCI, bivalirudin is useful as an anticoagulant with or without prior treatment with UFH.



For patients with heparin-induced thrombocytopenia, it is recommended that bivalirudin or argatroban be used to replace UFH.

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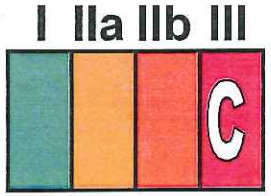
Antiocoagulant Therapy: Fondaparinux



Harm

Fondaparinux should not be used as the sole anticoagulant to support PCI. An additional anticoagulant with anti-IIa activity should be administered because of the risk of catheter thrombosis.

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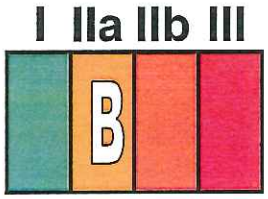
No-Reflow Pharmacologic Therapies



Administration of an intracoronary vasodilator (adenosine, calcium channel blocker, or nitroprusside) is reasonable to treat PCI-related no-reflow that occurs during primary or elective PCI.

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PCI in Specific Anatomic Situations

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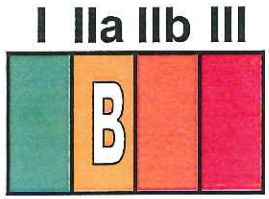
Chronic Total Occlusions



PCI of a CTO in patients with appropriate clinical indications and suitable anatomy is reasonable when performed by operators with appropriate expertise.

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Saphenous Vein Grafts

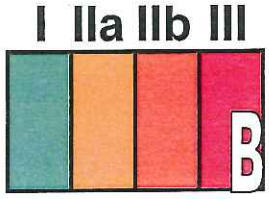


EPDs should be used during SVG PCI when technically feasible.



No Benefit

Platelet GP IIb/IIIa inhibitors are not beneficial as adjunctive therapy during SVG PCI.



Harm

PCI is not recommended for chronic SVG occlusions.

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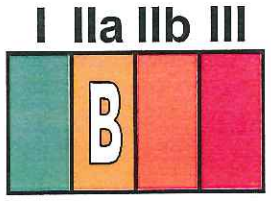
Bifurcation Lesions



Provisional side-branch stenting should be the initial approach in patients with bifurcation lesions when the side branch is not large and has only mild or moderate focal disease at the ostium.



It is reasonable to use elective double stenting in patients with complex bifurcation morphology involving a large side branch where the risk of side-branch occlusion is high and the likelihood of successful side-branch reaccess is low.

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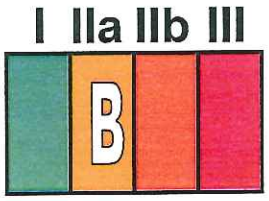
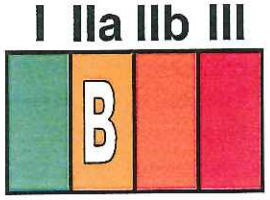
Aorto-Ostial Stenosis



IVUS is reasonable for the assessment of angiographically-indeterminant left main CAD.



Use of DES is reasonable when PCI is indicated in patients with an aorto-ostial stenosis.

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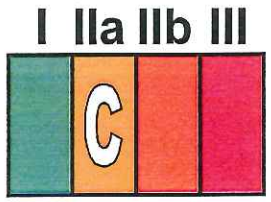
Calcified Lesions



Rotational atherectomy is reasonable for fibrotic or heavily calcified lesions that might not be crossed by a balloon catheter or adequately dilated before stent implantation.

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PCI in Specific Patient Populations

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Chronic Kidney Disease



In patients undergoing PCI, the glomerular filtration rate should be estimated and the dosage of renally-cleared medications should be adjusted.

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Periprocedural Myocardial Infarction Assessment



In patients who have signs or symptoms suggestive of MI during or after PCI, or in asymptomatic patients with significant *persistent* angiographic complications (e.g., large side-branch occlusion, flow limiting dissection, no-reflow phenomenon or coronary thrombosis), creatinine kinase-MB and troponin I or T should be measured.

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Periprocedural Myocardial Infarction Assessment (cont.)



Routine measurement of cardiac biomarkers (creatinine kinase-MB and/or troponin I or T) in all patients post-PCI may be reasonable.

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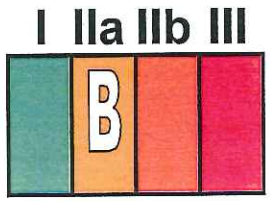
Vascular Closure Devices



Patients considered for vascular closure devices should undergo a femoral angiogram to ensure anatomic suitability for deployment.



The use of vascular closure devices is reasonable for the purposes of achieving faster hemostasis and earlier ambulation compared with the use of manual compression.



No Benefit

The routine use of vascular closure devices is not recommended for the purpose of decreasing vascular complications, including bleeding.

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Postprocedural Antiplatelet Therapy

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Helping Cardiovascular Professionals Learn. Advance. Heal.

American Heart Association.

SCAI The Society for Cardiovascular Angiography and Interventions

Postprocedural Antiplatelet Therapy



After PCI, aspirin should be continued indefinitely.

The duration of $P2Y_{12}$ inhibitor therapy after stent implantation should generally be as follows:

a) In patients receiving a stent (BMS or DES) during PCI for ACS, $P2Y_{12}$ inhibitor therapy should be given for at least 12 months (clopidogrel 75 mg daily); prasugrel 10 mg daily; and ticagrelor 90 mg twice daily.



b) In patients receiving a DES for a non–ACS indication, clopidogrel 75 mg daily should be given for at least 12 months if patients are not at high risk of bleeding.

c) In patients receiving a BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 month and ideally up to 12 months (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks).

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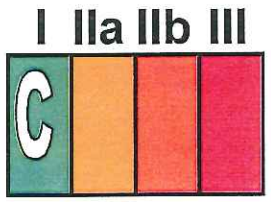
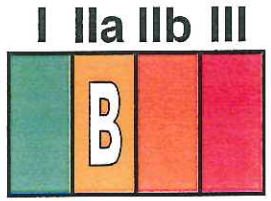
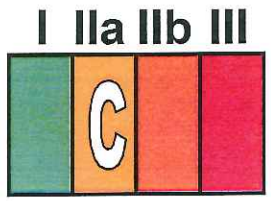
Postprocedural Antiplatelet Therapy (cont.)



Patients should be counseled on the importance of compliance with DAPT, and that therapy should not be discontinued before discussion with the relevant cardiologist.



After PCI, it is reasonable to use 81 mg per day of aspirin in preference to higher maintenance doses.



If the risk of morbidity from bleeding outweighs the anticipated benefit afforded by a recommended duration of $P2Y_{12}$ inhibitor therapy after stent implantation, earlier discontinuation (e.g., >12 months) of $P2Y_{12}$ inhibitor therapy is reasonable.

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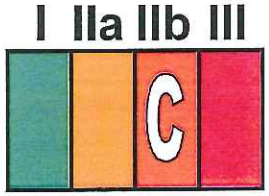
Postprocedural Antiplatelet Therapy (cont.)



Continuation of clopidogrel, prasugrel or ticagrelor beyond 12 months may be considered in patients undergoing DES placement.

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Proton Pump Inhibitors and Antiplatelet Therapy

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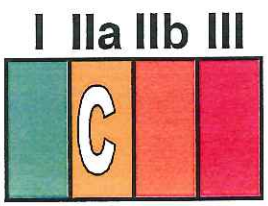
PPIs and Antiplatelet Therapy



PPI should be used in patients with history of prior GI who require DAPT.



PPI use is reasonable in patients with increased risk of gastrointestinal bleeding (advanced age, concomitant use of warfarin, steroids, nonsteroidal anti-inflammatory drugs, H pylori infection, etc.) who require DAPT.



No Benefit

Routine use of a PPI is not recommended for patients at low risk of gastrointestinal bleeding, who have much less potential to benefit from prophylactic therapy.

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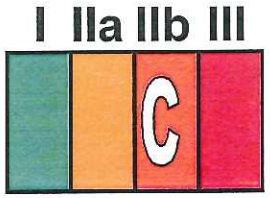
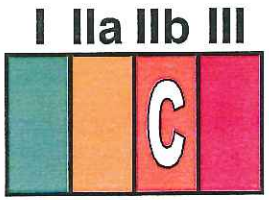
Clopidogrel Genetic Testing



Genetic testing might be considered to identify whether a patient at high risk for poor clinical outcomes is predisposed to inadequate platelet inhibition with clopidogrel.



When a patient predisposed to inadequate platelet inhibition with clopidogrel is identified by genetic testing, treatment with an alternate $P2Y_{12}$ inhibitor (e.g., prasugrel or ticagrelor) might be considered.



No Benefit

The routine clinical use of genetic testing to screen clopidogrel-treated patients undergoing PCI is not recommended.

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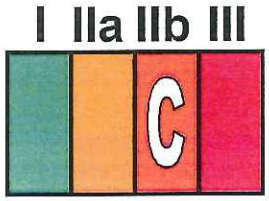
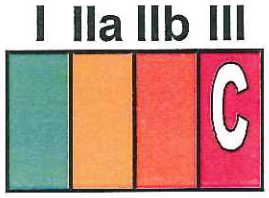
Platelet FunctionTesting



Platelet function testing may be considered in patients at high risk for poor clinical outcomes.



In clopidogrel-treated patients with high platelet reactivity, alternative agents, such as prasugrel or ticagrelor, might be considered.



No Benefit

The routine clinical use of platelet function testing to screen clopidogrel-treated patients undergoing PCI is not recommended.

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Restenosis



Patients who develop clinical restenosis after balloon angioplasty should be treated with BMS or DES if anatomic factors are appropriate and if the patient is able to comply with and tolerate DAPT.



Patients who develop clinical restenosis after BMS should be treated with DES if anatomic factors are appropriate and the patient is able to comply with and tolerate DAPT.

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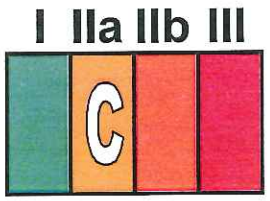
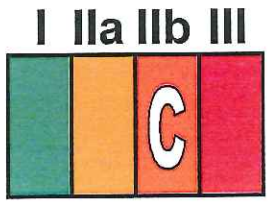
Restenosis (cont.)



IVUS is reasonable to determine the mechanism of stent restenosis.



Patients who develop clinical restenosis after DES may be considered for repeat PCI with balloon angioplasty, BMS, or DES containing the same drug or an alternative antiproliferative drug if anatomic factors are appropriate and patient is able to comply with and tolerate DAPT.

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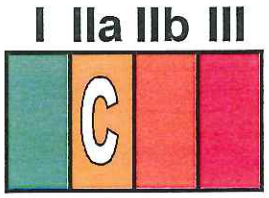
Exercise Testing



In patients entering a formal cardiac rehabilitation program after PCI, treadmill exercise testing is reasonable.



No Benefit

Routine, periodic stress testing of asymptomatic patients after PCI without specific clinical indications should not be performed.

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Cardiac Rehabilitation



Medically-supervised exercise programs (cardiac rehabilitation) should be recommended to patients after PCI, particularly for moderate- to high-risk patients for whom supervised exercise training is warranted.

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Quality and Performance

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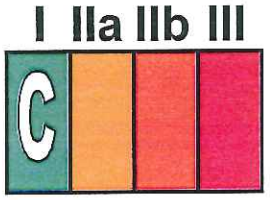
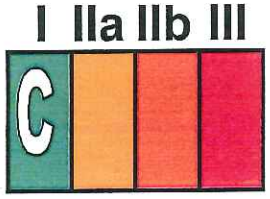
Quality and Performance



Every PCI program should operate a quality improvement program that routinely: a) reviews quality and outcomes of the entire program; b) reviews results of individual operators; c) includes risk adjustment; d) provides peer review of difficult or complicated cases, and; e) performs random case reviews.



Every PCI program should participate in a regional or national PCI registry for the purpose of benchmarking its outcomes against current national norms.

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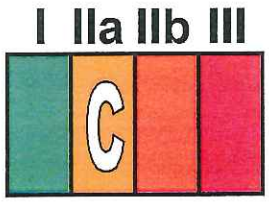
Certification and Maintenance of Certification



It is reasonable for all physicians that perform PCI to participate in the American Board of Internal Medicine interventional cardiology board certification and maintenance of certification program.

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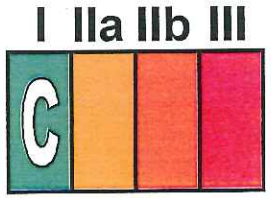
Operator and Institutional Competency and Volume



Elective/urgent PCI should be performed by operators with acceptable annual volume (≥75 procedures) at high-volume centers (>400 procedures) with onsite cardiac surgery.



Elective/urgent PCI should be performed by operators and institutions whose current risk-adjusted outcomes statistics are comparable to those reported in contemporary national data registries.

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Operator and Institutional Competency and Volume (cont.)



Primary PCI for STEMI should be performed by experienced operators who perform more than 75 elective PCI procedures per year and, ideally, at least 11 PCI procedures for STEMI per year. Ideally, these procedures should be performed in institutions that perform more than 400 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year.



It is reasonable that operators with acceptable volume (≥75 PCI procedures per year) perform elective/urgent PCI at low-volume centers (200 to 400 PCI procedures per year) with onsite cardiac surgery.

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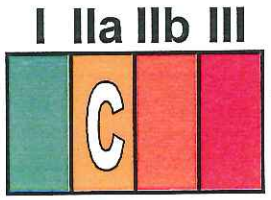
Operator and Institutional Competency and Volume (cont.)



It is reasonable that low-volume operators (<75 PCI procedures per year) perform elective/urgent PCI at high-volume centers (>400 PCI procedures per year) with onsite cardiac surgery. Ideally, operators with an annual procedure volume <75 should only work at institutions with an activity level of more than 600 procedures per year. Operators who perform <75 procedures per year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume of at least 150 procedures per year.

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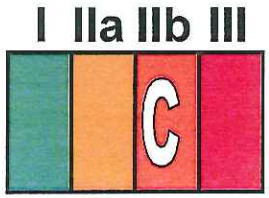
Operator and Institutional Competency and Volume (cont.)



The benefit of primary PCI for STEMI patients eligible for fibrinolysis when performed by an operator who performs <75 procedures per year (<11 PCIs for STEMI per year) is not well established.



No Benefit

It is not recommended that elective/urgent PCI be performed by low-volume operators (<75 procedures per year) at low-volume centers (200 to 400 procedures per year) with or without onsite cardiac surgery. An institution with a volume of <200 procedures per year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer this service.

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Advisory Board Company Daily Briefing

The Daily Briefing

For PCI, no surgeons required

STUDY: ELECTIVE PCI NO LONGER REQUIRES ON-SITE SURGICAL BACKUP

November 16, 2011

Hospitals without on-site cardiac surgery perform elective percutaneous coronary interventions (PCIs) as safely as facilities that have on-site surgical backup, according to a study presented at the **American Heart Association**'s (AHA) annual meeting.

Each year, nearly one million PCIs are performed in the United States, and most of those cases are non-emergency procedures for patients experiencing chest pain. The AHA and the **American College of Cardiologists** currently recommend that PCI be performed only at hospitals that offer coronary artery bypass grafting procedures. Many states also have criteria for which hospitals can offer PCI.

For the first large study to investigate surgical backup for elective PCI procedures, **Johns Hopkins University** researchers assessed data for 4,500 patients who underwent PCI at hospitals with an available cardiovascular surgeon and 14,000 patients who underwent PCI at hospitals without on-site surgical backup. Hospitals performing the procedure with no surgeon on duty were required to complete special PCI training and perform at least 200 PCI procedures annually.

The study found that success, complication, and death rates did not vary between the two patient groups in the six weeks after the procedure. In addition, surgery was only necessary in 30 cases, and patients at hospitals with no on-site surgical backup were transferred to another facility.

The researchers said they hope the findings provide evidence to policymakers that performing elective PCI at smaller community hospitals is safe. However, they warn that not all hospitals should offer the procedure. "Having the ability to perform elective cases, as well as emergency ones, increases quality that comes with more experience," says Thomas Aversano, the study's lead author.

The findings ultimately may prompt regulatory changes that could effectively decouple PCI and open heart surgery, allowing more flexibility for hospitals pursuing a regionalization strategy (Marchione, *AP/Google*, 11/14; *Medical News Today*, 11/15; Phend, *MedPage Today*, 11/14; Phend, *MedPage Today*, 11/15).

November 16, 2011
Daily Briefing

ATTACHMENT X

Curriculum Vitae

FRANK A. CORVINO
408 West Lyon Farm Drive
Greenwich, CT 06831

(203)863-3901 office
(203)344-9612 home

PROFESSIONAL EXPERIENCE

President and Chief Executive Officer	Greenwich Hospital Greenwich, Connecticut	November 1991 - Present
Executive Vice President	Yale New Haven Health System	1998 - Present

Selected Accomplishments:

- Work with Yale New Haven Health System to develop strategic goals and initiatives.
- Facilitated the affiliation with Yale New Haven Health System in 1997.
- Developed a Strategic Plan and Mission Statement in concert with the Board of Trustees, Medical Staff and Community to position Greenwich Hospital for health care delivery in the 21st century.
- Maintained a positive financial position for the institution.
- Aided the Medical Staff in the development of an IPA and developed a hospital-physician partnership.
- Developed integrated approach to health care delivery in the Town of Greenwich.
- Developed and implemented a culture change to the Continuous Quality Improvement philosophy.
- Developed and implemented a communications and community education program.
- Obtained approval from the State of Connecticut for $240 million replacement hospital.
- Developed and opened a free-standing Cancer Center.
- Developed and implemented strategies to increase market share and utilization.
- Led the hospital in its effort to raise $140 million for its Capital Campaign.
- Currently, implementing a plan to effectively downsize and re-engineer the organization to more efficiently deliver higher quality patient care.
- Developed with town government a plan for prevention and wellness.
- Developed a strategic plan with the Board of Directors on affiliations and integration of healthcare.

Chief Operating Officer	Greenwich Hospital	July 1988- November 1991

Selected Accomplishments:

- Responsible for all inpatient and outpatient hospital operations as well as operations of subsidiary corporations of Greenwich Hospital Association Corporation, the Holding Company. These subsidiaries include the following: two walk-in centers, nurse registry, for-profit pharmacy, and real estate company.
- Worked with the President to develop goals and objectives for the hospital and sister corporations in concert with policies set forth by the Board.
- Developed and implemented a marketing and planning department.
- Worked with the Chief Financial Officer in a multi-disciplinary committee structure to reduce accounts receivable by 60 days.
- Developed and implemented a new Quality Assurance, Risk Management Program.
- Worked with the Connecticut Commission on Hospitals and Health Care, the Greenwich Planning and Zoning Commission, and the Building Committee of the Board in preparation for an $117 million renovation and expansion project which includes a free-standing Cancer Center, a 610-car parking garage and modernization of the main hospital.

Chief Operating Officer/Executive Vice President	Our Lady of Mercy Medical Center Bronx, New York	September 1987 - July 1988

Selected Accomplishments:

- Responsible for all inpatient and outpatient hospital operations.
- Worked with the Board of Trustees, Administrative Staff and Medical Staff to develop a strategy for dealing with the nursing shortage.
- Implemented policies and procedures which brought the Medical Center into compliance with new Quality Assurance and Credentialing Regulations.
- Developed a free-standing Department of Emergency Medicine and insured compliance with EMS 911 receiving hospital standards.
- Participated in corporate restructuring plan at Our Lady of Mercy Medical Center in which OLM Holding Company and its subsidiaries were formed.
- Participated in planning and negotiations for acquisition or merger of other health care facilities.

Senior Vice President Professional Services	Our Lady of Mercy Medical Center	July 1986 - September 1987

Selected Accomplishments:

- Worked with Staff to improve clinical departmental operations in order that optimum patient care be delivered in a cost effective efficient way.
- Coordinated application and participated in on-site visit which led to approval of a free-standing residency program in Obstetrics and Gynecology in 1987.
- Developed a program to bring the Institution into compliance with Organ Donation Law.
- Implemented a system of generic screens in the Utilization Review - Quality Assurance departments.
- Developed a working relationship with the Medical Staff in both problem solving an institutional policies and procedures.
- Implemented a guest relations program.

Vice President Medical Support Services	Our Lady of Mercy Medical Center	September 1981 - July 1986

Selected Accomplishments:

- Implemented a computer and case mix management system for Admitting, Medical Records and Utilization Review.
- Designed and implemented a pre-admission testing center.
- Developed a process for effectively dealing with Federal Medicare regulations and Peer Review Organizations.
- Developed policies and strategies which have increased admissions, decreased length of stay and increased efficiency of ancillaries.
- Made numerous educational presentations on all facets of hospital administration at the national, statewide and local level.

Director of Pharmacy and Materials Management	Our Lady of Mercy Medical Center	February 1980 - September 1981

Selected Accomplishments:

- Formulated and implemented a materials management system.
- Coordinated equipment purchase for a $54 million expansion and renovation project.

Director of Pharmacy Services	Our Lady of Mercy Medical Center	February 1979 - February 1980
Asst. Director of Pharmacy Services	Our Lady of Mercy Medical Center	March 1973 - February 1979
Staff Pharmacist	Our Lady of Mercy Medical Center	June 1971 - February 1973

EDUCATION

Fordham University, B.S.	1971
St. John's University, M.S.	1973

FACULTY POSITIONS

New York Medical College - September 1985 - 1990
Clinical Assistant Professor
School of Community and Preventive Medicine

St. John's University - September 1973 - 1988
College of Pharmacy and Allied Health Professions
Affiliated Clinical Professor of Clinical Pharmacy

COMMUNITY AND PROFESSIONAL AFFILIATIONS

- Member - Board of Trustees - Connecticut Hospital Association, 1994 - 2000
- Member - Board of Directors, United Way of Greenwich, 1992 - 1996
- Member - Board of Directors, Boys & Girls Club of Greenwich, 1993 - 1995
- Member - Rotary International, Greenwich Chapter, 1990 - 1994
- Member - American College of Health Care Executives
- Member - Board of Directors, Connecticut Hospital Association Workers' Compensation Trust, 1991 - 1993
- Member of the Board of Pharmacy, Department of Education, State of New York, 1985 – 1988
- Member - Board of Trustees – Norwalk Community College, 2005 to present
- Member – Board of Trustees – Providence Rest Nursing Home, 2003
  Chairman - 2008

EUGENE J. COLUCCI

76 Wilmot Road
Scarsdale, New York 10583
(914) 725-8509

EXPERIENCE

GREENWICH HOSPITAL 1989 to Present
Greenwich, Connecticut

CHIEF FINANCIAL OFFICER

Direct all areas of financial management for a 176-bed acute care facility. These include General Accounting, Budget, Reimbursement, Accounts Receivable, Credit, Collections, Registration, Medical Records, Case Management and Information Systems. Oversee a staff of 225 employees, including the hiring and supervision of management staff. Investigate, plan and monitor areas for new business development. Review investment strategies and develop long and short-term plans to maximize return on assets.

THE MOUNT VERNON HOSPITAL 1985 to 1989
Mount Vernon, New York

CHIEF FINANCIAL OFFICER/CONTROLLER
Direct all aspects of financial management for a 223-bed acute care facility. These include General Accounting, Medical Records, Purchasing, Budget, Reimbursement, Accounts Receivable, Credit, Collections, Admissions and Data Processing Departments. Oversee a staff of 120 employees, including the hiring and supervision of management staff. Investigate, plan and monitor areas for new business development. Review investment strategies and develop long and short-term plans to maximize return on assets.

TOUCHE ROSS & COMPANY 1981 to 1985
New York, New York

AUDIT MANAGER

Supervised financial audits of hospitals. Prepared analyses and reports utilizing various software packages on personal computers. Assisted clients in implemented procedures to ensure collection of detailed financial information.

NEW YORK CITY HEALTH AND HOSPITALS CORP. 1977 to 1981
New York, New York

ASSISTANT DIRECTOR OF REIMBURSEMENT

Coordinated reimbursement reports and third party audits for 18 hospitals and 5 SNFs. Initiated Medicare appeals for cost adjustments.

BLUE CROSS AND BLUE SHIELD 1976 to 1977
New York, New York

AUDITOR

Conducted Blue Cross, Medicaid and Medicare audits on the uniform financial reports.

EDUCATION

ST. JOHN'S UNIVERSITY, Jamaica, New York
M.B.A. - 1979

NIAGARA UNIVERSITY, Niagara Falls, New York
B.B.A. Accounting – 1976

CERTIFICATION

Certified Public Accountant, State of New York – 1984

AFFILIATIONS

American Institute of Certified Public Accountants
New York State Institute of Certified Public Accountants
Healthcare Financial Management Association

REFERENCES

Available upon request.

QUINTON J. FRIESEN
2 Revere Road
Riverside, Connecticut 06878

(203) 863-3903 Office
(203) 698-1722 Home

SUMMARY OF QUALIFICATIONS

Hospital executive with proven track record achieving operational improvements in a highly competitive environment. Career reflects thirty-five years of progressively responsible positions in all aspects of hospital operations, total quality management, budget and financial performance, strategic planning, policy analysis, program planning and implementation.

PROFESSIONAL EXPERIENCE

Executive Vice President - and Chief Operating Officer — **Greenwich Hospital, Greenwich, Connecticut (174 bed, community teaching hospital, $280 million budget, 1600 employees)** — **2003 – Present**

Senior Vice President - and Chief Operating Officer — **Greenwich Hospital** — **1993 - 2003**

Selected Accomplishments:

- **Reorganized hospital around six service lines; recruited and appointed program directors. Wrote program strategic plans, implemented strategic plans.**
- **Directed hospital re-engineering and redesign process designed to streamline major hospital systems and to significantly reduce hospital costs.**
- **Lead facility program planning effort to construct a 400,000 sq. ft. replacement facility valued at $230 million. Coordinated with finance, legal, zoning and planning.**
- **Supervised new hospital construction; directed activation/occupancy process; facilitated training of physicians, staff and volunteers.**
- **Lead and facilitated service excellence, resulting in patient satisfaction greater than or equal to 98% for nine years.**
- **Installed hospital productivity reporting system with benchmark standards in all operating departments; implemented variable staffing system.**
- **Directed efforts to write mission, vision, values, and goal statements in all operating departments; 650 employees participated in writing departmental mission, vision, values, and goal statements.**
- **Lead interventional cardiology program planning and implementation.**

1991-1993

Executive Vice President - and Chief Operating Officer — **Champlain Valley Physicians Hospital Medical Center, Plattsburgh, New York (420 beds, rural referral center, $66 million budget, 1,500 employees)**

Selected Accomplishments:

- **Developed strategic and operational plan to revitalize Human Resources function; introduced organizational development activities; recruited and appointed Vice President/Human Resources to provide organizational leadership; organized policy/ procedure writing process, and coordinated implementation of two first term union contracts.**

- Directed planning and implementation of hospital-wide managerial/supervisory compensation system, pay practices clarified, and compensation policy and procedure written.

- Implemented hospital-wide team building effort involving nearly 140 department managers and supervisors; directed successful effort to write hospital mission, vision, and values statement linked with 45 department mission, vision, and values statements.

- Built total quality management infrastructure; established and currently implementing four quality management teams who are studying their customers' needs and wants, and what can be done to improve customer satisfaction.

- Organized and directed more than 30 departmental total improvement teams.

- Negotiated hospital based physician contracts that resulted in appropriate renewal terms while maintaining positive medical staff/administration relations.

- Established physician/administrative capital budget committee to review and recommend purchase of capital budget items.

1981 - 1991

Vice President - The Valley Hospital, Ridgewood, New Jersey
(421 beds, $118 million budget, 2,200 employees)

1980 - 1981

Assistant Director - The Valley Hospital, Ridgewood, New Jersey

Selected Accomplishments:

- Organized and managed installation of cardiac surgery/angioplasty program that completed nearly 400 cases in its first year of operation. Program implemented in 139 days.

- Directed planning process for new facilities valued in excess of $45 million; facilities occupied and functioning as planned, included OR, Lab, Radiology, and Obstetrics.

- Planned and implemented four hospital joint ventures that opened a free standing magnetic resonance imaging center - $3.6 million capitalization accomplished through a SEC registered offering.

- Created and organized hospital/medical staff (MeSH) organization; recruited and enrolled 145 physicians representing 14 departments; organized MeSH sponsored preferred provider organization which is available to approximately 6,000 employees and dependents; $650,000 claims first year.

- Recruited and trained new managerial leadership; built management skills; developed managerial training programs, resolved chronic medical staff complaints; improved morale, and reduced turnover rates (14%).

- Directed installation of hospital material management program (actual cost of supplies/admission decreased 1986 vs. 1985).

- Extensive experience working with the medical staff; planned and implemented new medical programs; resolved medical staff concerns.

1975 - 1980

Assistant Vice President - Rhode Island Hospital, Providence, Rhode Island
(719 bed university teaching hospital, 4,000 employees, 250 residents, 60 full time M.D. faculty)

Selected Accomplishments:

- Planned construction of $25 million emergency trauma and operating room facility; wrote role and program specifications.

- Reorganized outpatient clinics into decentralized subsidiary corporation group practices and directed implementation of free standing ambulatory surgery program that serves more than 6,000 patients per year.

1970 - 1973

Staffing Coordinator - Methodist Hospital, St. Louis Park, Minnesota
(475 beds, suburban community hospital)

- Introduced a management engineering based patient classification nurse staffing program with documented savings of $220,000 in first year of operation.

EDUCATION

University of Minnesota, Minneapolis, Minnesota, Master of Hospital Administration - 1975
Administrative Residency, Mount Sinai Hospital, Minneapolis, Minnesota

Tabor College, Hillsboro, Kansas; Bachelor of Arts in Business Administration - 1970

PROFESSIONAL AND COMMUNITY AFFILIATIONS

Fellow - American College of Healthcare Executives

Past Board Member - Valley Health Services and MRI of Northern New Jersey

Past Chairman - Private Academy, Hawthorne, New Jersey

TEACHING EXPERIENCE IN HEALTHCARE MANAGEMENT

Adjunct Faculty – St. Peter College, Englewood Cliffs, NJ 1981 - 1990
Adjunct Faculty – Providence College, Providence, RI 1976 - 1980
Guest Lecturer – Columbia University, Yale University
Preceptor in Healthcare Management, Yale University

Marc Kosak PT, MBA, FACHE
59 Brookside Dr. Trumbull, CT 06611 (203) 268-5217
CT License # 007447

Experience

GREENWICH HOSPITAL GREENWICH, CONNECTICUT
Vice President, Administration **Sept. 2008 - Present**

Responsible for the operations of various clinical and non clinical areas of the hospital. Work closely with the Hospital's Chief Operating Officer and Senior Vice President Health Systems Development on hospital wide projects and initiatives.

Administrative Director, Physical Medicine & Occupational Health Services **Jan. 2004 – Sept. 2008**

Direct an interdisciplinary team of 66 employees across multiple physical locations. Responsible for all operations/finances/program planning over 4 separate cost centers. Set mission/vision over these areas. Scored as a Tier 1 department on employee opinion survey. Improved overall Press Ganey mean scores for areas surveyed from 92.1 to 94.1. Increased outpatient Physical Medicine volume 47%. Initiated implementation of electronic medical record. Wrote business plan which gained board approval for new satellite physical medicine site. Successfully planned for and activated the site. Completed Dale Carnegie, Six Sigma, 21st Century Leadership and Lean Training.

BURKE REHABILITATION HOSPITAL WHITE PLAINS, NEW YORK
Administrator, Rehabilitation Services **Mar. 2002 –Jan. 2004**
(Terence Cardinal Cooke Health Care Center, New York New York)

Manage an Interdisciplinary Department of 37 FTE's (Audiology, Occupational, Physical and Speech Therapy), with a 2 million dollar operating budget. Accountable for all rehabilitation services in a 729-bed, multi-diagnostic Skilled Nursing Facility, and Article 16 Developmental Disabilities outpatient clinic. Specialties include Geriatrics, Short Term Rehabilitation, Dialysis, Huntington's Disease, Alzheimer's Disease, End Stage Pulmonary Disorders, Discrete Units for Residents with AIDS, and an OMRDD governed 50-bed Pediatric Hospital. Reduced overtime and salary costs, improved Medicare/Medicaid compliance, instituted productivity standards, improved performance improvement measures and overall efficiency of the department.

Coordinator Network Development **Jan 2001 – March 2002**

Responsible for the coordination and development of a multi-institutional rehabilitation continuum of care. Implement systems of productivity and outcomes measurement. Coordinate staffing for off site departments. Collaborate with department managers to coordinate consistent treatment protocols, and quality of care standards.

Director of Rehabilitation **Jul. 1999 – Dec. 2000**
(The Wartburg, Mount Vernon New York)

Responsible for the interdisciplinary management of the rehabilitation department including, Audiology, Occupational, Physical, and Speech Therapy. Settings include Sub Acute Rehabilitation, Long Term Care, Adult Day Care, Assisted Living and Outpatient Services. Created and completed performance improvement and quality assurance reports relative to the department. Reviewed and revised policies and procedures to comply with JCAHO, CARF, and DOH standards. Acted as a liaison between staff and administration. Participated on the program evaluation, falls risk, and safety committees. Responsible for creating and monitoring department budget. Worked with MDS coordinator and finance department ensuring that rehabilitation documentation and billing were in compliance with Medicare/Medicaid/PPS guidelines.

Physical Therapy Supervisor **Oct. 1996 – Jul. 1999**

Responsible for the day-to-day operations on a dedicated stroke unit. Acted as a liaison between staff physical therapists and other disciplines. Provided supervision, and acted as a mentor, fostering professional growth and education. Responsible for orienting new staff and for writing scheduled performance evaluations. Completed quality management and research studies specific to the stroke population. Served on the cross training committee and professional advisory committee.

Senior Physical Therapist **Jan. 1996 - Oct. 1996**

Assisted supervisor with daily tasks of unit. Co - Treated with new staff. Instructed multiple physical therapy students. Treated caseload appropriate to the stroke unit employing varied techniques learned from continuing education courses. Wrote evaluations on the performance of physical therapy aides. Conducted research in conjunction with supervisor and physician.

Staff Physical Therapist **May. 1994 - Jan. 1996**

Provided physical therapy care to adult inpatients with various cardiac, orthopedic and neurological disorders. Gave patient and family education lectures on stroke, congestive heart failure, and physical conditioning.

MERCY COLLEGE DOBBS FERRY, NEW YORK

Clinical Faculty **Jan. 1997 - Sept 1998**

Responsible for planning lessons and instructing college level students in kinesiology lab exercises. Assisted in creating and grading examinations.

THE THERAPY RESOURCE CENTER MIDDLETOWN, NEW YORK

Physical Therapist **Apr. 1997 - Feb 1998**

Responsible for the evaluation and treatment of residents at the Richmond Children's Center. Evaluated and treated Clients with Profound Cerebral Palsy. Trained nurses and aides.

HOME THERAPISTS ASSOCIATION ARDSLEY, NEW YORK

Home Care Physical Therapist **Aug. 1994 - Feb. 1995**

Provided home care physical therapy to patients with orthopedic, neurologic, pulmonary, and cardiac disorders. Trained home health aides to care for the clients by following through with written home exercise programs.

Presentations

- BRYN MAYR REHABILITATION BRYNMAYR, PENNSYLVANIA
  Body Weight Supported Treadmill Training **Jan. 1997**

- 23rd INTERNATIONAL CONFERENCE ON STROKE AND CEREBRAL CIRCULATION ANAHEIM, CALIFORNIA
  Body Weight Supported Treadmill Training **Feb. 1997**

- BURKE REHABILITATION HOSPITAL WHITE PLAINS, NEW YORK
  Stroke Rehabilitation: Early Mobility **Sept. 1998**

- NORTH AMERICAN STROKE MEETING CANCUN, MEXICO
  Body Weight Supported Treadmill Training **Oct. 1998**

- NORTH AMERICAN STROKE MEETING ASPEN, COLORADO
  Effectiveness of KAFO's in Patients with Stroke **Oct. 1999**

- AMERICAN COLLEGE OF HEALTHCARE EXECUTIVES CHICAGO, ILLINOIS
  Creating and Managing a Multi-Institutional Rehabilitation Continuum of Care **Mar. 2001**

- AMERICAN COLLEGE OF HELATHCARE EXECUTIVES — CHICAGO, ILLINOIS
  Rehabilitation Outcomes in Sub-Acute Care — **Mar. 2003**

Publications

- STROKE; Jan. 1997
  Body Weight Supported Treadmill Training vs. Traditional Physical Therapy
- JOURNAL OF STROKE AND CERBRAL VASCULAR DISEASES; Sept. – Oct. 1998
  Early Aggressive Mobilization is as Effective as Treadmill Training for Ambulation Recovery in Patients with Stroke
- JOURNAL OF STROKE AND CERBRAL VASCULAR DISEASES; Sept. – Oct. 1999
  Effectiveness of Knee-Ankle-Foot-Orthoses in Patients with Stroke
- NEUROREHABILITATION AND NEURAL REPAIR; March 2000
  Comparison of Partial Body Weight Supported Treadmill Gait Training vs. Aggressive Brace Assisted Walking Post Stroke
- AMERICAN COLLEGE OF HEALTHCARE EXECUTIVES, March 2001
  Creating and Managing a Multi-Institutional Rehabilitation Continuum of Care
- AMERICAN COLLEGE OF HEALTHCARE EXECUTIVES, March 2003
  Rehabilitation Outcomes in Sub-Acute Care
- JOURNAL OF REHABILITATION RESEARCH AND DEVELOPMENT, January/February 2005
  Comparison of the 2-, 6-, and 12-Minute Walk Tests in Patients with Stroke

Education and Certifications

DAEMEN COLLEGE — AMHERST, NEW YORK
B.S. in Physical Therapy — **May, 1994**
CUM LAUDE

UNIVERSITY OF PHOENIX
M.B.A with concentration in Healthcare Management — **April, 2006**

CERTIFIED NEURO DEVELOPMENTAL TREATMENT IN ADULTS WITH HEMIPLEGIA — **March, 1998**

DALE CARNEGIE TRAINING — **March, 2005**

SIX SIGMA GREENBELT — **November, 2005**

GREENWICH HOSPITAL MENTOR — **January, 2006**

YNHHS 21st CENTURY LEADERSHIP — **June, 2006**

FELLOW OF THE AMERICAN COLLEGE OF HEALTHCARE EXECUTIVES — **November, 2007**

YNHHS CERTIFIED LEAN PRACTITIONER — **June, 2008**

CURRICULUM VITAE:

Name: Christopher J. Howes, M.D, F.A.C.C, F.A.S.E.

Appointment
Assistant Professor of Medicine, Department of Internal Medicine, Clinician Educator Track

Term: July 1, 2010 to June 30, 2013

School Assignment: Yale University School of Medicine

Born: March 27, 1962

Education: B.A., Brown University 1984
M.D., Albert Einstein College of Medicine, 1989

Career: 1989-1990 Intern, Internal Medicine, Yale-New Haven Hospital, New Haven, CT
1990-1992 Resident, Internal Medicine, Yale New Haven Hospital, CT
1992-1993 Attending Physician, West Haven VAMC, West Haven, CT
1993-1997 Cardiovascular Fellow, Yale University School of Medicine, New Haven, CT
1997-present Assistant Professor, Department of Internal Medicine, Section of Cardiology, YSM, New Haven, CT

Administrative Positions:
1997-2000 Director Outpatient CV services WHVA, West Haven CT.
2000-2005 Medical Director Echo Lab, Branford Cardiology Clinic
2005-present: Medical Director of PAMI program and Cath Lab, Greenwich Hospital

Board Certification:

National Board of Medical Examiners	1990
American Board of Internal Medicine (ABIM)	1992, recertified 2002
ABIM: Cardiovascular Medicine	1997, recertified 2007
ABIM: Interventional Cardiology	1999, recertified 2009
National Board of Echocardiography	2001

Professional Honors or Recognition:

A) 2008, 2009, 2010 Castle Connolly Top Doctors: Interventional Cardiology, NY area
2001 Fellow American Society of Echocardiography
1998 Fellow American College of Cardiology
1989 A.O.A Medical Student Honor Society

B) 2006-7 Housestaff "Teacher of Year" award: Greenwich Hospital
2010-11 Housestaff "Teacher of the Year award: Greenwich Hospital

Grant History for last 12 years:
The Ethel F. Donahue Women's Health Investigator Program at Yale
#1003737.HOWES1.R02524
The effect of antidepressant medication on nitric oxide synthase in platelets and endothelial function in women. P.I. Christopher J. Howes, M.D. 5% total effort, $50,000, 2/01 -2/02, extended -6/03. Expired.

Professional Service

Journal Service

2008-present: Reviewer Southern Medical Journal

Policy Review

2004-present: Anthem BC/BS medical policy & appropriateness criteria.

Yale University Service

2004-2006: YNHH Credentials committee
2005-present: Int. Med. Housestaff Interviews (Greenwich Hospital)
2002-2005: YSM Internal Medicine Housestaff Interviews
1997-present: Cath Lab committee

Public Service

2005-present: Guest Speaker- Heart Awareness Month WGCH (radio) & GCTV
2005-present Guest Speaker: Community Health at Greenwich Hospital

Bibliography:

1. Peer Reviewed

Krumholz HM, **Howes CJ**, Murillo J, Vaccarino V, Radford MJ, Ellerbeck E: Validation of a clinical prediction rule for left ventricular ejection fraction after myocardial infarction in patients greater or equal 65 years old. Am J Card. 7/97, 80 (1): 11-15

Howes CJ, Reid CM, Brandt C, et al: Exercise tolerance and quality of life in elderly patients with chronic atrial fibrillation. J. of Cardiovascular Pharmacology & Therapeutics. 1/01, 6(1): 23-9

Patel PB. Pfau SE. Cleman MW. Brennan JJ. **Howes C**. Remetz M. Cabin HS. Setaro JF. Rinder HM. Comparison of coronary artery specific leukocyte-platelet conjugate formation in unstable versus stable angina pectoris. American Journal of Cardiology. 93(4):410-3, 2004 Feb 15.

Ranjbaran H. Sokol SI. Gallo A. Eid RE. Iakimov AO. D'Alessio A. Kapoor JR. Akhtar S. **Howes CJ**. Aslan M. Pfau S. Pober JS. Tellides G. An inflammatory pathway of IFN-gamma production in coronary atherosclerosis. Journal of Immunology. 178(1):592-604, 2007 Jan 1.

2. Case Reports

Weisman G. Scandrett, RM. **Howes CJ.** Russell RR 3rd: Coronary vasospasm during an adenosine stress test. Journal of Nuclear Cardiology. 11(6): 747-50 2004 Nov-Dec.

3. Reviews

Howes CJ: Percutaneous Angioplasty: Debulking Techniques. Applications in Imaging, Cardiac Interventions. 8/97, 17-25

Howes CJ: Atrial fibrillation in the elderly: Who is at risk. Am J of Geriatric Card. 9/98, 7 (5), 13-23

Howes CJ, Ezekowitz MD: Editorial: Alternate-day dosing of aspirin in atrial fibrillation: a critical evaluation. Am Heart J. 7/99, 138(1): 13

MARNA PARKE BORGSTROM

Home: 458 Three Mile Course
Guilford, Ct. 06437

(203) 453-8782

Business: Yale-New Haven Hospital
20 York Street
New Haven, CT 06510
(203) 688-2608

EDUCATION

1977-1979 Yale University School of Medicine
Department of Epidemiology and Public Health
Program in Hospital Administration, M.P.H.

1972-1976 Stanford University
Bachelor of Arts in Human Biology awarded June, 1976

EXPERIENCE

2005-Present President and Chief Executive Officer: Yale New Haven Health System (YNHHS)

Yale New Haven Health System is a regional, integrated health care delivery system composed of three local health care delivery networks,as well as a physician foundation, Northeast Medical Group. Anchored by Yale-New Haven Hospital, the Yale-New Haven Children's Hospital, and the Yale-New Haven Psychiatric Hospital totaling 1008-beds, the System includes a Bridgeport network led by the 425-bed Bridgeport Hospital and a Greenwich network anchored by 180-bed Greenwich Hospital. Westerly Hospital (Rhode Island) is a network participant.

Feb. 2012 - Present Chief Executive Officer: Yale-New Haven Hospital and Delivery Network (YNHH)

2005- Feb. 2012 President and Chief Executive Officer: Yale-New Haven Hospital and Delivery Network (YNHH)

Yale-New Haven, a private not-for-profit 1008-bed hospital founded in 1826. It serves as the primary teaching hospital for the Yale University School of Medicine and provides tertiary and quaternary patient care for patients referred, as well as general acute care services for the Greater New Haven metropolitan area.

1993-2005 Executive Vice President & Chief Operating Officer: Yale-New Haven Hospital
Executive Vice President and Secretary: Yale-New Haven Health Services Corporation

Responsible for New Haven Delivery Network operations including Yale-New Haven Hospital operations, finance, human resources and planning and marketing; and Yale-New Haven Ambulatory Services Corporation, which operates two independent surgery centers and a large, full-service radiology business in New Haven and Guilford. Served as the senior Hospital interface for Yale School of Medicine operational issues.

Represented the YNHH Delivery Network in all Health System strategic and operational activities.

1992-1993 Senior Vice President, Administration: Yale-New Haven Hospital
Senior Vice President and Secretary: Yale-New Haven Health Services Corporation

Responsible for Hospital strategic planning and marketing, facilities planning and design, risk management and medicolegal affairs, managed care contracting, Service Quality Improvement, Community Relations, Public Affairs and Engineering.

Project Executive for implementation of Yale-New Haven's $156 million Facilities Renewal Project.

1985-1992 Vice President, Administration: Yale-New Haven Hospital

Responsible for Hospital strategic planning and marketing, facilities planning and design, risk management and medicolegal affairs, managed care contracting, Service Quality Improvement, Community Relations, Public Affairs and Engineering. Provided administrative leadership to Yale-New Haven Health Services Corporation corporate affairs and strategic initiatives.

1984-1985 Assistant Vice President: Yale-New Haven Hospital

Directed the development and implementation of annual Hospital business plan format derived from strategic plan. Completed $6 million renovation of Hospital clinical laboratories. Represented Hospital on underwriting and eligibility and finance activities in malpractice insurance captive.

Dec. 1982-1984 Associate Administrator: Yale-New Haven Hospital

Responsible for Hospital planning activities, including Strategic Planning and general facilities planning and related capital budget activities. Also responsible for Clinical Laboratories ($23 million gross revenue and $11 million expense) and Risk Management and Medicolegal Affairs.

Dec. 1980-Nov. 1982 Assistant Administrator: Yale-New Haven Hospital

Responsible for planning and implementing $11 million renovation program done in concert with major facility replacement project, and for planning and overseeing the move of five major departments and three clinical services (including 80 ICU beds) to a new $73 million facility, during the Spring of 1982. Prepared and presented to the Health Systems Agency and Commission on Hospitals and Health Care, three Certificates of Need; all were approved. Also responsible for Hospital space planning and management, and provided general staff support to the Executive Vice President.

Jan. 1980-Dec. 1980 Administrative Associate: Yale-New Haven Hospital

Provided general staff support to Executive Vice President. Major activities included employee fundraising and campaign to support $73 million facility replacement and renovations program (50% of Hospital employees contributed almost $500,000) and preparation of capital and operating budget materials.

Jan. 1979-Dec. 1980 Administrative Resident: Yale-New Haven Hospital

Summer 1978 Administrative Intern: Alexian Brothers Hospital, San Jose, California

PROFESSIONAL AWARDS:

1992 Up and Comers Award - Sponsored by Modern Healthcare and 3M Health Systems
Women In Leadership Award, 1993 - YWCA
Junior Achievement Hall of Fame, 1998
20 Noteworthy Women, New Haven Business Times, 1999
Gateway Community College Hall of Fame, 2002

Hill Health Center Leadership Award, 2006
Connecticut Women in Leadership, 2009 (Women & Families Center Award)
Girl Scouts of Connecticut Women of Achievement Award, 2010
Anti-Defamation League Torch of Liberty Award, 2010
Business New Haven's Business Person of the Year, 2010
American Hospital Association 2010 Grassroots Champion Award
Doctor of Humane Letters, Quinnipiac University, 2011

MAJOR PROFESSIONAL AFFILIATIONS, BOARDS AND ACTIVITIES:

Yale-New Haven Hospital Board of Trustees (1994 – present)
Yale New Haven Health System Board of Directors (2005 - present)
The Connecticut Hospital Association, Chair, Board of Trustees (2008-2010); Vice Chair (2006-2008); Member, Executive Committee (2006-), Secretary and Member, Executive Committee (1999-2001)
VHA, Inc. (Dallas, Texas), Board of Directors (2009 -)
Council of Teaching Hospitals (COTH) Administrative Board (2008 - present); Chair-elect (2010)
Healthcare Executives Study Society (2006-present)
Greater New Haven Regional Leadership Council (2005-present)
The Hole in the Wall Gang Camp Board of Directors (2007 - 2010)
Northwestern Mutual Policyowners' Examining Committee (2009)
Fellow – American College of Healthcare Executives
Association of American Medical Colleges Board of Directors, 2010-present
Coalition to Protect America's Health, 2011-present

University Appointments

Yale University – Lecturer, Department of Epidemiology & Public Health, Health Policy & Administration Division.

PERSONAL:
Married: Eric N. Borgstrom (5/27/78)
Children: Christopher (4/14/85) and Peter (8/4/89)

CURRICULUM VITAE

RICHARD D'AQUILA
282 Boston Post Road
Westbrook, CT 06498
Telephone: (860) 669-0871

PERSONAL DATA:
Married
U.S. Citizen
Birth Date: 6/29/55

BUSINESS ADDRESS:

Yale-New Haven Hospital
20 York Street
New Haven, CT 06510
Telephone: (203)-688-2606

PROFESSIONAL EXPERIENCE:

February, 2012

President and Chief Operating Officer
Yale-New Haven Hospital
Executive Vice President
Yale New Haven Health System

May, 2006 to
February, 2012

Executive Vice President and Chief Operating Officer
Yale-New Haven Hospital/Yale New Haven Health System

Organizational Profile

Yale New Haven Health System (YNHHS) is a 1545-bed delivery network formed in 1995 which consists of Yale-New Haven, Bridgeport and Greenwich Hospitals. YNHHS has revenues in excess of $1.1 billion in FY '05 based on 80,000 discharges and 1.3 million outpatient visits. Yale-New Haven Hospital is a 944-bed tertiary referral medical center that includes the 201-bed Yale New Haven Children's Hospital and the 76-bed Yale New Haven Psychiatric Hospital. Both Yale New Haven Health System and Yale-New Haven Hospital are formally affiliated with Yale University School of Medicine.

Responsibilities

Overall responsibility for all aspects of day to day operations for Yale-New Haven Hospital (YNHH) and the senior network leader at the Yale New Haven Health System representing the YNHH delivery network. Hospital leadership responsibilities include direct accountability for the senior leadership team, strategic planning, organizational performance, quality improvement, labor relations and human resources management, system integrations, external relations and service line development. Senior leadership and implementation responsibility for all aspects of the hospital's annual business (operating) plan. Senior level oversight of the hospital's facility plan including

construction of a 112-bed, $450 million Comprehensive Cancer Pavilion commencing construction in the fall of 2006.

August, 2000 to April, 2006

Senior Vice President/Chief Operating Officer
New York Presbyterian Hospital/
Weill Cornell Medical Center
New York, New York

Organizational Profile
New York Presbyterian Hospital is a 2,369 bed Academic Medical Center created from the merger between the New York Hospital and the Presbyterian Hospital in the City of New York. The Weill Cornell Medical Center consists of an 880 bed acute care facility in Manhattan and the 239 bed Westchester Division campus in White Plains specializing in behavioral health.

Responsibilities
Overall responsibility for all aspects of day to day operations for the Weill Cornell Medical Center and the Westchester Division, a two campus Academic Medical Center of 1120 beds. Direct responsibility for a total operating expense budget in excess of $450,000,000 and revenues of $850,000,000. Senior leadership and implementation for all aspects of the Medical Center's operating plan including quaternary and tertiary service development, medical staff relations and recruitment, employee relations and labor strategy. System level member of the Corporate Management Team with involvement in strategic and facilities planning, service line development, information technology and performance improvement.

May 1992 to June 2000

Executive Vice President/Chief Operating Officer
St. Vincent's Medical Center
Bridgeport, Connecticut

President
Vincentures, Inc.

President
St. Vincent's Development Corporation, Inc.

Chief Operating Officer of 391 bed, university-affiliated acute care hospital and health system. President/CEO of affiliated subsidiaries with management responsibility at

the Medical Center and corporate level. Medical Center responsibilities including day to day operations oversight for patient care services; support services and facilities planning and development. Corporate responsibilities including information systems, ambulatory network development, managed care contracting network oversight and real estate/satellite facility development.

January 1987-April 1992

President/CEO
Health Initiatives Corporation
Providence, Rhode Island

Chief Executive Officer of a consulting practice specializing in strategic planning, business development and project implementation assistance for acute care and specialty hospitals, state planning agencies and private investors. Specific responsibilities included:

- Practice Leadership
- Engagement Planning and Management
- Project Supervision and Control
- Client Interface
- Practice Marketing and Business Development

June 1984-December 1986

Vice President
The Mount Sinai Hospital Corporation
Hartford, Connecticut

June 1981-June 1984

Vice President, Division of Planning and Community Services
The Mount Sinai Hospital
Hartford, Connecticut

June 1979-June 1981

Assistant Executive Director
The Mount Sinai Hospital
Hartford, Connecticut

January 1979-May 1979

Administrative Resident
The Mount Sinai Hospital
Hartford, Connecticut

OTHER APPOINTMENTS:

November 2000
To Present

Member, Board of Directors
Voluntary Hospitals of America/Metro New York
New Rochelle, New York

January 1995- June 2000	**Member, Board of Directors** Goodwill Industries Bridgeport, Connecticut
December 1993- June 2000	**Founding Board Member** Park City Primary Care Center Bridgeport, Connecticut
May, 1992- June 2000	**Member, Board of Directors** St. Vincent's Development Corporation Vincentures, Inc. Omicron, Inc. Connecticut Health Enterprises Bridgeport, Connecticut
January 1992- December 1994	**Member, Board of Directors** Visiting Nurses Association of Fairfield County Bridgeport, Connecticut
January 1989- December 1991	**Member, Board of Directors** Easter Seal Society/Meeting Street Rehabilitation Center, Inc. of Rhode Island Providence, Rhode Island
January 1980- December 1989	**Member, Board of Directors** Combined Hospitals Alcohol Program Hartford, Connecticut
September 1985- December 1986	**President, Board of Directors** Regional Alcohol and Drug Abuse Resources, Inc. Hartford, Connecticut
September 1981- December 1986	**Adjunct Faculty/Lecturer** University of Hartford, Barney School of Business and Public Administration West Hartford, Connecticut
January 2001 - Present	**Adjunct Faculty/Residency Preceptor and Lecturer** Robert F. Wagner Graduate School of Public Service New York University New York, N.Y.
December 2000 - Present	**Adjunct Faculty/Lecturer** Weill Medical College of Cornell University Department of Public Health, New York New York, N.Y.

EDUCATION:

Yale University School of Medicine
Graduate Program in Hospital Administration
Academic Distinctions: Research Excellence Award (1979)
1979 Graduate

Central Connecticut State University
Bachelor of Arts: Economics/Business
Academic Distinctions: Omicron Delta Epsilon
Economics Honor Society
1977 Graduate

PROFESSIONAL AFFILIATIONS:
Fellow, American College of Health Care Executives
Yale Hospital Administration Alumni Association
Connecticut Hospital Association
Habitat of Greater New Haven

CURRICULUM VITAE

NAME: James M. Staten
BIRTHDATE: September 26, 1958
EDUCATION: 1980 – B.S. – Business / Economics / State University College of NY

Yale New Haven Health System (YNHHS) and Yale-New Haven Hospital (YNHH)

October 2000 - Present

Executive Vice President of Finance and Corporate Services, YNHHS
Senior Vice President and CFO, YNHH

Yale New Haven Health system is a regional, integrated health care system composed of three regional health care delivery networks. The New Haven-based delivery system is anchored by Yale-New Haven Hospital, the Yale-New Haven Children's Hospital, and the Yale-New Haven Psychiatric Hospital, which total 944-beds. The system includes a Bridgeport-based delivery system led by the 425-bed Bridgeport Hospital and Greenwich-based delivery system anchored by 160-bed Greenwich Hospital. The System is also affiliated with the Westerly Hospital in Rhode Island. The Yale New Haven Health System has a formal affiliation with the Yale University School of Medicine, as does Yale-New Haven Hospital which serves as the Medical School's primary teaching hospital. System services include acute care hospitals, ambulatory surgery and outpatient diagnostic imaging centers, as well as primary care centers. In total, the System has 1,500 beds, 74,000 admissions, 10,000 employees, assets of $1.6 billion, and annual net revenues of over $1.4 billion.

Responsible for financial and corporate services of YNHHS including managed care, information systems, materials management, admitting/registration, and medical records, as well as all financial responsibilities such as accounting, budgeting, financial and operational reporting, tax, reimbursement, and treasury.

OTHER EMPLOYMENT

New York-Presbyterian Hospital (NYPH) and New York-Presbyterian Healthcare System (NYPHS)

July 1999 – October 2000 Senior Vice President of Finance

Responsible for assuring the financial viability of a $3 billion Health System, including monitoring financial condition of approximately 15 corporately-controlled Sponsored/Member Hospitals and other healthcare related organizations. Report regularly to the NYPHS Board and NYPH Board Executive Committee on financial performance.

January 1997 - June 1999 Vice President of Financial Planning
June 1993 - December 1996 Director of Financial Planning

Responsible for complete integration of financial planning at all Sponsored Hospital Members including NYPH and leading the financial group of approximately 70 professionals in performing budget, reimbursement, managed care contracting, decision support and business plan development functions.

Ernst & Young

January 1991 - June 1993 Senior Manager - Consulting Services

Directed and coordinated Ernst & Young's New York State Reimbursement Consulting Services.

Pannell Kerr Forster

October 1980 – December 1990 Partner

Elected Partner in June 1990 after working 10 years in the firm's large healthcare practice as a certified public accountant. 11th Largest Public Accounting Firm in United States during late 1980s.

PROFESSIONAL MEMBERSHIPS

American Institute of Certified Public Accountants (1982 – 1998)
New York State Society of Certified Public Accountants (1982 – 1996)
- Healthcare Committee (1988 – 1991)
- Chairman of the Hospital Sub-Committee (1990/1991)

Healthcare Financial Management Association (1984 – 1994)
- Chairman of various Committees (1984 – 1994)
- Trustee (1990/1991)
- President Elect (1993/1994)

Greater New York Hospital Association
- Fiscal Policy Committee (1993 – 2000)
- Managed Care Committee (1995 – 2000)

Connecticut Hospital Association
- Finance Committee (2000 – 2004)
- Special Committee on Medicaid Reimbursement (2000 – 2004)

Blue Ribbon Committee on the Future of Healthcare in Connecticut (2000 – 2003)

OTHER PROFESSIONAL ACTIVITIES

Presenter at New Jersey Health Care Financing Authority on Medicare Payment System
Presenter on Hospital Reimbursement Issues for the NYS Society of CPAs
Presenter on Accounts Receivable Issues for the Connecticut Hospital Association
Guest Speaker at NYU's graduate program in Hospital Administration on Healthcare Financing
Guest speaker at Cornell University's Sloan Program in Health Services on Managed Care
Presenter on Mergers and Acquisitions to New York State Hudson Valley HFMA
Guest speaker at Chicago Municipal Bond Analysts Society on New York State Hospital Deregulation
Guest speaker at Yale's School of Epidemiology and Public Management on Health Systems

THOMAS D. LEARY

20 Morgan Point
Noank, Connecticut 06340
(860) 536-2698

EDUCATION

Business Administration, M.B.A.	Boston University	1982
Economics, B.A..	College of the Holy Cross	1975

PROFESSIONAL HISTORY

2000	-	Present	Yale-New Haven Hospital
1994	-	1999	Yale New Haven Health Services Corporation
1992	-	1994	Yale-New Haven Hospital
1991	-	1992	Harbor Health Plans
1988	-	1991	Healthcare Venture Associates
1983	-	1988	VHA (Voluntary Hospitals of America)
1977	-	1983	John Hancock Financial Services
1975	-	1976	General Dynamics, Electric Boat Division

PROFESSIONAL EXPERIENCE

Yale-New Haven Hospital
New Haven, Connecticut

As Vice President, Mr. Leary is responsible for clinical program development and physician recruiting with the Yale School of Medicine. He also serves as the Service Line executive for the operation of the Heart & Vascular Center, Organ Transplantation Center and the Level I Trauma Center. These programs are all leading New England providers of tertiary care services.

As Vice President, Physician Development, Mr. Leary was responsible for medical staff outreach to community based physicians and managed medical staff development programs, including computer networking. He restructured the Hospital's diagnostic service privileging and physician reporting systems. The Hospital MDLink Program expanded to 1600 physicians and ancillary staff users. He also served as the Executive Director of the YNHH-Physician Corporation and the Yale-New Haven Community Medical Group with responsibilities for managed care contracting and clinical integration program development.

Yale New Haven Health Services Corporation
New Haven, Connecticut

As Vice President, Mr. Leary was responsible for the Health System's managed care plans and contracting functions. He also managed the system's physician network development programs in primary care and specialty services. Mr. Leary also organized the Health System's central contracting organization. Mr. Leary was responsible for Yale New Haven Health's acquisition of a 50% interest of a 150,000 member PPO plan. He also developed and managed an HMO serving 25,000 Medicaid beneficiaries in Connecticut, as well as a fifty physician primary care group. Mr. Leary also negotiated the sale of the Hospital's interest in a regional HMO.

Yale-New Haven Hospital
New Haven, Connecticut

As Administrative Director, Mr. Leary was responsible for HMO/PPO contracting and payer relations for Yale-New Haven Hospital. He served as Executive Director of its PHO and Medical Staff IPA. Contract revenue exceeded $300 million.

Harbor Health Plans
Mystic, Connecticut

As President, Mr. Leary had overall responsibility for managed care consulting engagements, PPO and workers compensation health plan product development. Mr. Leary founded the company.

Healthcare Venture Associates
Irving, Texas

As a partner in this consulting firm, Mr. Leary was responsible for managed care and physician service programs. Mr. Leary's consulting engagements included HMO turnaround, market development for a leading physician referral service, and physician networking product development for a major communications company.

VHA Physician Services
Irving, Texas

As Vice President, Mr. Leary was responsible for all computer, practice management, and marketing services delivered to over one thousand physicians in twelve network locations. Mr. Leary also created physician network designs for VHA Physician Services hospital clients.

Partners National Health Plans
Irving, Texas

As Vice President of Marketing for this Aetna/VHA joint venture, Mr. Leary was responsible for marketing the Partners' product line including advertising, product development, and national

account sales. Mr. Leary created a 70,000 member PPO for the Teamsters and Partners' National Advantage, the largest hospital PPO in the country.

As Director of Alternative Delivery Systems Consulting, Mr. Leary provided development consulting services to hospitals, medical groups and large employers to create HMOs, PPOs, and other alternative delivery systems.

John Hancock Financial Services
Boston, Massachusetts

As Director of Cost Containment Marketing, Mr. Leary's responsibilities included market management and product development. Mr. Leary helped the company develop its first PPO plan.

As Senior Sales Representative, Mr. Leary was responsible for the sale of $1,000,000 premium accounts. Mr. Leary earned several Production Leader Awards for his efforts.

General Dynamics
Groton, Connecticut

As a Production Planner, Mr. Leary's responsibilities included scheduling, procurement, and materials management for nuclear submarines at the Electric Boat Division.

Board Positions
New England Organ Bank
Board of Trustees, Executive Committee
Waltham, Massachusetts

Hygeia Foundation and Institute for Perinatal Loss and Bereavement
Hygeia Foundation Board
New Haven, CT

CURRICULUM VITAE

Name: Michael Simons, M.D.

Professor with Tenure, Department of Medicine
Traditional Track

Term: *Primary:* with Tenure beginning September 1, 2008

School: Yale University School of Medicine (and the Graduate School)

Education:
B.S. Massachusetts Institute of Technology, Cambridge, MA, June 1980
M.D. *cum laude* Yale University School of Medicine, New Haven, CT, June 1984

Career/Academic Appointments:

1984-1985	Intern in Internal Medicine, New England Medical Center, Boston, MA
1985-1986	Resident in Internal Medicine, New England Medical Center, Boston, MA
1986-1989	Medical Staff Fellow, NIH, NHLBI, Bethesda, MD
1987-1989	Postdoctoral Fellow, Laboratory of Molecular Cardiology, NIH, NHLBI, Bethesda, MD
1989-1991	Fellow in Cardiology, Beth Israel Hospital, Boston, MA
1990-1993	Associate Scientist, Program for Excellence in Molecular Biology of the Cardiovascular System, MIT, Cambridge, MA
1991 - 1993	Instructor in Medicine, Harvard Medical School, Boston MA
1993 - 1997	Assistant Professor of Medicine, Harvard Medical School, Boston MA
1997 - 2001	Associate Professor of Medicine, Harvard Medical School, Boston MA
2001 – 2008	A.G. Huber Professor of Medicine, Dartmouth Medical School, Lebanon NH
2002 – 2008	Professor of Pharmacology & Toxicology, Dartmouth Medical School, Lebanon NH
2008 - Present	Professor with Tenure, Yale University School of Medicine
2008 - Present	Robert W. Berliner Professor of Medicine, Yale University School of Medicine
2008 - Present	Honorary Professor of Medicine, University College London, London, UK
2009 - Present	Professor of Cell Biology, Yale University School of Medicine

Administrative Positions:

2008 – Present	Chief, Section of Cardiovascular Medicine, Yale University School of Medicine
2006 - 2008	Director, Cardiovascular Center, Dartmouth-Hitchcock Medical Center
2003 - 2006	Associate Chair of Medicine for Research, Dartmouth-Hitchcock Medical Center
2001 - 2008	Chief of Cardiology, Dartmouth-Hitchcock Medical Center
2001 - 2008	Director, Angiogenesis Research Center, Dartmouth Medical School
1996 - 2001	Director, Angiogenesis Research Center, Beth Israel Hospital/BIDMC
1995 - 1999	Director, Morse Coronary Care Unit, Beth Israel Hospital/BIDMC
1993 - 2001	Attending Cardiologist, Beth Israel Hospital/BIDMC
1993 - 2001	Associate in Medicine, Beth Israel Hospital/BIDMC

Board Certification:

National Board of Medical Examiners, 1985
Diplomate, American Board of Internal Medicine, 1987
Diplomate, ABIM, Subspecialty of Cardiovascular Disease, 1991, re-certified 2001
Diplomate, Certification Board of Nuclear Cardiology, 1996

Professional Honors & Recognition

A) International/National/Regional

2010	Chair, Keystone Conference Angiogenesis in Health and Disease
2009	Chair, Gordon Research Conference on Vascular Biology
2005-2006	President, North American Vascular Biology Organization
2005	Excellence in Cardiovascular Science Award, AHA Northeast
2005	Elected member, Association of American Physicians (AAP)
2004	Elected member, Association of University Cardiologists (AUC)
2002	Fellow (elected), CV Section, American Physiological Society
2001	Fellow (elected), Basic Science Council, AHA
1999-2003	Established Investigator, American Heart Association
1999	Honorary Citation, Cardiovascular Society of India
1998	Fellow (elected), ATVB Council, AHA
1998	Elected Member, American Society for Clinical Investigations (ASCI)
1995	Honorary Citation, Japanese Circulation Society
1991-1996	Clinician-Scientist of the American Heart Association
1984	A. Richman Research Award of the American College of Chest Physicians

B) University

2005	Excellence in Teaching Award, Department of Medicine, Dartmouth
1986	Teaching Resident Award, Tufts University School of Medicine
1984	Cum Laude, Yale University School of Medicine

Grant History:
A) Current Grants

Agency	Leducq Foundation
Program:	Transatlantic Network
Title:	ARTEMIS Network
PI:	Michael Simons MD & Peter Carmeliet, Ph.D.
Percent effort:	20%
Direct costs for project period	$5,400,000
Project period	9/1/09-8/31/2014

Agency:	NIH/NHLBI
I.D.#	R01 HL62289
Title:	Syndecan function in endothelial cells
P.I.:	Michael Simons, M.D.
Percent effort:	20%

Direct costs per year (last year): $388,563
Total costs for project period: $1,877,013
Project period: 10/01/2008 – 11/30/2013

Agency: NIH/NHLBI
I.D.# R01 HL53793
Title: Angiogenesis and ischemia
P.I.: Michael Simons, M.D.
Percent effort: 20%
Direct costs per year: $322,382
Total costs for project period: $1,711,524
Project period: 06/16/2008 – 05/30/2013

Agency: NIH/NHLBI
ID#: R01 HL084619
Title: Arteriogenesis and arterial branching
P.I.: Michael Simons, M.D.
Percent effort: 20%
Direct costs per year: $316,875
Total costs for project period: $1,637,287
Project period: 07/01/2007 – 06/30/2011

Agency: NIH/NHLBI
I.D.# P50 HL084945
Title: Molecular determinants of pulmonary arterial hypertension
P.I.: Laura Nofke, MD
Role on the project: Co-PI
Percent effort: 5%
Direct costs per year: $49,270
Total costs for project period: $197,080
Project period: 01/01/2007 – 12/31/2010

Agency: NIH/NHLBI
I.D.# HL069948
Title: Mechanism of PAI-1-induced anti-angiogenesis
P.I.: Mary Jo Mulligan-Kehoe, Ph.D.
Role on the project: Co-PI
Percent effort: 5%
Direct costs per year: $9,300
Total costs for project period: $37,200
Project period: 12/01/2007 – 11/30/2011

B) Past Grants

Agency: NIH/NHLBI
I.D.# R13 HL093922A
Title: NAVBO workshop: biology of signaling in the cardiovascular system
P.I.: Michael Simons MD and Timothy Hla, PhD (dual PI)
Percent effort: 0%

Direct costs per year: $15,000
Total costs for project period: $15,000
Project period: 09/01/2008 – 08/31/2009

Agency: NIH/NHLBI
I.D.# R01 HL53793
Title: Angiogenesis and ischemia
P.I.: Michael Simons, M.D.
Percent effort: 25%
Direct costs per year: $213,341
(Last funding year)
Total costs for project period:
Project period: 08/01/1997 – 08/31/2008

Agency: NIH/NHLBI
I.D.# R01 HL62289
Title: Syndecan function in endothelial cells
P.I.: Michael Simons, M.D.
Percent effort: 25%
Direct costs per year (last year): $225,000
Total costs for project period:
Project period: 05/01/1999 – 06/18/2008

Agency: NIH/NHLBI
I.D.# R01 HL070247
Title: Peptide regulators of angiogenesis
P.I.: Michael Simons, M.D.
Percent effort: 25%
Direct costs per year: $249,915
Total costs for project period: $999,600
Project period: 04/01/2002 – 03/31/2006

Agency: NIH/NHLBI
I.D.# P50 HL63609
Title: Endothelial signaling and cardiac angiogenesis
P.I.: Michael Simons, M.D.
Percent effort: 25%
Total costs for project period: $5,884,895
Project period: 04/01/2000 – 03/31/2005

Agency: NIH/NHLBI
I.D.# P50 HL56993
Title: Stimulation of coronary angiogenesis with bFGF
P.I.: Lewis Cantley, Ph.D
Role on the grant: Project PI
Percent effort: 25%
Total costs for project period:
Project period: 04/01/1997 – 03/31/2002

Agency: Scleroderma Research Foundation
I.D.# Investigator Grant

Title:	Angiogenic defects in scleroderma
P.I.:	Michael Simons, M.D.
Percent effort:	0%
Total costs for project period:	$160,000
Project period:	04/01/2005 – 03/31/2008

Agency:	American Heart Association
I.D.#	Established Investigator Grant
Title:	Inflammation and angiogenesis
P.I.:	Michael Simons, M.D.
Percent effort:	25%
Total costs for project period:	$300,000
Project period:	01/01/1999 – 12/31/2003

Agency:	American Heart Association
I.D.#	Clinician-Scientist Award
Title:	Molecular control of restenosis
P.I.:	Michael Simons, M.D.
Percent effort:	75%
Total costs for project period:	$175,000
Project period:	07/01/1991 – 06/30/1996

Lectures, Courses, Web-based Education:

Courses:

2006-2008	Leader, Vascular biology curriculum, Program in experimental molecular medicine
2005-2008	Receptors Course, Department of Pharmacology, Dartmouth
2005	Vasculata Course, Dartmouth College
2004	Vasculata Course, University of Washington
2001	Dartmouth-Hitchcock Cardiology Course

Grand Rounds/Medical School Lectures:

2009	Cardiology Grand Rounds, MGH, Boston, MA
2009	Cardiovascular Research Center Seminar, MGH, Boston, MA
2009	Cardiology Grand Rounds, NYU, NY, NY
2009	Visiting Professor, CBVR, BIDMC, Boston, MA
2009	Cardiovascular Seminar, University of Connecticut
2009	Molecular Biology & Biochemistry Seminar, Mayo Clinic, Rochester, MN
2009	NIH TARP Vascular Biology Seminar, NIH, Bethesda, MD
2009	Cardiology Grand Rounds, University of Massachusetts
2009	Cardiology Grand Rounds, University of Pennsylvania
2009	Cardiovascular Seminar, University of Pennsylvania
2008	Medicine Grand Rounds, Yale University School of Medicine
2008	Vascular biology seminar, Institute of Ophthalmology, University College, London, UK
2008	Seminar, Institute for Cardiovascular Sciences, UCL, London, UK
2008	Cardiology seminar, University of Hawaii, Honolulu, HI
2007	Vascular biology seminar, Yale University School of Medicine
2006	Plenary lecturer, University of North Carolina Vascular Biology Day
2006	Medicine Grand Rounds, University of Rochester, Rochester, NY
2006	Cardiovascular Research Center Seminar, MGH, Boston, MA

2006	Cardiovascular Center Seminar, University of Rochester, Rochester, NY
2005	Vascular Biology Seminar, Emory University
2005	Seminar, Sol Sherry Thrombosis Center, Temple University School of Medicine
2005	Medicine Grand Rounds, University of Texas, Houston
2005	Cell Biology & Biochemistry seminar, University of Texas, Houston
2005	Cardiology Grand Rounds, University of California San Francisco
2005	Cardiology Grand Rounds, Dartmouth Medical School
2004	Medicine Grand Rounds, Dartmouth Medical School
2004	Lecturer, ECM Society, Okayama University School of Medicine
2004	Cardiology Grand Rounds, Yale University School of Medicine
2004	Barry Zaret Symposium, Yale University School of Medicine
2003	Vascular Biology Seminar, University of Washington
2003	Research Seminar, British Heart Foundation/University College London
2003	CARIM Seminar, University of Maastricht School of Medicine
2003	Cardiology Grand Rounds, The University of Chicago
2003	Cardiology Grand Rounds, New England Medical Center
2002	Surgery Grand Rounds, Dartmouth Medical School
2002	ICVBM Seminar, Indiana University School of Medicine
2001	Medicine Grand Rounds, Dartmouth Medical School
2001	Cardiology lecturer, Chiba University, Chiba, Japan
2000	Hematology seminar, NYU School of Medicine
2000	Cardiology Research Seminar, Albert Einstein College of Medicine
2000	Cardiology Grand Rounds, University of California, Irvine
2000	Cardiology Grand Rounds, NYU School of Medicine
2000	Cardiology Grand Rounds, Massachusetts General Hospital
2000	Cardiology Grand Rounds, Dartmouth Medical School
2000	Cardiology Grand Rounds, College of Physicians & Surgeons, Columbia University
1999	Vascular Biology Seminars, Harvard University
1999	Physiology Research Seminar, University of Wisconsin
1999	Physiology Research Seminar, University of Iowa
1999	Medical Grand Rounds, UC Davis Medical Center
1999	Medical Grand Rounds, BIDMC
1999	Cardiology Research Grand Rounds, New England Medical Center
1998	Vascular Biology Seminars, Harvard University
1998	Cardiovascular Research Seminars, St. Elizabeth Hospital
1998	Cardiovascular Grand Rounds, Brigham and Women's Hospital
1997	Cardiovascular Grand Rounds, Northwestern University School of Medicine
1997	Cardiology Grand Rounds, University of Calgary School of Medicine
1996	TCT Conference, Washington, DC, Invited Speaker
1996	Cardiovascular Grand Rounds, Albert Einstein College of Medicine
1995	Nuclear Medicine Grand Rounds, JPNM, Harvard University
1995	Cardiovascular Research Seminars, St. Elizabeth Hospital
1995	Cardiology Grand Rounds, Yamaguchi University School of Medicine, Japan
1995	Cardiology Grand Rounds, University of Montreal, Notre Dame Hospital
1994	Physiology Research Seminar, Texas A&M University
1994	Cardiology Grand Rounds, New York University
1993	Physiology Research Seminar, University of Vermont
1993	Pathology Research Seminar, Beth Israel Hospital
1993	Department of Physiology, Southwestern University School of Medicine
1993	Cardiology Grand Rounds, University of Montreal, Notre Dame Hospital
1992	Nephrology Research Seminar, Beth Israel Hospital

Regional, National and International Contributions:

2009	Speaker and Session Chair, TCT 2009, San Francisco, CA
2009	Speaker, Vesalius Research Center Symposium, KU Leuven, Belgium
2009	CRT 2009, Washington, DC, Invited Speaker
2008	Kloster Seeon 5th International Angiogenesis conference, Kloster Seeon, Germany. Invited Speaker
2008	Biology of signaling in cardiovascular system. NAVBO workshop. Cape Cod, MA. Chair and organizer
2008	Angiogenesis in cancer and other diseases. University of Helsinki symposium. Invited Speaker, Helsinki, Finland.
2008	EECPS/Leopoldina symposium, Bad Nauheim, Germany, Invited speaker
2008	The US-Japan cooperative cancer research program invitational meeting, Kyoto, Japan
2007	USA-France NIH/INSERM Vascular Biology invitational meeting, Paris, France
2007	European Vascular Biology and Microcirculation Conference, Plenary lecturer, Heidelberg, Germany
2007	European Society of Cardiology meeting, Invited Speaker, Vienna, Austria
2007	ESH Conference on Angiogenesis, Albufiera, Portugal, Invited speaker
2007	5th International Proteoglycans conference, Invited speaker, Rio de Janeiro, Brazil
2006	USA-France NIH/INSERM Vascular Biology invitational meeting, Denver, CO
2006	State-of-the-Art lecture, International Vascular Biology Meeting, Amsterdam, NL
2006	Plenary lecture, ATVB Conference, Denver, CO
2006	Nature Biotechnology Conference, Invited Speaker, Miami, FL
2006	Frontiers in Cardiology, Invited Speaker, Munich, Germany
2006	Detours'Sils '06, Invited Speaker, Sils-Maria, Switzerland
2005	NHLBI Arteriogenesis Panel, Bethesda, MD
2005	International Society for Heart Research, Invited Speaker, New Orleans, LA
2005	Gordon Conference on Vascular Biology, Invited Speaker, Ventura Beach, CA
2005	CRT 2005 Meeting. Associate Course Director, Washington, DC
2005	Association of University Cardiologists, Invited Speaker, Phoenix, AZ
2005	AHA Scientific Sessions. Session Chair and Invited Speaker, Dallas, TX
2005	ACC Annual meeting, Invited Speaker, Orlando, FL
2004	PULSE 2004 University of Crete and Hellenic Cardiovascular Society, Invited Speaker, Crete, Greece
2004	NIH Workshop on Trans-institute Angiogenesis Program, Towson, MD
2004	Molecular Imaging, Invited Speaker, Bethesda, MD
2004	International Society for Differentiation, Invited Speaker, Honolulu, HI
2004	Cardiovascular Revascularization Therapy, Invited Speaker ,Washington, DC
2004	2nd International Gene Therapy Conference, Invited Speaker, Osaka, Japan
2003	XXX Argentine Cardiovascular Society Meeting, Invited Speaker, Buenos Aires
2003	XIII International Atherosclerosis Society Mtg, Invited Speaker, Kyoto, Japan
2003	TCT Symposium, Washington, DC, Plenary lecture
2003	Japanese Circulation Society, Fukuoka, Japan, Invited Speaker
2003	International Society for Heart Research, Invited Speaker, Newport, CT
2003	Heart Failure Society of America, Invited Speaker, Las Vegas, NV
2003	Gordon Conference on Angiogenesis, Invited Speaker, Newport, RI
2003	EB2003, Invited Speaker
2003	ACC Annual Meeting, Chicago, IL, Invited Speaker
2002	TCT Symposium, Washington, DC, Plenary lecture
2002	Society of Vascular Surgery, Boston, Invited Speaker

2002	Society of Vascular Biology & Medicine, Boston, Invited Speaker
2002	Keystone Conference on Angiogenesis, Banff, Canada, Invited Speaker
2002	International Vascular Biology Meeting, Kuruizawa, Japan, Invited Speaker
2002	International Society for Heart Research, Landmark Lecture
2002	European PCR 2002 Meeting, Paris, France. Invited Speaker
2002	ACC Annual meeting, Atlanta, GA, Invited Speaker
2002	6th Invitational meeting of the American Society of Nuclear Cardiology
2002	3rd Annual Conference on Atherosclerosis, Thrombosis and Vascular Biology, Salt Lake City, NV, Invited Speaker
2002	2nd Interdisciplinary Euroconference on Angiogenesis, Cascais, Portugal, Invited Speaker
2001	VII World Congress on Microcirculation, Sydney, Australia, Invited Speaker
2001	TCT Symposium, Washington, DC, Invited Speaker
2001	Keystone Conference, Angiogenesis and Chronic Disease, Keystone, CO, Invited speaker
2001	Japanese Cardiovascular Society Annual Meeting, Kyoto, Japan, Invited Speaker
2001	Indian Interventional Society Meeting, Bombay, India, Plenary lecture
2001	Cardiology Frontiers Conference, Tokyo, Japan, Invited Speaker
2001	Angiogenesis & DMR, Washington, DC, Invited Speaker
2001	ACC Annual meeting, Orlando, FL, Invited Speaker
2000	Research Seminar, Proctor & Gamble, Inc.
2000	Research Seminar, Genentech, Inc.
2000	Research Seminar, Biogen, Inc.
2000	Research Initiatives Conference in Vascular Disease, Invited Speaker
2000	Plenary lecturer, XXI Congresso Da Sociedade de Cardiologia Do Estado DeSao Paolo, Campos do Jordao
2000	NIH/NSF Technology Assessment Panel, member
2000	International Society for Vascular Biology, Geneva, Invited Speaker
2000	Guidant Angiogenesis & DMR Workshop, Invited Speaker
2000	European Cardiovascular Society, Amsterdam, Session Chair & Invited Speaker
2000	EB2000, Plenary lecture
2000	EB2000, Featured research symposium, Invited Speaker
2000	Angiogenesis experts panel/Expert forum in bio-interventional cardiology
2000	Angiogenesis & DMR Symposium, Invited Speaker
2000	AHA Symposium and Angiogenesis and DMR, Meeting Co-Chair
2000	ACC Mini-symposium, Invited Speaker
2000	1st R. Ross Memorial Conference, Ulm University, Germany, Invited Speaker
1999	TCT Conference, Invited Speaker
1999	Plenary lecture, Cardiac Society of India, New Delhi, India
1999	Medical University of Beijing, Beijing, China, Invited Speaker
1999	International Society for Heart Research, Invited Speaker
1999	Guest lecturer, Madras and Bombay, India
1999	EPIC Course, Emory University, Invited Speaker
1999	ACCIS Symposium, Plenary Speaker
1999	ACC Minicourse, Invited Speaker
1999	3rd International Seminar on Cardiovascular Biology and Medicine, Pamplona, Spain, Invited Speaker
1999	2nd Annual meeting, International Institute for Research, Co-Chair
1999	2nd Angiogenesis & DMR Symposium, Invited Speaker
1998	Update in Cardiology, University of Toronto, Invited Speaker
1998	TCT Conference, Invited Speaker

1998	Schering Workshop on Angiogenesis, Invited Speaker
1998	Merck Research Labs, Invited Speaker
1998	Gordon Research Conference on Proteoglycans, Invited Speaker
1998	Cleveland Clinic Foundation Mini-Symposium on Angiogenesis, Invited Speaker
1998	4th Local Drug Delivery Conference, Geneva, Switzerland, Invited Speaker
1997	Philip T. Goldenberg Lecture St. Francis Hospital, University of Connecticut
1997	NIH Workshop on Antisense Therapeutics, Invited Speaker
1997	Bristol Myers Squibb Symposium on Promotion of Angiogenesis as Therapy for Cardiovascular Disease, Invited Speaker
1996	NHLBI Workshop on Current Directions in Ischemic Heart Disease, Invited Speaker
1996	Fireside seminar, ACC Annual Meeting, Invited Speaker
1996	2nd International Symposium on Local Cardiovascular Drug Delivery, Invited Speaker
1995	Plenary lecture, Japanese Circulation Society Annual Meeting, Nagoya, Japan
1995	Joint Program in Nuclear Medicine, Harvard University, Invited Speaker
1995	First International Symposium on Local Cardiovascular Drug Delivery, Invited Speaker
1995	Boston Biomedical Research Institute, Invited Speaker
1995	AFCR Featured Research Symposium, Invited Speaker
1994	Program of Excellence in Molecular Biology Meeting, Santa Barbara,
1994	Merck Research Labs, Invited Speaker
1994	Hewlett-Packard Medical Advisory Board Meeting, Invited Speaker
1994	Eighth International Workshop on Future Directions in Interventional Cardiology, Santa Barbara, CA, Invited Speaker
1994	Cell cycle workshop, NHLBI, NIH, Invited Speaker
1993	Society of Experimental Pathology, Invited Speaker
1993	Seventh International Workshop on Future Directions in Interventional Cardiology, Santa Barbara, CA, Invited Speaker
1993	Restenosis Summit, Cleveland Clinic, Invited Speaker
1993	New York Cardiovascular Society, Invited Speaker

PROFESSIONAL SERVICE

Peer Review Groups/Grant Study Sections

2009	Chair, Special Emphasis panel ZRG CVS-F02, NIH
2008	Member, Special emphasis panel ZRG1 CVS D02, NIH
2003-2007	Member, Vascular Cell Molecular Biology Study Section, NIH
1998-2003	Ad hoc member, PPG and SCOR Study section, NIH
1995-2000	National referee, VA Merits Grants Program
1997-1999	Panel Member, US Civilian Research and Development Foundation

Journal Service

2008- Present	Editorial Board, *Circulation Genetics*
2006- Present	Editorial Board, *Circulation*
2005- Present	Editorial Board, *American Journal of Physiology: Heart & Circulatory Physiology*
2004- Present	Editorial Board, *Circulation Research*
1999 - 2003	Editorial Board, *American Journal of Physiology: Heart & Circulatory Physiology*
1998-2007	Editorial Board, Vascular Pharmacology
1993-Present	Reviewer for *American Journal of Pathology; Atherosclerosis; Arteriosclerosis, Thrombosis and Vascular Biology; Circulation; Circulation Research; Developmental Cell, FASEB Journal; Journal of Biological*

Chemistry; Journal of Cell Biology; Journal of Cell Science; Journal of Clinical Investigations; Journal of Leukocyte Biology; Journal of Molecular and Cellular Cardiology; Journal of Nuclear Medicine; Journal of Pathology; Microcirculation; Nature; Nature Medicine; Nature Biotechnology; Nature Cell Biology; New England Journal of Medicine; PNAS; Science

Professional Organizations

North American Vascular Biology Organization (NAVBO)

2003- 2007	Member, NAVBO Council
2003- 2004	Secretary-Treasurer
2005- 2006	President

Meeting Planning/Participation

2010	Chair & Organizer, Keystone conference on angiogenesis
2009	Chair & Organizer, Gordon Research Conference on Vascular Biology
2008	Chair & Organizer, NAVBO workshop on Cardiovascular Signaling
2007	Vice-Chair, Gordon Research Conference on Vascular Biology
2007	Program Committee Chair, Vascular Biology '07 national meeting
2005	Chair and organizer, Vasculata annual conference
2004	Chair and organizer, Angiogenesis: basic science to clinical reality, Dartmouth Science Day conference
2001	Co-chair and organizer, AHA conference on angiogenesis
2001-present	Transcatheter Therapeutics Conference (TCT), Abstract selection committee
1997-present	American College of Cardiology, Abstract Selection Committee
1996-present	American Heart Association, Abstract selection committee

Yale University School of Medicine

2008-Present	Steering Committee, Vascular Biology & Therapeutics Program

Main Medical Center Research Institute

2006- Present	Chair, External Advisory Board

Dartmouth College/Dartmouth Medical School

2002-2008	Dartmouth Advanced Imaging Center Steering committee
2004-2008	Dartmouth-Philips Research Steering committee
2006-2008	Dean's Advisory Board
2006-2008	Clinical chairs committee
2004-2008	Executive Committee, Program in Experimental Molecular Medicine
2002-2006	Dean's committee on translational research

Dartmouth-Hitchcock Medical Center

2006 - 2008	Board of Governors
2006 - 2008	Senior Leadership Committee
2004 - 2008	Web Oversight Committee

Beth Israel Hospital/Beth Israel-Deaconess Medical Center

1998 - 2001	Technology Transfer Committee
1997 - 1999	Clinical Practice Assessment Committee
1996 - 1999	Chair, Institutional Animal Care and Utilization Committee
1995 - 1999	Critical Care Committee

1995 - 1999	Quality Assurance Committee
1995 - 1999	Cardiovascular Practice Guidelines
1995 - 1999	Patient Care Committee

Public Service

2004-2008	Data Safety Monitoring Board, NHLBI, NIH
2004-2006	Advisory Board, FDA

BIBLIOGRAPHY:

Peer-Reviewed Manuscripts

1. **Simons M**, Cabin HS, Jaffe CC. Lipomatous hypertrophy of the atrial septum: diagnosis by combined echocardiography and computerized tomography. *Am J Cardiol* 1984;54:465-466
2. Leppo JA, **Simons M**, Hood WB Jr. Effect of adenosine on transmural flow gradients in normal canine myocardium. *J Cardiovasc Pharmacol* 1984; 6:1115-1119.
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A. National

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Papers in Press

CURRICULUM VITAE

HENRY S. CABIN, M.D., F.A.C.C.

Address: Home: 154 Peck Hill Rd.
Woodbridge, CT 06525

Office: Yale University School of Medicine
Section of Cardiovascular Medicine
333 Cedar Street, P.O. Box 208017, Rm 307-FMP
New Haven, CT 06520-8017

Birth Date: April 18, 1950, New York City, New York

Education:

June 1967 -	Graduated from Public High School
June 1971 -	B.A. Cum Laude, University of Pennsylvania, Philadelphia, PA
June 1975 -	M.D. Cum Laude, Yale University School of Medicine, New Haven, CT

Board Certification:

1978 -	Diplomate of the American Board of Internal Medicine
1983 -	Diplomate of the American Board of Internal Medicine, Subspecialty of Cardiovascular Disease
2000 -	Diplomate of the American Board of Internal Medicine, Subspecialty of Interventional Cardiology

Career:

1975-1976	Internship in Internal Medicine, Yale-New Haven Hospital, New Haven, CT
1976-1978	Residency in Internal Medicine, Yale-New Haven Hospital, New Haven, CT'
1978-1981	Clinical Associate, National Heart, Lung and Blood Institute, National Institutes of Health, Bethesda, MD
1981-1982	Clinical Fellow in Cardiology, Yale-New Haven Hospital, New Haven, CT
1982-1987	Assistant Professor of Medicine and Pathology, Yale University, University Director of the Coronary Care Unit, Yale-New Haven Hospital, New Haven, CT Director of the Yale Cardiovascular Pathology Study Unit
1987-1992	Associate Professor of Medicine and Pathology, Yale University, University Director of the Coronary Care Unit, Yale-New Haven Hospital, New Haven, CT Director of the Yale Cardiovascular Pathology Study Unit Associate Director of the Cardiac Catheterization Laboratory, Yale-New Haven Hospital, New Haven, CT

1992-present	Professor of Medicine and Pathology, Yale University, University Director of the Coronary Care Unit, Yale-New Haven Hospital, New Haven, CT Associate Director of the Cardiac Catheterization Laboratory, Yale-New Haven Hospital, New Haven, CT
1994-present	Associate Section Chief of Cardiovascular Medicine Chief of Clinical Cardiology Services, Yale-New Haven Hospital
1999-2005	Associate Director Yale-New Haven Heart Center
2005-present	Associate Chief, Yale-New Haven Heart and Vascular Center Clinical Chief, Section of Cardiovascular Medicine Yale University School of Medicine
2004–2009	Associate Chairman of Medicine for Clinical Affairs, Department of Internal Medicine, Yale University School of Medicine

Medical Licensure: Connecticut, 1977-present

Military Service: U.S. Public Health Service, July 1, 1978 - October 31, 1981

Honors: Phi Beta Kappa - Elected in 1975
Samuel Kushlan Award - 1977

Department of Internal Medicine
Yale University School of Medicine
Housestaff Teacher of the Year Award 1984-1985

New York's Best Doctors, June 2007
New York's Best Doctors, June 2008

Professional Societies: Fellow - American College of Cardiology
Member, American Medical Association

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Francine LoRusso, RN, MHA, CCRN, NE-BC
171 Curve Hill Road
Cheshire, Connecticut 06410
203-271-0214
E-mail: lorusso@ynhh.org

Summary of Qualifications

- Over 29 years as a critical care nurse with 9 years as direct caregiver ICU nurse, 15 years spent as a Patient Services Manager and 6 years as Director of Patient Services
- Experienced executive leader responsible for over 15 diverse cost centers.
- Accomplished leader responsible for over 500 FTEs with annual budgets over $60 million.

Professional Experience

Director Patient Services, Heart and Vascular Center
Yale New Haven Hospital, New Haven Conn.
June 2008- Present

- Responsible for executive leadership and clinical and financial oversight of 15 diverse cost centers. Areas include two ICUs, cardiac and cardiothoracic; two stepdown units, cardiac medicine and cardio-vascular; one cardiac telemetry unit; one 26 bed observation unit; five cardiac cath labs and three electrophysiology labs; six vascular and neuro interventional labs; nuclear cardiology areas; cardiac exercise lab; ECHO labs; HVC recovery area ,PICC service; HVC procedural nursing and Yale Cardiology practice at Shoreline and Branford.

- Accountable for attaining high performance in all elements of four business pillars: Quality/ safety, Provider of Choice; Employer of Choice; Financial

Director Patient Services, Medicine
Yale New Haven Hospital, New Haven Conn.
September 2006- June 2008

- Responsible for executive leadership and clinical and financial oversight of 13 cost centers. Areas include one cardiac ICU, two medical ICUs, one cardiac telemetry floor, one cardiac stepdown floor, one pulmonary stepdown floor, 5 general medicine floors, PICC Service, ICU resource unit and diagnostic radiology / cardiac nursing.
- Accountable for attaining high performance in all elements of four business pillars: Quality/ safety, Provider of Choice; Employer of Choice; Financial

Patient Services Manager of PICC Service
Yale New Haven Hospital, New Haven Conn.

June 1999- September 2006

- Created bedside PICC insertion service. Service developed to meet both adult and pediatric patient population needs. Coverage provided 7 days; operating 12 hour days Monday-Friday, and 4 hours on-call weekends and holidays.
- Responsible for consulting on approximately 2400 cases a year.

Patient Services Manager of DI Recovery Area
Yale New Haven Hospital, New Haven, Conn.
December 1998-September 2006

- Oversaw site location and creation of 13 bed outpatient recovery area for Diagnostic Imaging and Heart Center procedural patients.
- Patient population includes cardiac cath, EPS, and cardiac biopsy patients.
- Interventional radiology population includes oncology, renal, and vascular.
- Neuro interventional patients are also cared for in this setting.

Patient Services Manager of Diagnostic Imaging
Yale New Haven Hospital, New Haven, Conn.
May 1995-September 2006

- 24 hour accountability for nursing practice and nursing staff in Diagnostic Imaging
- Patient populations include inpatients and outpatients of varying acuity levels and with multiple diagnoses.
- General nursing oversight of 10 principal interventional labs, including 4 cardiac cath labs, 5 peripheral vascular/ neuro interventional labs, 1 electrophysiology lab.
- Primary nursing coverage for 5 MRI scanners with flexible staffing provided for CT biopsies, bronchoscopies, ultrasound, and x-ray.
- Accountable for personnel management, staffing, scheduling, clinical practice, fiscal planning, quality improvement, environmental management, education, orientation, and patient satisfaction.

Patient Services Manager Cardiac ICU
Yale New Haven Hospital, New Haven, Conn.
July 1991-September 2006

- 24 hour responsibility for the clinical, fiscal, and environmental management of a 14 bed cardiac intensive care unit.
- Patient population includes patients with medical diagnosis of cardiogenic shock; end stage cardiomyopathy; acute coronary syndrome; as well as patients with unstable cardiac arrhythmias.
- Accountable for interviewing, selecting, and professional development of approximately 90 staff.

Staff Nurse Cardiac ICU
Yale New Haven Hospital, New Haven, Conn.
July 1982-1991

- Primary nurse responsible for coordinating and implementing care of critically ill patients.
- Preceptor Coordinator
- One of first Clinical Nurse IV recognitions and advancements.

Recent Committee Memberships

- EPIC ancillary committee : Cardiovascular Work group
- Administrative liaison PCA steering committee
- Co-chair BSI steering committee
- Chest Pain Center Steering committee
- HVC Quality / Safety Committee
- D2B steering committee
- Hospital Patient Safety Committee (PSQC)
- SCM steering committee
- Co-Chair Patient Hourly Rounding Steering Committee
- Chair HVC newsletter committee
- Westerly Hospital Cardiac oversight committee
- Women's Heart Program steering committee
- Administrative liaison Cardiac Cluster
- ICU Leadership Group
- Magnet steering Committee
- Nursing Operations Group
- Nursing Cabinet

Recent Special Projects

- Opened 14 bed Observation Unit 5/2011
- Successful Oversight of Chest Pain Center accreditation process
- Successful Oversight of TJC VAD Destination Therapy Accreditation
- Project lead on Telemetry project
- One of several authors on ST-Map ECG software research poster/ article
- CON process, design and opening of 5th Cardiac Cath Lab and 3rd EP Lab
- Replacement and implementation of new EKG Tracemaster View System
- Co-lead development and implementation PCA career ladder
- Opened 9 bed Cardiac / Medicine Step Down Unit 1/2008

- CON process, design and opening of second EPS lab
- Cardiac Nuclear design , construction and relocationto 2EP .
- CON process, design, and opening of two Interventional labs
- CON process design, opening of Neuro Interventional lab
- Design and replacement of Cardiac Swing Lab
- Design and creation of third EPS lab
- Provided operations support for shared services model of Guilford / Branford programs

Professional Organizations/ Certifications

- 1987-present Critical Care Nurse (CCRN)
- 2004-present Certified Nurse Executive (NE-BC)
- 1985- present American Association of Critical Care Nurses (AACN)
- 1992- present American Association of Critical Care Nurses/ South Central Connecticut Chapter (AACN / SCCC)
- American Heart Association – Council of Cardiovascular Nursing
- 2006 –present American Organization Nurse Executives (AONE)
- 2006-present Organization of Nurse Executives, Conn. Chapter (ONE-CT)

Education

- 2002 Quinnipiac University, Hamden, Conn.
  Masters in Health Administration with Distinction
- 1997 Quinnipiac University, Hamden, Conn.
  Bachelors of Science in Nursing, Magna cum Laude
- 1982 Quinnipiac University, Hamden, Conn.
  Associate Degree in Nursing, Cum Laude

ATTACHMENT XI

NCDR™ CathPCI Registry®
Greenwich Hospital's Institutional
Outcomes Report 2011Q2

NCDR™
National Cardiovascular Data Registry
CathPCI Registry®
Version 4.4

Institutional Outcomes Report
2011Q2

Greenwich Hospital
187346

Aggregation Date: Sep 30, 2011 11:59:59 PM

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National Cardiovascular Data Registry
CathPCI Registry®
800-257-4737
www.ncdr.com •ncdr@acc.org
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Inclusion Summary

Quarters included in this report:

Timeframe	Benchmark Inclusion Status	Submission Type	Included in Executive Summary
2010Q3	G	All Patients	Yes
2010Q4	G	All Patients	Yes
2011Q1	Y	All Patients	No
2011Q2	G	All Patients	Yes

Comparison group included in this report:

Volume Groups	Number of PCI Procedures per R4Q	Number of Hospitals per Volume Group	Your Hospital's Volume Group	Your Annualized PCI Procedure Volume	Your Declared Procedure Volume
1	0-10	51			
2	11-200	274	X	38	40
3	201-400	299			
4	401-600	233			
5	601-1000	255			
6	1001-2000	139			
7	2001+	23			

Release Notes:

CathPCI Outcomes Registry® Report Release notes for 2011Q2

Report Modifications:

1. This is the first release of the Version 4.4 Outcomes Report.
2. In the Executive Summary Footnote there is a change in the text in regard to bleeding. It now reads, 'To qualify, the event must be associated with a hemoglobin drop of >= 3g/dl...' Where the '>=' symbol is the change.
3. We have now added indicators so that a site can see what lines Leapfrog is looking for in our report. Please see the 'Frequently used terminology' section that follows for information about those changes. We did not specify line numbers as those can change, so we put the acronym '(LFHS)' in the report line description to identify those lines that the Leapfrog Hospital Survey wishes for the sites to report to them.

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Frequently used terminology:

R4Q (Rolling Four Quarters)	The four (4) consecutive quarters included in this report. (Example: The 2011Q1 report includes 2010Q2, 2010Q3, 2010Q4 and 2011Q1. The "Q" in 'R4Q" indicates the last quarter of the rolling four quarters).
Benchmark Inclusion Status	Indicates whether a submission will be included in the R4Q aggregated data (benchmark) and comparison group statistics. "Green," "Yellow" and "Red" stoplights denote the status. A "Green" status indicates the submission (one quarter/timeframe) is included in the benchmark and comparison group statistics. The data has successfully passed all data assessment and completeness checks. A "Yellow" status indicates the submission (one quarter/timeframe) is not included in the benchmark and comparison group statistics. Data is displayed in the quarterly column, but is not included in the "My Hospital R4Q" summary. The data has not passed the overall completeness assessment checks. A "Red" status indicates the submission (one quarter/timeframe) is not included in the benchmark or comparison group statistics. Data is not displayed in the quarterly column. A null or blank status indicates no submission has been received for that quarter/timeframe. Data is not displayed in the quarterly column.
Submission Type	Indicates the Submission Type based on the percentage of procedures performed in the submission file. A file with fewer than 50% of the procedures performed indicated as Diagnostic Catheterizations are designated as "PCI Only" submissions.
My Hospital R4Q	The values for a metric/measure (over R4Q) of data submitted by your facility with a Benchmark Inclusion Status of "Green".
All Hospital 50th Pctl	The median (or midpoint or 50th percentile) of all participant aggregated data for the metric or measure. Half of all participants will be above the median, and half will be below. This value will correspond to the midpoint of the box/whisker plot.
All Hospital 90th Pctl	The 90th percentile of all participant aggregated data for the metric or measure. 10% of all participants will be above the 90th percentile value, and 90% will be below. This value will correspond to the right-most endpoint of the box/whisker plot.
Annualized Volume	Annualized Volume is the total number of PCI procedures submitted over the R4Q period, adjusted for the number of quarters in which valid submissions were received during the R4Q period.
Volume Group Pts R4Q	The aggregated value for the metric/measure across all patients in the specified comparison group (over R4Q). Comparison Groups are based on annualized procedure volume. See the Comparison Group chart on the Inclusion Summary page of this report. To be included, data must have a Benchmark Inclusion Status of "Green".
All Registry Pts R4Q	The aggregated value for the measure/metric across all patients (over R4Q). To be included, data must have a Benchmark Inclusion Status of "Green". Only facilities in the United States and outlying territories are included.
Declared Procedure Volume	Indicates the estimated annual procedure volume as reported by the facility on the NCDR website Site Profile.
LFHS	This stands for Leapfrog Hospital Survey. This is to help identify the lines that are used for Leapfrog reporting for our participants. Please note that in the detail lines you will see "(LFHS)" to denote the lines that are to be used for Actual and Risk Adjusted Mortality Rate calculations.
Actual Mortality Rate (LFHS)	Enter your hospital's (actual) observed mortality rate (OMR) as a percentage. Using data from the My Hospital R4Q "Num" column in the current NCDR CathPCI Registry Institutional Outcomes Reports, OMR must be calculated by dividing the number for "Observed Mortality (among eligible) (LFHS)" by the number for "Eligible pts (LFHS)" to obtain the % rate for the most recent rolling four quarters where 12 consecutive months of data was submitted [i.e., Observed Mortality (among eligible) (LFHS)/Eligible pts (LFHS)].
Expected Mortality Rate (LFHS)	Enter your hospital's expected mortality rate (EMR) as a percentage. Using data from the Hospital R4Q "Num" column in the current NCDR CathPCI Registry Institutional Outcomes Reports, EMR must be calculated by dividing the number for "Expected Mortality (among eligible) (LFHS)" by the number for "Eligible pts (LFHS)" to obtain the % rate for the most recent rolling four quarters where 12 consecutive months of data was submitted [i.e., Expected Mortality (among eligible) (LFHS)/Eligible pts (LFHS)].

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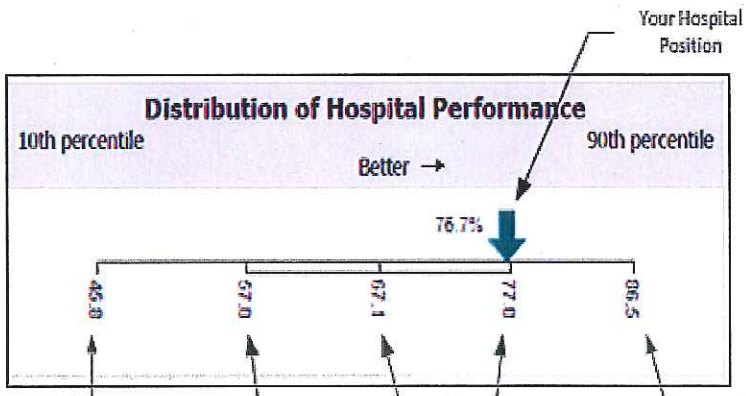
Box and Whisker Plots

Interpreting Box and Whisker Plots



10th percentile
If your hospital scores below the 10th percentile, the arrow will be on the left of this number.

25th Percentile

Median

75th Percentile

90th Percentile
If your hospital scores above the 90th percentile, the arrow will be on the right of this number.

10th Percentile
90% of the hospitals achieved "better" scores than the 10th percentile.

25th Percentile or 1st Quartile
75% of the hospitals achieved "better" scores than the 25th percentile.

50th Percentile or 2nd Quartile
Middle of the distribution: Half of the hospitals data is above and half are below the median.

75th Percentile or 3rd Quartile
25% of the hospitals achieved "better" scores than the 75th percentile.

90th Percentile
10% of the hospitals achieved "better" scores than the 90th percentile.

Your Hospital Position
Your 'Hospital Position' in relation to all other hospitals' data.

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Executive Summary

CathPCI Registry®

Greenwich Hospital(187346) compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2011Q2

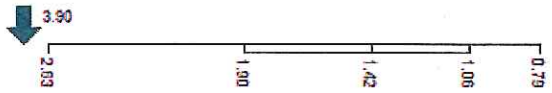
Section I: PCI Performance Measures

Endorsed by the National Quality Forum and appropriate for public reporting

PCI Performance Measures	Distribution of Hospital Performance (10th percentile — 90th percentile; Better →)
1 **PCI in-hospital risk adjusted mortality (all patients)**	

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
3.90	1.42	0.79

Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1997]



Note

In-hospital risk adjusted mortality for PCI is the only performance measure in the CathPCI Registry® that has been endorsed by the National Quality Forum. Such performance measures meeting the requirement for approval are intended not only for clinical quality improvement, but also may be considered for purposes of public reporting.

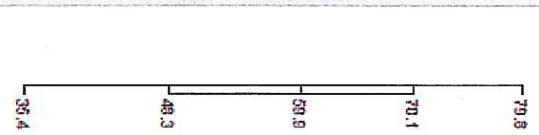
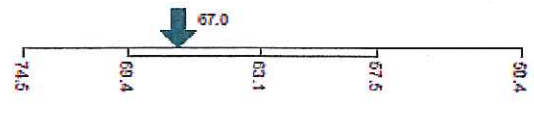
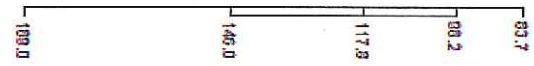
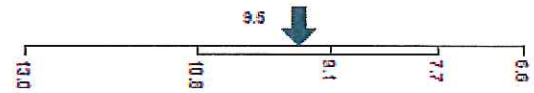
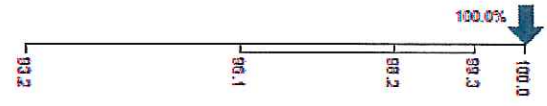
The "Registry Metrics" on the subsequent pages of this report are those measures that have been developed to support self assessment and quality improvement at the provider, hospital, and/or health care system level. While these metrics have not been formally developed by the American College of Cardiology/American Heart Association Task Force for Performance Measures Task Force, they may be identified as evolving measures worthy of consideration for further development into performance measures.

Executive Summary

CathPCI Registry®

Greenwich Hospital(187346) compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2011Q2

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

	PCI Process Metrics	Distribution of Hospital Performance (10th percentile — 90th percentile; Better →)
2	**Proportion of elective PCIs with prior positive stress or imaging study** My Hospital: — | All Hospitals 50th Pctl: 59.9% | All Hospitals 90th Pctl: 79.8% Proportion of elective PCI procedures (excluding patients with ACS) with an antecedent stress or imaging study with a positive result (suggestive of ischemia) or with a fractional flow reserve value of <=0.8 during the PCI procedure [Detail Line:1511]	
3	**Median time to immediate PCI for STEMI patients (in minutes)** My Hospital: 67.0 | All Hospitals 50th Pctl: 63.1 | All Hospitals 90th Pctl: 50.4 Your hospital's median time from hospital arrival to immediate PCI for STEMI patients in minutes. Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1500]	
4	**Proportion of STEMI patients receiving immediate PCI w/in 90"** My Hospital: 100.0% | All Hospitals 50th Pctl: 91.4% | All Hospitals 90th Pctl: 100.0% Proportion of STEMI patients with a time from your hospital arrival (or subsequent ECG if ST elevation first noted on subsequent ECG) to immediate PCI <=90". Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1501]	
5	**Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.** My Hospital: — | All Hospitals 50th Pctl: 85.5 | All Hospitals 90th Pctl: 57.8 Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1503]	
6	**Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)** My Hospital: — | All Hospitals 50th Pctl: 117.8 | All Hospitals 90th Pctl: 83.7 Your hospital's median time from arrival at referring facility to immediate PCI at STEMI receiving facility among transferred patients. Exclusions: Reasons for delay does not equal none. [Detail Line:1504]	
7	**Median fluoro time (in minutes)** My Hospital: 9.5 | All Hospitals 50th Pctl: 9.1 | All Hospitals 90th Pctl: 6.6 Inclusion criteria: PCI of one vessel/lesion. Exclusion criteria: Prior CABG, or "other" procedure during the same lab visit; PCI of >1 vessel/lesion. [Detail Line:1629]	
8	**Proportion of patients with aspirin prescribed at discharge** My Hospital: — | All Hospitals 50th Pctl: 98.2% | All Hospitals 90th Pctl: 100.0% Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1959]	
9	**Proportion of patients with thienopyridine prescribed at discharge** My Hospital: — | All Hospitals 50th Pctl: 99.1% | All Hospitals 90th Pctl: 100.0% Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine prescribed at discharge. [Detail Line: 1968]	

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Executive Summary

CathPCI Registry®

Greenwich Hospital(187346) compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2011Q2

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

10 **Statins prescribed at discharge**

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
100.0%	91.5%	97.3%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:1964]



PCI Outcome Metrics

Distribution of Hospital Performance

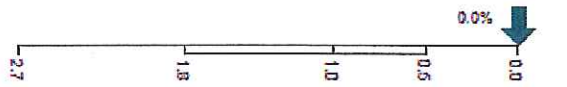
10th percentile — 90th percentile

Better →

11 **Proportion of PCI procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
0.0%	1.0%	0.0%

Your hospital's proportion of patients (excluding CABG or other surgery during same admission) with major access site related injury requiring treatment or major bleeding. [Detail Line:1836]



12 **Proportion of PCI patients with emergency CABG**

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
0.0%	0.1%	0.0%

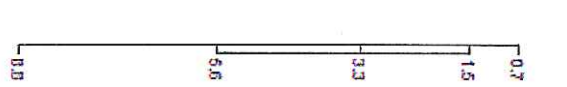
Your hospital's proportion of patients having emergency CABG (at your facility or transferred to another facility). [Detail Line:1941]



13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
	3.3%	0.7%

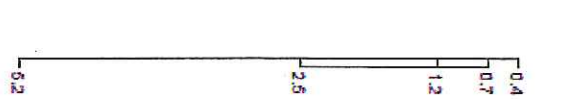
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with >= 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1799]



14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
	1.2%	0.4%

Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with < 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1800]



15 **Proportion of PCI procedures with acute kidney injury*****

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
	2.2%	1.0%

Your hospital's proportion of patients who had a rise of serum creatinine of > 50% over the pre-procedure baseline (excluding patients on dialysis pre-procedure). Inclusions: >= 90% of patients with a pre and post creatinine coded; LOS >=1 day. [Detail Line:1933]



16 **Proportion of PCI procedures with post procedure stroke**

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
0.0%	0.0%	0.0%

Your hospital's proportion of patients with stroke post procedure. [Detail Line:1807]



17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
6.9%	2.3%	0.9%

Your hospital's proportion of patients with death, emergency CABG, stroke or repeat target vessel revascularization post procedure up to hospital discharge. Excludes patients with stroke and an elective, urgent or salvage CABG during same admission. [Detail Line:1797]



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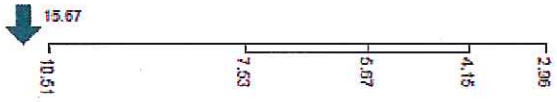
Greenwich Hospital(187346) compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2011Q2

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
15.67	5.67	2.96

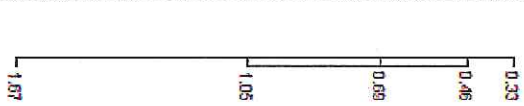
Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2006]



19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
	0.69	0.33

Your hospital's PCI in-hospital risk adjusted mortality rate for patients with other diagnoses (not STEMI) using the NCDR® risk adjustment model. [Detail Line:2015]



Diagnostic Cath Process Metrics

Distribution of Hospital Performance

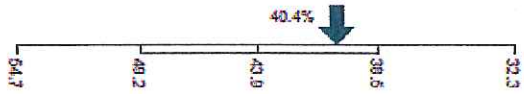
10th percentile — 90th percentile

Better →

20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
40.4%	43.9%	32.3%

Patients with an elective diagnostic cath and coronary angiography with all native coronary territories <50% Exclusions: Patients with prior CABG, cardiac transplant evaluation; pre-op evaluation for non-cardiac surgery and diagnostic cath treatment recommendation of "other cardiac therapy without CABG or PCI". [Detail Line:1252]



Diagnostic Cath Outcomes Metrics

Distribution of Hospital Performance

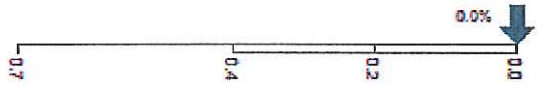
10th percentile — 90th percentile

Better →

21 **Proportion of Diagnostic Catheterization procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
0.0%	0.2%	0.0%

Your hospital's proportion of patients with major access site related injury requiring treatment or major bleeding. [Detail Line:1301]



Utilization Metrics

Distribution of Hospital Performance

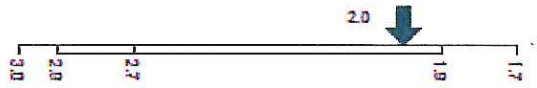
10th percentile — 90th percentile

Better →

22 **Median post-procedure length of stay (in days) for PCI patients with STEMI**

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
2.0	2.7	1.7

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2071]



Data Quality Metrics

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →

24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
79.3%	86.0%	96.1%

Proportion of PCI patients with creatinine assessed pre and post procedure. Inclusions: LOS >=1 day. [Detail Line:1932]



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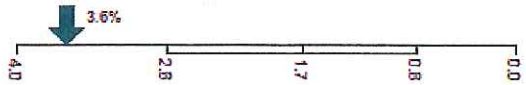
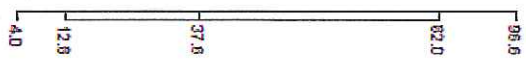
Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

Test Metrics		Distribution of Hospital Performance
		10th percentile — 90th percentile; Better →
25	**Test Metric: Proportion of PCI procedures with transfusion of whole blood or RBCs** My Hospital: 3.6% | All Hospitals 50th Pctl: 1.7% | All Hospitals 90th Pctl: 0.0% Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Exclusions: Patients having CABG or other major surgery during the same admission. [Detail Line:1838]	
26	**Test Data Quality Metric: Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients** My Hospital: | All Hospitals 50th Pctl: 37.6% | All Hospitals 90th Pctl: 96.6% Proportion of elective procedures with biomarkers assessed post PCI. Inclusion criteria: LOS >= 1 day and hospital status is "not outpatient". [Detail Line:1930]	

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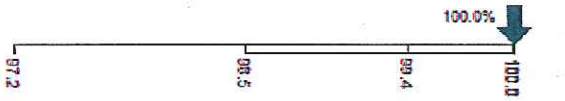
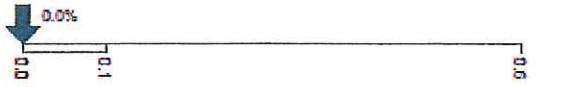
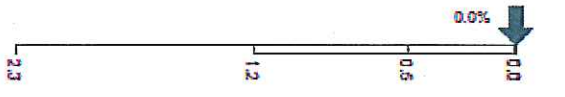
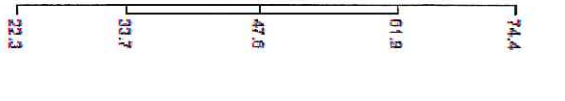
Greenwich Hospital(187346) compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2011Q2

Section III: PCI Appropriate Use Criteria (AUC) Test Metrics – These data are based upon the 2009 Appropriateness Criteria for Coronary Revascularization (J Am Coll Cardiol 2009;53:530-53) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These test metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level. Test metrics are not appropriate for public/external reporting.

Test Metrics: PCI Appropriate Use Criteria (AUC)	Distribution of Hospital Performance (10th percentile – 90th percentile; Better →)
30 **Test Metric: Proportion of PCI procedures not classifiable for AUC reporting** My Hospital: 0.0% | All Hospitals 50th Pctl: 11.9% | All Hospitals 90th Pctl: 2.7% Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1587]	
31 **Patients WITH Acute Coronary Syndrome (Test Metric): Proportion of evaluated PCI procedures that were appropriate** My Hospital: 100.0% | All Hospitals 50th Pctl: 99.4% | All Hospitals 90th Pctl: 100.0% Proportion of PCI procedures that were evaluated as "Appropriate", among patients with ACS, meaning coronary revascularization is generally acceptable and is a reasonable approach for the indication and is likely to improve the patients' health outcomes or survival. [Detail Line:1579]	
32 **Patients WITH Acute Coronary Syndrome (Test Metric): Proportion of evaluated PCI procedures that were of uncertain appropriateness** My Hospital: 0.0% | All Hospitals 50th Pctl: 0.0% | All Hospitals 90th Pctl: 0.6% Proportion of PCI procedures that were evaluated as "Uncertain", among patients with ACS, meaning coronary revascularization may be acceptable and may be a reasonable approach for the indication. However, some degree of uncertainty exists, implying that more research and/or patient information is needed to determine whether the procedure would improve patients' health outcomes or survival. [Detail Line:1580]	
33 **Patients WITH Acute Coronary Syndrome (Test Metric): Proportion of evaluated PCI procedures that were inappropriate** My Hospital: 0.0% | All Hospitals 50th Pctl: 0.5% | All Hospitals 90th Pctl: 0.0% Proportion of PCI procedures that were evaluated as "Inappropriate", among patients with ACS, meaning coronary revascularization is not generally acceptable and is not a reasonable approach for the indication and is unlikely to improve the patients' health outcomes or survival. [Detail Line:1581]	
34 **Patients WITHOUT Acute Coronary Syndrome (Test Metric): Proportion of evaluated PCI procedures that were appropriate** My Hospital: | All Hospitals 50th Pctl: 47.6% | All Hospitals 90th Pctl: 74.4% Proportion of PCI procedures that were evaluated as "Appropriate", among patients without ACS, meaning coronary revascularization is generally acceptable and is a reasonable approach for the indication and is likely to improve the patients' health outcomes or survival. [Detail Line:1583]	
35 **Patients WITHOUT Acute Coronary Syndrome (Test Metric): Proportion of evaluated PCI procedures that were of uncertain appropriateness** My Hospital: | All Hospitals 50th Pctl: 39.1% | All Hospitals 90th Pctl: 61.5% Proportion of PCI procedures that were evaluated as "Uncertain", among patients without ACS, meaning coronary revascularization may be acceptable and may be a reasonable approach for the indication. However, some degree of uncertainty exists, implying that more research and/or patient information is needed to determine whether the procedure would improve patients' health outcomes or survival. [Detail Line:1584]	

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Greenwich Hospital(187346) compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2011Q2

Section III: PCI Appropriate Use Criteria (AUC) Test Metrics – These data are based upon the 2009 Appropriateness Criteria for Coronary Revascularization (J Am Coll Cardiol 2009;53:530-53) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These test metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level. Test metrics are not appropriate for public/external reporting.

36 **Patients WITHOUT Acute Coronary Syndrome (Test Metric): Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
	9.5%	0.0%

Proportion of PCI procedures that were evaluated as "Inappropriate", among patients without ACS, meaning coronary revascularization is not generally acceptable and is not a reasonable approach for the indication and is unlikely to improve the patients' health outcomes or survival. [Detail Line:1585]



Executive Summary Footnotes

*Vascular access site injury requiring treatment or major bleeding is defined as:

1.Bleeding at access site, hematoma at access site, or retroperitoneal bleed that occur within 72 hours of the procedure. To qualify, the event must be associated with a hemoglobin drop of >= 3 g/dL; transfusion of whole or packed red blood cells, or a procedural intervention/surgery at the bleeding site to reverse/stop or correct the bleeding. This excludes "GI", "GU" and "Other" bleeds.

2.Major access site related injury requiring treatment includes access site occlusion, peripheral embolization, dissection, pseudoaneurysm, AV fistula requiring treatment anytime from the procedure until discharge.

**Your rate of post procedure MI cannot be reported if you only collected cardiac biomarkers on <90% of your patients who were in the hospital >=1 day.

***Your rate of acute kidney injury cannot be reported if you only collected creatinine pre and post procedure on <90% of your patients who were in the hospital >=1 day.

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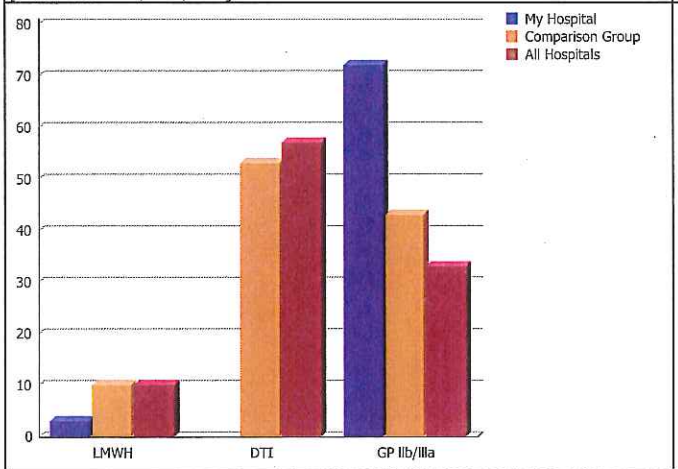
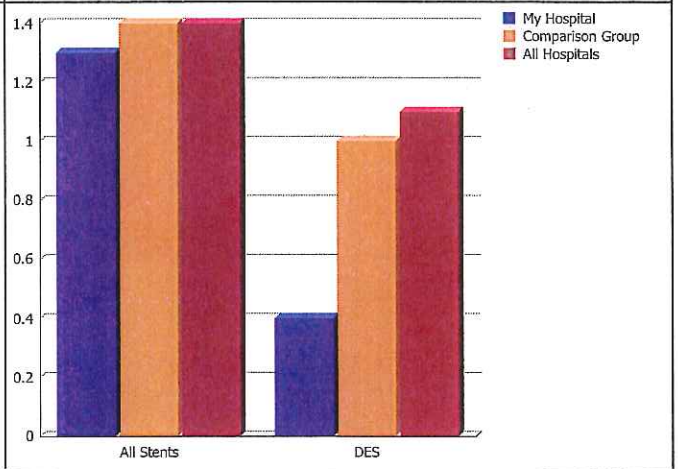
Section IV: PCI Process Comparison Metrics

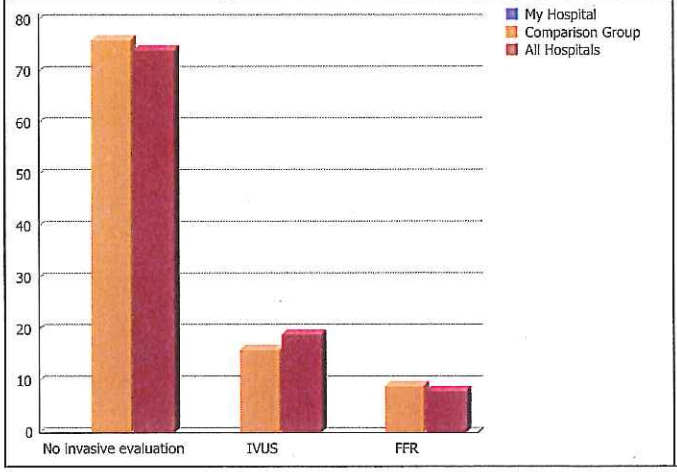
Anticoagulant Use: Low molecular weight heparin, direct thrombin inhibitors, GP IIb/IIIa inhibitor(pts with acute coronary syndrome).
[Detail Line:1596,1598,1603]



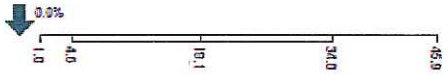
Stent Use: Average # of stents per PCI admission.
[Detail Line:1789,1790]



Intermediate stenosis lesions(40-70%): Further invasive evaluation performed (IVUS or FFR).
[Detail Line:1728,1729,1730]



Outpatients: Proportion of PCI patient admissions whose hospital status was coded as "outpatient".
[Detail Line:1388]



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Detail Section Line Reference

Population	Section	First Line #	Last Line #
All Diagnostic Cath and PCI Patients	Volume Summary	1000	1014
	Demographics and Payors	1015	1049
Diagnostic Cath with/without PCI	Demographics and Payors	1050	1084
	History and Risk Factors (on arrival)	1085	1102
	Clinical Evaluation Leading to the Procedure	1103	1139
	Stress and Imaging Studies	1140	1201
	Procedure Information	1202	1246
	Procedure Findings	1247	1273
	Discharge Information	1302	1323
Diagnostic Cath (No PCI)	Adverse Events	1274	1301
	Length of Stay	1324	1360
PCI	Demographics and Payors	1361	1399
	History and Risk Factors (on arrival)	1400	1431
	Clinical Evaluation Leading to the Procedure	1432	1472
	Procedure Indications	1473	1505
	Stress and Imaging Studies	1506	1569
	Appropriate Use Criteria	1570	1590
	Medications	1591	1608
	Procedure Information	1609	1673
	Procedure Findings	1674	1705
	PCI Lesion Information	1706	1793
	Lab Results	1929	1935
	Discharge Information	1936	2018
PCI (all patients)	Adverse Events	1794	1840
	Length of Stay	2019	2057
PCI (patients with STEMI)	Adverse Events	1841	1882
	Length of Stay	2058	2096
PCI (patients without STEMI)	Adverse Events	1883	1928
	Length of Stay	2097	2135

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All Diagnostic Cath and PCI Patients
Volume Summary
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1000	Summary																			
1001	**Number of Patients treated at this facility**	**53**			**67**			**71**			**71**			**191**			**79,997**		**1,343,820**	
1002	Dx cath	53	53	100.0	67	67	100.0	71	71	100.0	71	71	100.0	191	191	100.0	78,284	97.9	1,273,505	94.8
1003	PCI	5	53	9.4	14	67	20.9	8	71	11.3	10	71	14.1	29	191	15.2	27,644	34.6	619,579	46.1
1004	Other procedure in conjunction w/ a dx cath or PCI	0	53	0.0	1	67	1.5	0	71	0.0	27	71	38.0	28	191	14.7	7,031	8.8	153,348	11.4
1005	Pts w/ dx cath and PCI in the same lab visit	5	53	9.4	14	67	20.9	8	71	11.3	10	71	14.1	29	191	15.2	25,382	31.7	533,939	39.7
1006	Pts w/ dx cath then a PCI in a subsequent lab visit	0	53	0.0	0	67	0.0	0	71	0.0	0	71	0.0	0	191	0.0	545	0.7	15,254	1.1
1007	PCI procedures per PCI admission	5	5	100.0	14	14	100.0	8	8	100.0	10	10	100.0	29	29	100.0	28,171	101.9	636,415	102.7
1008	Pts w/ >1 PCI on the same coronary segment/lesion	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	111	0.4	3,293	0.5
1009	Procedures																			
1010	Dx cath procedures	53	53	100.0	68	68	100.0	71	71	100.0	71	71	100.0	192	192	100.0	78,943	96.9	1,287,327	93.0
1011	Dx coronary angiography	52	53	98.1	67	68	98.5	71	71	100.0	70	71	98.6	189	192	98.4	76,956	97.5	1,259,255	97.8
1012	Left heart cath	52	53	98.1	68	68	100.0	68	71	95.8	71	71	100.0	191	192	99.5	69,309	87.8	1,155,748	89.8
1013	PCI procedures	5	53	9.4	14	68	20.6	8	71	11.3	10	71	14.1	29	192	15.1	28,171	34.6	636,415	46.0
1014	Dx cath and PCI during same lab visit	5	53	9.4	14	68	20.6	8	71	11.3	10	71	14.1	29	192	15.1	25,657	31.5	540,061	39.0

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All Diagnostic Cath and PCI Patients
Demographics and Payors
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1015	Demographics																			
1016	**Sex**																			
1017	Male	32	53	60.4	45	67	67.2	47	71	66.2	52	71	73.2	129	191	67.5	47,651	59.6	822,078	61.2
1018	Female	21	53	39.6	22	67	32.8	24	71	33.8	19	71	26.8	62	191	32.5	32,346	40.4	521,742	38.8
1019	**Age at admission**																			
1020	Mean age	67			65			67			68			67			63		64	
1021	Median age	71			64			64			70			68			63		64	
1022	18-44	2	53	3.8	7	67	10.5	5	71	7.0	3	71	4.2	12	191	6.3	5,500	6.9	82,367	6.1
1023	45-54	6	53	11.3	10	67	14.9	14	71	19.7	10	71	14.1	26	191	13.6	15,012	18.8	232,307	17.3
1024	55-64	12	53	22.6	17	67	25.4	17	71	23.9	16	71	22.5	45	191	23.6	22,114	27.6	366,992	27.3
1025	65-69	6	53	11.3	4	67	6.0	3	71	4.2	6	71	8.5	16	191	8.4	11,071	13.8	197,967	14.7
1026	70-74	10	53	18.9	6	67	9.0	6	71	8.5	13	71	18.3	29	191	15.2	9,381	11.7	169,598	12.6
1027	75-79	7	53	13.2	10	67	14.9	5	71	7.0	7	71	9.9	24	191	12.6	8,082	10.1	141,955	10.6
1028	>= 80	10	53	18.9	13	67	19.4	21	71	29.6	16	71	22.5	39	191	20.4	8,837	11.1	152,624	11.4
1029	Medicare age (>= 65)	33	53	62.3	33	67	49.3	35	71	49.3	42	71	59.2	108	191	56.5	37,371	46.7	662,150	49.3
1030	**Race**																			
1031	White	48	53	90.6	62	67	92.5	66	71	93.0	69	71	97.2	179	191	93.7	66,220	82.8	1,164,171	86.6
1032	Black/African American	2	53	3.8	1	67	1.5	4	71	5.6	2	71	2.8	5	191	2.6	10,785	13.5	134,609	10.0
1033	Asian	2	53	3.8	4	67	6.0	0	71	0.0	0	71	0.0	6	191	3.1	1,550	1.9	26,433	2.0
1034	American Indian/Alaskan	1	53	1.9	0	67	0.0	0	71	0.0	0	71	0.0	1	191	0.5	647	0.8	7,468	0.6
1035	Hawaiian/Pacific Islander	0	53	0.0	0	67	0.0	1	71	1.4	0	71	0.0	0	191	0.0	212	0.3	2,446	0.2
1036	**Hispanic or Latino ethnicity**	**8**	**53**	**15.1**	**8**	**66**	**12.1**	**8**	**71**	**11.3**	**4**	**71**	**5.6**	**20**	**190**	**10.5**	**5,466**	**6.9**	**67,661**	**5.1**
1037	**Insurance payors**																			
1038	Private	23	53	43.4	39	67	58.2	57	71	80.3	61	71	85.9	123	191	64.4	45,601	57.0	848,672	63.2
1039	Medicare	31	53	58.5	31	67	46.3	36	71	50.7	39	71	54.9	101	191	52.9	37,136	46.4	676,557	50.4
1040	Medicaid	1	53	1.9	2	67	3.0	5	71	7.0	2	71	2.8	5	191	2.6	8,126	10.2	140,630	10.5
1041	Military	0	53	0.0	0	67	0.0	0	71	0.0	0	71	0.0	0	191	0.0	1,672	2.1	36,545	2.7
1042	State-specific (non-medicaid)	1	53	1.9	1	67	1.5	2	71	2.8	0	71	0.0	2	191	1.1	1,917	2.4	21,900	1.6
1043	Indian Health Service	0	53	0.0	0	67	0.0	0	71	0.0	0	71	0.0	0	191	0.0	211	0.3	2,336	0.2
1044	Non-U.S. insurance	0	53	0.0	0	67	0.0	0	71	0.0	0	71	0.0	0	191	0.0	41	0.1	857	0.1
1045	None	2	53	3.8	7	67	10.5	2	71	2.8	4	71	5.6	13	191	6.8	5,721	7.2	79,535	5.9
1046	**CABG during episode of care**	**5**	**53**	**9.4**	**2**	**67**	**3.0**	**6**	**71**	**8.5**	**2**	**71**	**2.8**	**9**	**191**	**4.7**	**4,065**	**5.1**	**62,992**	**4.7**
1047	**Discharge status**																			
1048	Alive	50	53	94.3	67	67	100.0	69	71	97.2	69	71	97.2	186	191	97.4	79,106	98.9	1,328,747	98.9
1049	Expired (excluding transplants)	3	53	5.7	0	67	0.0	2	71	2.8	2	71	2.8	5	191	2.6	823	1.1	14,282	1.1

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Diagnostic Cath with/without PCI
Demographics and Payors
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1050	Demographics																			
1051	**Sex**																			
1052	Male	32	53	60.4	45	67	67.2	47	71	66.2	52	71	73.2	129	191	67.5	46,504	59.4	775,181	60.9
1053	Female	21	53	39.6	22	67	32.8	24	71	33.8	19	71	26.8	62	191	32.5	31,780	40.6	498,324	39.1
1054	**Age at admission**																			
1055	Mean age	67			65			67			68			67			63		64	
1056	Median age	71			64			64			70			68			63		64	
1057	18-44	2	53	3.8	7	67	10.5	5	71	7.0	3	71	4.2	12	191	6.3	5,429	6.9	80,029	6.3
1058	45-54	6	53	11.3	10	67	14.9	14	71	19.7	10	71	14.1	26	191	13.6	14,753	18.9	222,938	17.5
1059	55-64	12	53	22.6	17	67	25.4	17	71	23.9	16	71	22.5	45	191	23.6	21,660	27.7	348,350	27.4
1060	65-69	6	53	11.3	4	67	6.0	3	71	4.2	6	71	8.5	16	191	8.4	10,809	13.8	186,267	14.6
1061	70-74	10	53	18.9	6	67	9.0	6	71	8.5	13	71	18.3	29	191	15.2	9,169	11.7	159,403	12.5
1062	75-79	7	53	13.2	10	67	14.9	5	71	7.0	7	71	9.9	24	191	12.6	7,871	10.1	133,230	10.5
1063	>= 80	10	53	18.9	13	67	19.4	21	71	29.6	16	71	22.5	39	191	20.4	8,593	11.0	143,279	11.3
1064	Medicare age (>= 65)	33	53	62.3	33	67	49.3	35	71	49.3	42	71	59.2	108	191	56.5	36,442	46.6	622,185	48.9
1065	**Race**																			
1066	White	48	53	90.6	62	67	92.5	66	71	93.0	69	71	97.2	179	191	93.7	64,695	82.6	1,102,556	86.6
1067	Black/African American	2	53	3.8	1	67	1.5	4	71	5.6	2	71	2.8	5	191	2.6	10,651	13.6	128,396	10.1
1068	Asian	2	53	3.8	4	67	6.0	0	71	0.0	0	71	0.0	6	191	3.1	1,524	2.0	25,078	2.0
1069	American Indian/Alaskan	1	53	1.9	0	67	0.0	0	71	0.0	0	71	0.0	1	191	0.5	643	0.8	7,193	0.6
1070	Hawaiian/Pacific Islander	0	53	0.0	0	67	0.0	1	71	1.4	0	71	0.0	0	191	0.0	211	0.3	2,344	0.2
1071	**Hispanic or Latino ethnicity**	**8**	**53**	**15.1**	**8**	**66**	**12.1**	**8**	**71**	**11.3**	**4**	**71**	**5.6**	**20**	**190**	**10.5**	**5,367**	**6.9**	**64,721**	**5.1**
1072	**Hospital status**																			
1073	Outpt	19	53	35.9	18	67	26.9	21	71	29.6	19	71	26.8	56	191	29.3	28,367	36.3	516,866	40.6
1074	Outpt converted to inpt	2	53	3.8	3	67	4.5	2	71	2.8	3	71	4.2	8	191	4.2	8,283	10.6	147,039	11.6
1075	Inpt	32	53	60.4	46	67	68.7	48	71	67.6	49	71	69.0	127	191	66.5	41,584	53.2	609,230	47.9
1076	**Insurance payors**																			
1077	Private	23	53	43.4	39	67	58.2	57	71	80.3	61	71	85.9	123	191	64.4	44,707	57.1	804,256	63.2
1078	Medicare	31	53	58.5	31	67	46.3	36	71	50.7	39	71	54.9	101	191	52.9	36,249	46.3	636,096	50.0
1079	Medicaid	1	53	1.9	2	67	3.0	5	71	7.0	2	71	2.8	5	191	2.6	8,014	10.2	133,764	10.5
1080	Military	0	53	0.0	0	67	0.0	0	71	0.0	0	71	0.0	0	191	0.0	1,655	2.1	34,566	2.7
1081	State-specific (non-medicaid)	1	53	1.9	1	67	1.5	2	71	2.8	0	71	0.0	2	191	1.1	1,872	2.4	21,044	1.7
1082	Indian Health Service	0	53	0.0	0	67	0.0	0	71	0.0	0	71	0.0	0	191	0.0	207	0.3	2,246	0.2
1083	Non-U.S. insurance	0	53	0.0	0	67	0.0	0	71	0.0	0	71	0.0	0	191	0.0	39	0.1	832	0.1
1084	None	2	53	3.8	7	67	10.5	2	71	2.8	4	71	5.6	13	191	6.8	5,614	7.2	76,508	6.0

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Diagnostic Cath with/without PCI
History and Risk Factors (on arrival)
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1085	Cardiac history and risk factors																			
1086	**Body mass index**																			
1087	Overweight (BMI>=25)	39	53	73.6	45	67	67.2	55	71	77.5	51	71	71.8	135	191	70.7	61,911	79.4	1,014,502	79.8
1088	Obese (BMI>=30)	18	53	34.0	16	67	23.9	24	71	33.8	22	71	31.0	56	191	29.3	35,859	46.0	582,700	45.8
1089	Morbidly obese (BMI>=40)	1	53	1.9	3	67	4.5	0	71	0.0	1	71	1.4	5	191	2.6	7,487	9.6	113,885	9.0
1090	**Family history of premature CAD**	**15**	**53**	**28.3**	**18**	**67**	**26.9**	**21**	**71**	**29.6**	**19**	**71**	**26.8**	**52**	**191**	**27.2**	**23,210**	**29.7**	**321,681**	**25.3**
1091	**Prior MI (>7 days)**	**12**	**53**	**22.6**	**13**	**67**	**19.4**	**22**	**71**	**31.0**	**26**	**71**	**36.6**	**51**	**191**	**26.7**	**16,616**	**21.2**	**310,833**	**24.4**
1092	**Prior PCI**	**7**	**53**	**13.2**	**9**	**67**	**13.4**	**6**	**71**	**8.5**	**17**	**71**	**23.9**	**33**	**191**	**17.3**	**18,943**	**24.2**	**396,406**	**31.1**
1093	Previous PCI timeframe																			
1094	<=1 year	0	1	0.0							0	2	0.0	0	3	0.0	2,411	30.5	67,449	31.4
1095	>1 year	1	1	100.0							2	2	100.0	3	3	100.0	5,483	69.5	147,415	68.6
1096	**Prior CABG**	**3**	**53**	**5.7**	**6**	**67**	**9.0**	**3**	**70**	**4.3**	**7**	**71**	**9.9**	**16**	**191**	**8.4**	**8,813**	**11.3**	**197,026**	**15.5**
1097	Timeframe of prior CABG																			
1098	<=5 years																723	24.4	24,276	24.8
1099	> 5 years																2,242	75.6	73,754	75.2
1100	Other history																			
1101	**Currently on dialysis**	**0**	**53**	**0.0**	**0**	**67**	**0.0**	**0**	**71**	**0.0**	**1**	**71**	**1.4**	**1**	**191**	**0.5**	**2,128**	**2.7**	**30,893**	**2.4**
1102	**Diabetes mellitus**	**13**	**53**	**24.5**	**12**	**67**	**17.9**	**15**	**71**	**21.1**	**17**	**71**	**23.9**	**42**	**191**	**22.0**	**26,563**	**34.0**	**443,170**	**34.8**

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Diagnostic Cath with/without PCI
Clinical Evaluation Leading to the Procedure
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1103	Clinical evaluation leading to the Dx cath																			
1104	**CAD presentation**																			
1105	No symptoms,no angina	18	53	34.0	8	68	11.8	5	71	7.0	4	71	5.6	30	192	15.6	10,636	13.5	166,969	13.0
1106	Symptoms unlikely to be ischemic	17	53	32.1	13	68	19.1	18	71	25.4	17	71	23.9	47	192	24.5	9,743	12.4	142,687	11.1
1107	Stable angina	1	53	1.9	7	68	10.3	5	71	7.0	5	71	7.0	13	192	6.8	15,183	19.2	240,649	18.7
1108	Unstable angina	9	53	17.0	18	68	26.5	15	71	21.1	23	71	32.4	50	192	26.0	24,013	30.4	448,653	34.9
1109	Non-STEMI	2	53	3.8	8	68	11.8	19	71	26.8	11	71	15.5	21	192	10.9	10,378	13.2	176,400	13.7
1110	STEMI	6	53	11.3	14	68	20.6	9	71	12.7	11	71	15.5	31	192	16.2	8,957	11.4	111,628	8.7
1111	**Timeframe from sx onset to arrival (for acute MI)**																			
1112	<=6 hrs	3	8	37.5	8	22	36.4	13	28	46.4	8	22	36.4	19	52	36.5	9,498	49.1	124,420	43.2
1113	>6 hrs	1	8	12.5	4	22	18.2	4	28	14.3	4	22	18.2	9	52	17.3	3,212	16.6	63,278	22.0
1114	Timeframe not available	4	8	50.0	9	21	42.9	10	27	37.0	8	22	36.4	21	51	41.2	5,099	26.8	84,307	29.5
1115	**STEMI pts receiving lytics**	**0**			**0**			**0**			**0**			**0**			**306**		**7,888**	
1116	**Anginal/CCS classification w/in past 2 wks**																			
1117	No symptoms	46	53	86.8	23	68	33.8	27	71	38.0	23	71	32.4	92	192	47.9	19,363	24.7	241,906	18.9
1118	CCS Class I	0	53	0.0	8	68	11.8	18	71	25.4	18	71	25.4	26	192	13.5	9,888	12.6	124,203	9.7
1119	CCS Class II	0	53	0.0	15	68	22.1	17	71	23.9	15	71	21.1	30	192	15.6	19,469	24.9	294,873	23.0
1120	CCS Class III	1	53	1.9	7	68	10.3	1	71	1.4	6	71	8.5	14	192	7.3	16,315	20.8	359,636	28.0
1121	CCS Class IV	6	53	11.3	15	68	22.1	8	71	11.3	9	71	12.7	30	192	15.6	13,315	17.0	262,372	20.5
1122	**Anti-anginal meds w/in past 2 wks**																			
1123	Anti-anginal meds w/in past 2 wks (pts w/ ACS)	9	17	52.9	19	40	47.5	31	43	72.1	29	45	64.4	57	102	55.9	24,182	55.9	493,789	67.1
1124	Anti-anginal meds w/in past 2 wks (pts w/out ACS)	20	36	55.6	14	28	50.0	18	28	64.3	15	26	57.7	49	90	54.4	17,598	49.6	328,606	59.8
1125	**Heart failure w/in past 2 wks**	**5**	**53**	**9.4**	**11**	**68**	**16.2**	**11**	**71**	**15.5**	**12**	**71**	**16.9**	**28**	**192**	**14.6**	**9,238**	**11.7**	**154,713**	**12.0**
1126	**NYHA classification w/in past 2 wks**																			
1127	NYHA Class I	0	5	0.0	0	11	0.0	0	11	0.0	1	12	8.3	1	28	3.6	986	10.8	16,882	11.0
1128	NYHA Class II	2	5	40.0	2	11	18.2	8	11	72.7	2	12	16.7	6	28	21.4	2,814	30.7	46,427	30.1
1129	NYHA Class III	2	5	40.0	3	11	27.3	1	11	9.1	6	12	50.0	11	28	39.3	3,494	38.2	56,873	36.9
1130	NYHA Class IV	1	5	20.0	6	11	54.6	2	11	18.2	3	12	25.0	10	28	35.7	1,863	20.4	33,868	22.0
1131	**Cardiogenic shock w/in the past 24 hrs**	**1**	**53**	**1.9**	**3**	**68**	**4.4**	**2**	**71**	**2.8**	**2**	**71**	**2.8**	**6**	**192**	**3.1**	**1,194**	**1.5**	**17,485**	**1.4**
1132	**Cardiac arrest w/in the past 24 hrs**	**2**	**53**	**3.8**	**0**	**68**	**0.0**	**0**	**71**	**0.0**	**0**	**71**	**0.0**	**2**	**192**	**1.0**	**1,404**	**1.8**	**17,660**	**1.4**

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Diagnostic Cath with/without PCI
Clinical Evaluation Leading to the Procedure
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1133	**Cardiomyopathy or left ventricular systolic dysfunction**	**8**	**53**	**15.1**	**8**	**68**	**11.8**	**11**	**71**	**15.5**	**16**	**71**	**22.5**	**32**	**192**	**16.7**	**9,205**	**11.7**	**160,003**	**12.4**
1134	**Pre-operative evaluation before non-cardiac surgery**	**2**	**53**	**3.8**	**1**	**68**	**1.5**	**1**	**71**	**1.4**	**1**	**71**	**1.4**	**4**	**192**	**2.1**	**3,075**	**3.9**	**46,706**	**3.6**
1135	**Cardiac transplant evaluation**	**0**	**53**	**0.0**	**0**	**68**	**0.0**	**0**	**71**	**0.0**	**0**	**71**	**0.0**	**0**	**192**	**0.0**	**297**	**0.4**	**3,582**	**0.3**
1136	Transplant evaluation type																			
1137	Donor for cardiac transplant																37	12.5	437	12.2
1138	Candidate to receive a cardiac transplant																65	21.9	571	16.0
1139	Post cardiac transplant follow-up																195	65.7	2,564	71.8

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Diagnostic Cath with/without PCI
Stress and Imaging Studies
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1140	Stress or imaging study																			
1141	Stress or imaging study performed	11	53	20.8	21	67	31.3	15	71	21.1	17	71	23.9	49	191	25.7	31,160	39.9	510,222	40.1
1142	Positive stress or imaging study	9	53	17.0	16	67	23.9	10	71	14.1	6	71	8.5	31	191	16.2	23,232	29.7	402,312	31.6
1143	Positive stress or imaging study w/ intermediate risk of ischemia	4	53	7.6	10	67	14.9	3	71	4.2	2	71	2.8	16	191	8.4	7,430	9.5	120,021	9.4
1144	Positive stress or imaging study w/ high risk of ischemia	1	53	1.9	5	67	7.5	5	71	7.0	3	71	4.2	9	191	4.7	3,009	3.9	55,386	4.4
1145	**Standard exercise stress test performed**	**1**	**11**	**9.1**	**2**	**21**	**9.5**	**0**	**10**	**0.0**	**1**	**17**	**5.9**	**4**	**49**	**8.2**	**2,837**	**9.2**	**40,398**	**7.9**
1146	Result																			
1147	Negative	0	1	0.0	0	2	0.0				0	1	0.0	0	4	0.0	507	17.9	5,446	13.5
1148	Positive	1	1	100.0	2	2	100.0				0	1	0.0	3	4	75.0	1,956	69.0	30,456	75.4
1149	Indeterminant	0	1	0.0	0	2	0.0				1	1	100.0	1	4	25.0	242	8.5	3,072	7.6
1150	Unavailable	0	1	0.0	0	2	0.0				0	1	0.0	0	4	0.0	127	4.5	1,404	3.5
1151	Risk or extent of ischemia for positive stress tests																			
1152	Low	0	1	0.0	0	2	0.0							0	3	0.0	208	10.6	2,534	8.3
1153	Intermediate	1	1	100.0	1	2	50.0							2	3	66.7	610	31.2	7,121	23.4
1154	High	0	1	0.0	1	2	50.0							1	3	33.3	308	15.8	4,050	13.3
1155	Unavailable	0	1	0.0	0	2	0.0							0	3	0.0	825	42.2	16,666	54.7
1156	**Stress echocardiogram**	**4**	**11**	**36.4**	**11**	**21**	**52.4**	**8**	**14**	**57.1**	**11**	**17**	**64.7**	**26**	**49**	**53.1**	**4,680**	**15.2**	**53,595**	**10.5**
1157	Result																			
1158	Negative	0	4	0.0	2	11	18.2	1	8	12.5	2	11	18.2	4	26	15.4	861	18.4	7,965	14.9
1159	Positive	4	4	100.0	8	11	72.7	6	8	75.0	5	11	45.5	17	26	65.4	3,273	69.9	40,140	74.9
1160	Indeterminant	0	4	0.0	1	11	9.1	1	8	12.5	4	11	36.4	5	26	19.2	429	9.2	4,429	8.3
1161	Unavailable	0	4	0.0	0	11	0.0	0	8	0.0	0	11	0.0	0	26	0.0	110	2.4	1,021	1.9
1162	Risk or extent of ischemia for positive stress echocardiograms																			
1163	Low	0	4	0.0	1	8	12.5	1	6	16.7	0	5	0.0	1	17	5.9	437	13.4	5,333	13.3
1164	Intermediate	3	4	75.0	5	8	62.5	2	6	33.3	1	5	20.0	9	17	52.9	1,002	30.6	13,580	33.8
1165	High	0	4	0.0	2	8	25.0	3	6	50.0	3	5	60.0	5	17	29.4	566	17.3	6,795	16.9
1166	Unavailable	1	4	25.0	0	8	0.0	0	6	0.0	1	5	20.0	2	17	11.8	1,262	38.6	14,380	35.8
1167	**Stress testing w/ SPECT MPI**	**6**	**11**	**54.6**	**8**	**21**	**38.1**	**7**	**10**	**70.0**	**6**	**17**	**35.3**	**20**	**49**	**40.8**	**22,350**	**71.9**	**402,118**	**78.6**
1168	Result																			
1169	Negative	1	6	16.7	1	8	12.5	1	7	14.3	2	6	33.3	4	20	20.0	2,746	12.3	46,541	11.6
1170	Positive	4	6	66.7	6	8	75.0	4	7	57.1	1	6	16.7	11	20	55.0	18,039	80.7	332,930	82.8

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Diagnostic Cath with/without PCI
Stress and Imaging Studies
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1171	Indeterminant	1	6	16.7	0	8	0.0	2	7	28.6	3	6	50.0	4	20	20.0	1,108	5.0	16,831	4.2
1172	Unavailable	0	6	0.0	1	8	12.5	0	7	0.0	0	6	0.0	1	20	5.0	381	1.7	5,481	1.4
1173	Risk or extent of ischemia for positive SPECT MPI tests																			
1174	Low	0	4	0.0	0	6	0.0	1	4	25.0	0	1	0.0	0	11	0.0	3,082	17.1	57,851	17.4
1175	Intermediate	0	4	0.0	4	6	66.7	1	4	25.0	1	1	100.0	5	11	45.5	5,817	32.3	99,529	29.9
1176	High	1	4	25.0	2	6	33.3	2	4	50.0	0	1	0.0	3	11	27.3	2,139	11.9	44,463	13.4
1177	Unavailable	3	4	75.0	0	6	0.0	0	4	0.0	0	1	0.0	3	11	27.3	6,961	38.6	130,694	39.3
1178	**Stress testing w/ CMR**	**0**	**11**	**0.0**	**0**	**21**	**0.0**	**0**	**9**	**0.0**	**0**	**17**	**0.0**	**0**	**49**	**0.0**	**301**	**1.0**	**3,687**	**0.7**
1179	Result																			
1180	Negative																31	10.3	370	10.0
1181	Positive																240	79.7	3,069	83.2
1182	Indeterminant																16	5.3	155	4.2
1183	Unavailable																12	4.0	82	2.2
1184	Risk or extent of ischemia for positive CMR tests																			
1185	Low																29	12.1	645	21.0
1186	Intermediate																78	32.5	898	29.3
1187	High																38	15.8	622	20.3
1188	Unavailable																95	39.6	898	29.3
1189	**CTA**	**0**	**11**	**0.0**	**0**	**21**	**0.0**	**0**	**9**	**0.0**	**0**	**17**	**0.0**	**0**	**49**	**0.0**	**382**	**1.2**	**10,822**	**2.1**
1190	Result of CTA																			
1191	No disease																43	11.3	615	5.7
1192	One vessel disease																101	26.4	3,781	34.9
1193	Two vessel disease																70	18.3	2,428	22.4
1194	Three vessel disease																94	24.6	2,132	19.7
1195	Indeterminant																25	6.5	608	5.6
1196	Unavailable																48	12.6	1,243	11.5
1197	**Coronary calcium score**	**0**	**11**	**0.0**	**0**	**21**	**0.0**	**0**	**9**	**0.0**	**0**	**17**	**0.0**	**0**	**49**	**0.0**	**290**	**1.0**	**7,014**	**1.4**
1198	Calcium scores																			
1199	<= 100 (none to mild)																28	9.7	954	13.6
1200	101-400 (moderate)																70	24.1	1,720	24.5
1201	>400 (extensive)																181	62.4	3,958	56.4

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Diagnostic Cath with/without PCI
Procedure Information
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1202	Dx cath procedure information																			
1203	Dx cath procedures	53	53	100.0	68	68	100.0	71	71	100.0	71	71	100.0	192	192	100.0	78,943	100.0	1,287,327	100.0
1204	Dx coronary angiography	52	53	98.1	67	68	98.5	71	71	100.0	70	71	98.6	189	192	98.4	76,956	97.5	1,259,255	97.8
1205	Left heart caths	52	53	98.1	68	68	100.0	68	71	95.8	71	71	100.0	191	192	99.5	69,309	87.8	1,155,748	89.8
1206	Dx cath and PCI during same lab visit	5	53	9.4	14	68	20.6	8	71	11.3	10	71	14.1	29	192	15.1	25,657	32.5	540,061	42.0
1207	**Status of dx cath procedure**																			
1208	Elective	24	53	45.3	22	68	32.4	26	71	36.6	22	71	31.0	68	192	35.4	43,102	54.6	717,382	55.8
1209	Urgent	23	53	43.4	29	68	42.7	34	71	47.9	34	71	47.9	86	192	44.8	25,253	32.0	435,525	33.9
1210	Emergent	6	53	11.3	17	68	25.0	11	71	15.5	15	71	21.1	38	192	19.8	10,404	13.2	131,529	10.2
1211	Salvage	0	53	0.0	0	68	0.0	0	71	0.0	0	71	0.0	0	192	0.0	140	0.2	2,200	0.2
1212	**Fluoro time in minutes**																			
1213	Procedure using fluoro time	53	53	100.0	67	67	100.0	71	71	100.0	44	44	100.0	164	164	100.0	70,749	98.9	1,120,452	98.8
1214	Mean	5.4			6.3			6.0			7.5			6.4			7.7		8.4	
1215	Median	3.1			5.0			4.2			4.6			4.2			4.8		5.4	
1216	Median fluoro time for pts w/ prev CABG	5.7			10.0			9.9			8.8			7.5			9.6		9.8	
1217	Median fluoro time for pts w/out prev CABG	2.9			4.3			4.1			2.8			3.3			4.3		4.7	
1218	**Fluoro dose in milligrays**	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1219	Procedure using fluoro dose	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1220	Mean	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1221	Median	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1222	Median fluoro dose for pts w/ prev CABG	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1223	Median fluoro dose for pts w/out prev CABG	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1224	**Contrast volume (in ml)**																			
1225	Procedures w/ contrast volume coded	53	53	100.0	67	67	100.0	71	71	100.0	44	44	100.0	164	164	100.0	71,815	99.6	1,140,674	99.7
1226	Mean	96.7			99.7			94.1			100.7			99.0			133.8		139.2	
1227	Median	90.0			80.0			86.0			82.5			86.0			115.0		120.0	
1228	Median contrast volume for pts w/ prev CABG	95.0			117.5			100.0			90.0			100.0			150.0		150.0	
1229	Median contrast volume for pts w/out prev CABG	90.0			80.0			86.0			82.5			85.0			110.0		110.0	
1230	**Arterial access site**																			
1231	Femoral	51	53	96.2	68	68	100.0	69	71	97.2	68	71	95.8	187	192	97.4	72,895	92.4	1,165,007	90.5
1232	Brachial	0	53	0.0	0	68	0.0	0	71	0.0	0	71	0.0	0	192	0.0	302	0.4	4,992	0.4
1233	Radial	2	53	3.8	0	68	0.0	2	71	2.8	3	71	4.2	5	192	2.6	5,675	7.2	116,396	9.1

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Diagnostic Cath with/without PCI
Procedure Information
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1234	Other	0	53	0.0	0	68	0.0	0	71	0.0	0	71	0.0	0	192	0.0	18	0.0	365	0.0
1235	**Methods of closure of arterial access site**																			
1236	Manual compression	9	46	19.6	12	52	23.1	11	57	19.3	11	56	19.6	32	154	20.8	27,496	35.5	514,671	38.5
1237	Mechanical compression	0	46	0.0	1	52	1.9	0	57	0.0	2	56	3.6	3	154	2.0	6,606	8.5	161,793	12.1
1238	Suture	0	46	0.0	0	52	0.0	0	57	0.0	0	56	0.0	0	154	0.0	3,323	4.3	85,060	6.4
1239	Staple	0	46	0.0	0	52	0.0	0	57	0.0	0	56	0.0	0	154	0.0	30	0.0	80	0.0
1240	Sealant	37	46	80.4	39	52	75.0	46	57	80.7	43	56	76.8	119	154	77.3	30,595	39.5	392,242	29.4
1241	Patch	0	46	0.0	0	52	0.0	0	57	0.0	0	56	0.0	0	154	0.0	6,270	8.1	117,345	8.8
1242	Other, unspecified device	0	46	0.0	0	52	0.0	0	57	0.0	0	56	0.0	0	154	0.0	3,105	4.0	64,365	4.8
1243	**Mechanical ventricular support**																			
1244	Any mechanical ventricular support (IABP, LVAD or other support)	1	53	1.9	3	68	4.4	2	71	2.8	2	71	2.8	6	192	3.1	1,912	2.4	25,130	2.0
1245	Intra-aortic balloon pump	1	53	1.9	3	68	4.4	2	71	2.8	1	71	1.4	5	192	2.6	1,709	2.2	22,943	1.8
1246	Other mechanical ventricular support (LVAD, etc)	0	53	0.0	0	68	0.0	0	71	0.0	1	71	1.4	1	192	0.5	333	0.4	3,217	0.3

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Diagnostic Cath with/without PCI
Procedure Findings
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1247	**Coronary dominance**																			
1248	Left	5	53	9.4	6	68	8.8	12	71	16.9	10	71	14.1	21	192	10.9	9,197	12.0	128,559	10.3
1249	Right	45	53	84.9	60	68	88.2	48	71	67.6	58	71	81.7	163	192	84.9	60,658	79.0	1,018,437	81.7
1250	Mixed	3	53	5.7	2	68	2.9	11	71	15.5	3	71	4.2	8	192	4.2	6,897	9.0	99,234	8.0
1251	Diagnostic cath procedure findings																			
1252	Non-obstructive CAD - all vessels <50%	4	17	23.5	8	16	50.0	7	22	31.8	7	14	50.0	19	47	40.4	14,171	46.0	205,587	44.2
1253	Pt with positive stress or imaging study	0	6	0.0	4	11	36.4	1	6	16.7	0	1	0.0	4	18	22.2	6,163	40.4	94,560	37.5
1254	Pt with No CAD (all native vessels <=10% stenosis) (w/o CABG)	19	45	42.2	10	60	16.7	26	61	42.6	13	62	21.0	42	167	25.2	16,831	27.3	226,724	24.4
1255	**Diseased vessels (including LM disease)**																			
1256	LM disease (>=50%)	3	53	5.7	3	68	4.4	7	71	9.9	5	71	7.0	11	192	5.7	5,421	6.9	95,269	7.4
1257	LM and RCA disease (triple vessel)	2	53	3.8	3	68	4.4	4	71	5.6	4	71	5.6	9	192	4.7	3,038	3.9	52,483	4.1
1258	LM w/out RCA disease (double vessel)	1	53	1.9	0	68	0.0	3	71	4.2	1	71	1.4	2	192	1.0	2,383	3.0	42,786	3.3
1259	**Diseased vessel w/or w/o LM**																			
1260	Single vessel disease	15	53	28.3	19	68	27.9	18	71	25.4	20	71	28.2	54	192	28.1	23,013	29.2	396,632	30.8
1261	Double vessel disease	5	53	9.4	13	68	19.1	12	71	16.9	14	71	19.7	32	192	16.7	14,463	18.3	262,667	20.4
1262	Triple vessel disease	4	53	7.6	9	68	13.2	7	71	9.9	7	71	9.9	20	192	10.4	9,095	11.5	155,950	12.1
1263	**Treatment recommendation after Dx cath**																			
1264	None	0	53	0.0	0	68	0.0	0	71	0.0	0	71	0.0	0	192	0.0	4,524	5.7	65,949	5.1
1265	Medical therapy and/or counseling	33	53	62.3	29	68	42.7	33	71	46.5	37	71	52.1	99	192	51.6	35,090	44.5	515,152	40.1
1266	PCI w/out planned CABG	11	53	20.8	31	68	45.6	25	71	35.2	20	71	28.2	62	192	32.3	28,835	36.6	553,730	43.1
1267	CABG (including hybrid CABG/PCI procedures)	5	53	9.4	2	68	2.9	8	71	11.3	3	71	4.2	10	192	5.2	7,234	9.2	102,973	8.0
1268	Other cardiac therapy w/out CABG or PCI	4	53	7.6	6	68	8.8	5	71	7.0	11	71	15.5	21	192	10.9	3,159	4.0	48,459	3.8
1269	**EF (closest to discharge)**																			
1270	Normal (EF >=50%)	27	53	50.9	39	67	58.2	46	71	64.8	39	71	54.9	105	191	55.0	47,195	60.3	789,000	62.0
1271	Mildly reduced (EF 40-49%)	6	53	11.3	13	67	19.4	11	71	15.5	6	71	8.5	25	191	13.1	7,994	10.2	135,363	10.6
1272	Moderately reduced (EF 25-39%)	7	53	13.2	3	67	4.5	4	71	5.6	10	71	14.1	20	191	10.5	6,442	8.2	105,907	8.3
1273	Severely reduced (EF <25%)	4	53	7.6	5	67	7.5	4	71	5.6	7	71	9.9	16	191	8.4	2,508	3.2	40,300	3.2

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Diagnostic Cath (No PCI)
Adverse Events
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1274	Post-procedure events																			
1275	**Any adverse event**	**0**	**48**	**0.0**	**0**	**53**	**0.0**	**0**	**63**	**0.0**	**2**	**61**	**3.3**	**2**	**162**	**1.2**	**751**	**1.4**	**10,541**	**1.5**
1276	Pts w/out CABG during admission	0	46	0.0	0	50	0.0	0	61	0.0	2	56	3.6	2	152	1.3	521	1.0	5,016	0.8
1277	**Cardiogenic shock**	**0**	**48**	**0.0**	**0**	**53**	**0.0**	**0**	**63**	**0.0**	**0**	**61**	**0.0**	**0**	**162**	**0.0**	**130**	**0.3**	**2,292**	**0.3**
1278	Pts w/out CABG during admission	0	46	0.0	0	50	0.0	0	61	0.0	0	56	0.0	0	152	0.0	107	0.2	1,094	0.2
1279	**Heart failure**	**0**	**48**	**0.0**	**0**	**53**	**0.0**	**0**	**63**	**0.0**	**0**	**61**	**0.0**	**0**	**162**	**0.0**	**255**	**0.5**	**3,046**	**0.4**
1280	Pts w/out CABG during admission	0	46	0.0	0	50	0.0	0	61	0.0	0	56	0.0	0	152	0.0	221	0.4	1,628	0.3
1281	**CVA/Stroke**	**0**	**48**	**0.0**	**0**	**53**	**0.0**	**0**	**63**	**0.0**	**2**	**61**	**3.3**	**2**	**162**	**1.2**	**65**	**0.1**	**1,243**	**0.2**
1282	Pts w/out CABG during admission	0	46	0.0	0	50	0.0	0	61	0.0	2	56	3.6	2	152	1.3	49	0.1	660	0.1
1283	**Hemorrhagic stroke**										**1**	**2**	**50.0**	**1**	**2**	**50.0**	**7**	**11.1**	**119**	**9.6**
1284	Pts w/out CABG during admission										1	2	50.0	1	2	50.0	6	12.5	76	11.6
1285	**Cardiac tamponade**	**0**	**48**	**0.0**	**0**	**53**	**0.0**	**0**	**63**	**0.0**	**0**	**61**	**0.0**	**0**	**162**	**0.0**	**16**	**0.0**	**235**	**0.0**
1286	Pts w/out CABG during admission	0	46	0.0	0	50	0.0	0	61	0.0	0	56	0.0	0	152	0.0	8	0.0	57	0.0
1287	**New requirement for dialysis**	**0**	**48**	**0.0**	**0**	**53**	**0.0**	**0**	**63**	**0.0**	**0**	**61**	**0.0**	**0**	**162**	**0.0**	**48**	**0.1**	**1,073**	**0.2**
1288	Pts w/out CABG during admission	0	46	0.0	0	50	0.0	0	61	0.0	0	56	0.0	0	152	0.0	29	0.1	396	0.1
1289	Post-procedure bleeding																			
1290	**Bleeding event w/in 72 hrs of the procedure**	**0**	**48**	**0.0**	**0**	**53**	**0.0**	**0**	**63**	**0.0**	**0**	**61**	**0.0**	**0**	**162**	**0.0**	**271**	**0.5**	**3,528**	**0.5**
1291	Pts w/out CABG during admission	0	46	0.0	0	50	0.0	0	61	0.0	0	56	0.0	0	152	0.0	163	0.3	1,778	0.3
1292	**Bleeding at access site**																**63**	**23.3**	**727**	**20.6**
1293	Pts w/out CABG during admission																58	35.6	574	32.3
1294	**Hematoma at access site**																**110**	**40.6**	**1,260**	**35.7**
1295	Pts w/out CABG during admission																100	61.4	998	56.2
1296	**Retroperitoneal bleeding**																**26**	**9.6**	**327**	**9.3**
1297	Pts w/out CABG during admission																19	11.7	238	13.4
1298	**Other vascular complications requiring treatment**	**0**	**48**	**0.0**	**0**	**53**	**0.0**	**0**	**63**	**0.0**	**0**	**61**	**0.0**	**0**	**162**	**0.0**	**93**	**0.2**	**1,155**	**0.2**
1299	Pts w/out CABG during admission	0	46	0.0	0	50	0.0	0	61	0.0	0	56	0.0	0	152	0.0	69	0.1	678	0.1

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Diagnostic Cath (No PCI)
Adverse Events
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1300	**Vascular access site injury requiring treatment or major bleeding**	**0**	**48**	**0.0**	**0**	**53**	**0.0**	**0**	**63**	**0.0**	**0**	**61**	**0.0**	**0**	**162**	**0.0**	**208**	**0.4**	**2,651**	**0.4**
1301	Pts w/out CABG during admission	0	46	0.0	0	50	0.0	0	61	0.0	0	56	0.0	0	152	0.0	172	0.3	1,891	0.3

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Diagnostic Cath with/without PCI
Discharge Information
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1302	Discharge Information																			
1303	**CABG**	**5**	**53**	**9.4**	**2**	**67**	**3.0**	**6**	**71**	**8.5**	**2**	**71**	**2.8**	**9**	**191**	**4.7**	**4,043**	**5.2**	**62,556**	**4.9**
1304	CABG Status																			
1305	Elective	2	5	40.0	2	2	100.0	5	6	83.3	2	2	100.0	6	9	66.7	1,202	29.8	14,622	23.4
1306	Urgent	3	5	60.0	0	2	0.0	1	6	16.7	0	2	0.0	3	9	33.3	2,515	62.3	43,520	69.6
1307	Emergent	0	5	0.0	0	2	0.0	0	6	0.0	0	2	0.0	0	9	0.0	309	7.7	4,211	6.7
1308	Salvage	0	5	0.0	0	2	0.0	0	6	0.0	0	2	0.0	0	9	0.0	12	0.3	151	0.2
1309	**CABG indication**																			
1310	PCI complication	0	5	0.0	0	2	0.0	0	6	0.0	0	2	0.0	0	9	0.0	44	1.1	945	1.5
1311	PCI failure w/out clinical deterioration	0	5	0.0	0	2	0.0	0	6	0.0	0	2	0.0	0	9	0.0	113	2.8	2,045	3.3
1312	Treatment of CAD w/out PCI immediately preceding CABG	4	5	80.0	1	2	50.0	6	6	100.0	2	2	100.0	7	9	77.8	3,588	88.9	55,581	88.9
1313	PCI/CABG hybrid procedure	1	5	20.0	1	2	50.0	0	6	0.0	0	2	0.0	2	9	22.2	292	7.2	3,926	6.3
1314	**Location**																			
1315	At your facility	0	5	0.0	0	2	0.0	0	6	0.0	0	2	0.0	0	9	0.0	1,413	35.0	55,931	89.5
1316	Transferred to other facility	5	5	100.0	2	2	100.0	6	6	100.0	2	2	100.0	9	9	100.0	2,624	65.0	6,589	10.5
1317	**Other major surgery**	**2**	**53**	**3.8**	**2**	**66**	**3.0**	**2**	**71**	**2.8**	**6**	**71**	**8.5**	**10**	**190**	**5.3**	**1,569**	**2.0**	**35,431**	**2.8**
1318	**Discharge status**																			
1319	Alive	50	53	94.3	67	67	100.0	69	71	97.2	69	71	97.2	186	191	97.4	77,427	98.9	1,258,816	98.9
1320	Expired (excluding donors)	3	53	5.7	0	67	0.0	2	71	2.8	2	71	2.8	5	191	2.6	823	1.1	14,282	1.1
1321	Expired (excluding donors and pts w/ PCI during same admission)	2	48	4.2	0	53	0.0	0	63	0.0	1	61	1.6	3	162	1.9	312	0.6	6,025	0.8
1322	Expired (excluding donors and pts w/ PCI, CABG or other major surgery)	2	42	4.8	0	49	0.0	0	55	0.0	0	54	0.0	2	145	1.4	264	0.6	4,033	0.6
1323	Death in lab	0	3	0.0				0	2	0.0	0	2	0.0	0	5	0.0	99	12.0	1,356	9.5

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Diagnostic Cath (No PCI)
Length of Stay
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1324	Length of stay (LOS) - pts w/out PCI																			
1325	**Total LOS- all pts**																			
1326	Mean	2.2			1.9			2.0			2.3			2.1			2.7		3.0	
1327	Median	1.0			1.0			2.0			1.0			1.0			1.0		1.0	
1328	Standard deviation	4.14			2.85			2.44			2.70			3.22			16.68		23.19	
1329	**Pre-procedure LOS- all pts**																			
1330	Mean	1.2			1.1			1.3			1.1			1.1			1.3		1.2	
1331	Median	1.0			1.0			1.0			0.0			1.0			0.0		0.0	
1332	Standard deviation	2.15			1.42			2.17			1.73			1.76			15.72		22.40	
1333	**Post-procedure LOS- all pts**																			
1334	Mean	1.0			0.9			0.7			1.1			1.0			1.3		1.8	
1335	Median	0.0			0.0			0.0			0.0			0.0			0.0		0.0	
1336	Standard deviation	2.18			1.78			1.06			1.79			1.90			4.99		5.61	
1337	**Total LOS- pts w/ CABG or other major surgery**																			
1338	Mean	2.0			6.0			4.1			5.6			4.3			6.2		10.8	
1339	Median	2.5			6.0			4.5			5.0			3.5			4.0		8.0	
1340	Standard deviation	1.67			5.00			2.47			3.74			3.65			12.26		26.55	
1341	**Pre-procedure LOS- pts w/ CABG or other major surgery**																			
1342	Mean	0.8			2.0			3.0			3.0			2.0			1.6		1.8	
1343	Median	0.5			3.0			2.5			2.0			1.5			1.0		1.0	
1344	Standard deviation	0.98			1.73			2.51			3.27			2.45			5.96		24.76	
1345	**Post-procedure LOS- pts w/ CABG or other major surgery**																			
1346	Mean	1.2			4.0			1.1			2.6			2.3			4.6		9.0	
1347	Median	0.5			3.0			0.5			3.0			2.0			1.0		7.0	
1348	Standard deviation	1.47			3.61			1.36			2.23			2.36			10.50		9.13	
1349	**Total LOS- pts w/out CABG or other major surgery**																			
1350	Mean	2.1			1.7			1.9			1.8			1.9			2.3		2.1	
1351	Median	1.0			1.0			1.0			1.0			1.0			1.0		0.0	
1352	Standard deviation	4.22			2.55			2.41			2.21			3.04			16.88		22.54	
1353	**Pre-procedure LOS- pts w/out CABG or other major surgery**																			
1354	Mean	1.3			1.0			1.3			0.9			1.0			1.3		1.1	

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Diagnostic Cath (No PCI)
Length of Stay
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1355	Median	1.0			0.0			1.0			0.0			0.0			0.0		0.0	
1356	Standard deviation	2.19			1.41			2.19			1.26			1.63			16.08		22.04	
1357	**Post-procedure LOS- pts w/out CABG or other major surgery**																			
1358	Mean	0.9			0.7			0.6			0.9			0.8			1.0		1.0	
1359	Median	0.0			0.0			0.0			0.0			0.0			0.0		0.0	
1360	Standard deviation	2.19			1.47			1.02			1.64			1.77			4.51		4.40	

PCI
Demographics and Payors
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1361	Demographics																			
1362	**Sex**																			
1363	Male	3	5	60.0	11	14	78.6	4	8	50.0	8	10	80.0	22	29	75.9	18,775	67.9	417,442	67.4
1364	Female	2	5	40.0	3	14	21.4	4	8	50.0	2	10	20.0	7	29	24.1	8,869	32.1	202,137	32.6
1365	**Age at admission**																			
1366	Mean age	63			58			65			72			64			64		65	
1367	Median age	63			55			59			71			59			63		65	
1368	18-44	1	5	20.0	3	14	21.4	1	8	12.5	0	10	0.0	4	29	13.8	1,582	5.7	29,000	4.7
1369	45-54	1	5	20.0	3	14	21.4	1	8	12.5	0	10	0.0	4	29	13.8	5,205	18.8	101,872	16.4
1370	55-64	1	5	20.0	5	14	35.7	4	8	50.0	4	10	40.0	10	29	34.5	8,044	29.1	173,014	27.9
1371	65-69	0	5	0.0	0	14	0.0	0	8	0.0	1	10	10.0	1	29	3.5	3,829	13.9	93,300	15.1
1372	70-74	0	5	0.0	0	14	0.0	0	8	0.0	1	10	10.0	1	29	3.5	3,133	11.3	79,641	12.9
1373	75-79	0	5	0.0	2	14	14.3	0	8	0.0	1	10	10.0	3	29	10.3	2,637	9.5	66,136	10.7
1374	>= 80	2	5	40.0	1	14	7.1	2	8	25.0	3	10	30.0	6	29	20.7	3,214	11.6	76,611	12.4
1375	Medicare age (>= 65)	2	5	40.0	3	14	21.4	2	8	25.0	6	10	60.0	11	29	37.9	12,813	46.4	315,691	51.0
1376	**Race**																			
1377	White	4	5	80.0	14	14	100.0	7	8	87.5	10	10	100.0	28	29	96.6	23,965	86.7	545,464	88.0
1378	Black/African American	0	5	0.0	0	14	0.0	1	8	12.5	0	10	0.0	0	29	0.0	2,596	9.4	50,913	8.2
1379	Asian	1	5	20.0	0	14	0.0	0	8	0.0	0	10	0.0	1	29	3.5	634	2.3	13,795	2.2
1380	American Indian/Alaskan	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	222	0.8	3,278	0.5
1381	Hawaiian/Pacific Islander	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	70	0.3	1,179	0.2
1382	**Hispanic or Latino ethnicity**	**1**	**5**	**20.0**	**2**	**14**	**14.3**	**1**	**8**	**12.5**	**0**	**10**	**0.0**	**3**	**29**	**10.3**	**1,849**	**6.7**	**30,597**	**5.0**
1383	**Admission source**																			
1384	Emergency department	5	5	100.0	14	14	100.0	8	8	100.0	9	10	90.0	28	29	96.6	17,055	61.8	223,626	36.1
1385	Transfer in from another acute care facility	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	1,337	4.9	116,704	18.9
1386	Other	0	5	0.0	0	14	0.0	0	8	0.0	1	10	10.0	1	29	3.5	9,196	33.3	278,627	45.0
1387	**Hospital status**																			
1388	Outpt	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	4,080	14.8	151,494	24.5
1389	Outpt converted to inpt	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	5,322	19.3	111,290	18.0
1390	Inpt	5	5	100.0	14	14	100.0	8	8	100.0	10	10	100.0	29	29	100.0	18,226	66.0	356,614	57.6
1391	**Insurance Payors**																			
1392	Private health insurance	3	5	60.0	11	14	78.6	6	8	75.0	7	10	70.0	21	29	72.4	16,226	58.7	393,846	63.6
1393	Medicare	2	5	40.0	3	14	21.4	2	8	25.0	4	10	40.0	9	29	31.0	12,245	44.3	317,735	51.3
1394	Medicaid	0	5	0.0	0	14	0.0	1	8	12.5	1	10	10.0	1	29	3.5	2,407	8.7	59,313	9.6
1395	Military health care	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	630	2.3	17,171	2.8
1396	State-specific (non-medicaid)	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	629	2.3	9,015	1.5

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PCI
Demographics and Payors
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1397	Indian Health Service	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	69	0.3	1,042	0.2
1398	Non-U.S. insurance	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	19	0.1	547	0.1
1399	None	0	5	0.0	1	14	7.1	0	8	0.0	2	10	20.0	3	29	10.3	2,376	8.6	40,799	6.6

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PCI
History and Risk Factors (on arrival)
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1400	History and risk factors (on arrival to CathPCI facility)																			
1401	**Current/recent smoker**	**0**	**5**	**0.0**	**3**	**14**	**21.4**	**3**	**8**	**37.5**	**4**	**10**	**40.0**	**7**	**29**	**24.1**	**8,614**	**31.2**	**171,212**	**27.7**
1402	**Hypertension**	**3**	**5**	**60.0**	**8**	**14**	**57.1**	**5**	**8**	**62.5**	**8**	**10**	**80.0**	**19**	**29**	**65.5**	**20,946**	**75.8**	**507,910**	**82.0**
1403	**Dyslipidemia**	**2**	**5**	**40.0**	**6**	**14**	**42.9**	**2**	**8**	**25.0**	**8**	**10**	**80.0**	**16**	**29**	**55.2**	**19,767**	**71.6**	**494,960**	**80.0**
1404	**Body mass index data**																			
1405	Overweight (BMI>=25)	4	5	80.0	12	14	85.7	7	8	87.5	7	10	70.0	23	29	79.3	21,975	79.7	494,675	80.0
1406	Obese (BMI>=30)	0	5	0.0	5	14	35.7	3	8	37.5	1	10	10.0	6	29	20.7	11,845	43.0	270,587	43.8
1407	Morbidly obese (BMI>=40)	0	5	0.0	2	14	14.3	0	8	0.0	0	10	0.0	2	29	6.9	1,976	7.2	43,479	7.0
1408	**Family history of premature CAD**	**2**	**5**	**40.0**	**3**	**14**	**21.4**	**2**	**8**	**25.0**	**3**	**10**	**30.0**	**8**	**29**	**27.6**	**8,263**	**29.9**	**153,941**	**24.9**
1409	**Prior MI (>7 days)**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**1**	**8**	**12.5**	**3**	**10**	**30.0**	**3**	**29**	**10.3**	**7,084**	**25.6**	**186,170**	**30.1**
1410	**Prior heart failure**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**2**	**10**	**20.0**	**2**	**29**	**6.9**	**2,417**	**8.8**	**74,097**	**12.0**
1411	**Prior valve surgery/procedure**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**328**	**1.2**	**9,098**	**1.5**
1412	**Prior PCI**	**1**	**5**	**20.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**2**	**10**	**20.0**	**3**	**29**	**10.3**	**8,765**	**31.7**	**252,138**	**40.7**
1413	Previous PCI timeframe prior to arrival																			
1414	<=1 year	0	1	0.0							0	2	0.0	0	3	0.0	2,784	32.5	85,959	34.5
1415	>1 year	1	1	100.0							2	2	100.0	3	3	100.0	5,795	67.6	163,016	65.5
1416	**Prior CABG**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**3,275**	**11.9**	**114,601**	**18.5**
1417	Prior CABG timeframe																			
1418	<=5 years																784	24.3	28,282	25.0
1419	> 5 years																2,442	75.7	84,939	75.0
1420	Other History																			
1421	**Currently on dialysis**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**610**	**2.2**	**14,654**	**2.4**
1422	**Cerebrovascular disease**	**1**	**5**	**20.0**	**1**	**14**	**7.1**	**1**	**8**	**12.5**	**4**	**10**	**40.0**	**6**	**29**	**20.7**	**2,552**	**9.2**	**76,721**	**12.4**
1423	**Peripheral arterial disease**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**4**	**10**	**40.0**	**4**	**29**	**13.8**	**2,570**	**9.3**	**77,949**	**12.6**
1424	**Chronic lung disease**	**0**	**5**	**0.0**	**1**	**14**	**7.1**	**0**	**8**	**0.0**	**2**	**10**	**20.0**	**3**	**29**	**10.3**	**3,739**	**13.5**	**94,424**	**15.3**
1425	**Diabetes mellitus**	**1**	**5**	**20.0**	**3**	**14**	**21.4**	**1**	**8**	**12.5**	**5**	**10**	**50.0**	**9**	**29**	**31.0**	**9,111**	**33.0**	**226,226**	**36.5**
1426	Diabetes control																			
1427	None	0	1	0.0	0	3	0.0	0	1	0.0	0	5	0.0	0	9	0.0	591	6.5	10,882	4.8
1428	Diet	0	1	0.0	0	3	0.0	0	1	0.0	1	5	20.0	1	9	11.1	630	6.9	14,674	6.5
1429	Oral	1	1	100.0	3	3	100.0	0	1	0.0	2	5	40.0	6	9	66.7	4,742	52.1	116,717	51.7
1430	Insulin	0	1	0.0	0	3	0.0	1	1	100.0	2	5	40.0	2	9	22.2	3,084	33.9	82,694	36.6
1431	Other	0	1	0.0	0	3	0.0	0	1	0.0	0	5	0.0	0	9	0.0	47	0.5	827	0.4

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PCI
Clinical Evaluation Leading to the Procedure
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1432	Clinical eval leading to the PCI																			
1433	**CAD presentation**	**5**	**5**	**100.0**	**14**	**14**	**100.0**	**8**	**8**	**100.0**	**10**	**10**	**100.0**	**29**	**29**	**100.0**	**28,163**	**100.0**	**636,294**	**100.0**
1434	No symptoms and no angina	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	1,970	7.0	58,759	9.2
1435	Symptoms unlikely to be ischemic	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	697	2.5	18,469	2.9
1436	Stable angina	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	3,970	14.1	108,417	17.0
1437	Unstable angina	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	8,413	29.9	233,994	36.8
1438	Non-STEMI	0	5	0.0	0	14	0.0	0	8	0.0	1	10	10.0	1	29	3.5	5,024	17.8	115,589	18.2
1439	STEMI	5	5	100.0	14	14	100.0	8	8	100.0	9	10	90.0	28	29	96.6	8,089	28.7	101,066	15.9
1440	Timeframe from symptom onset to procedure (for AMIs)																			
1441	<=6 hrs	4	5	80.0	10	14	71.4	6	8	75.0	7	10	70.0	21	29	72.4	6,264	47.8	76,033	35.1
1442	>6 hrs	0	5	0.0	3	14	21.4	0	8	0.0	0	10	0.0	3	29	10.3	4,065	31.0	83,140	38.4
1443	Timeframe not available	2	5	40.0	5	14	35.7	2	8	25.0	4	10	40.0	11	29	37.9	1,187	9.1	15,384	7.1
1444	**Anginal/CCS class w/in past 2 wks**																			
1445	No symptoms	0	5	0.0	0	14	0.0	0	8	0.0	1	10	10.0	1	29	3.5	5,410	19.3	84,305	13.3
1446	CCS Class I	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	2,234	8.0	37,838	6.0
1447	CCS Class II	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	6,087	21.8	126,942	20.0
1448	CCS Class III	0	5	0.0	0	14	0.0	0	8	0.0	2	10	20.0	2	29	6.9	6,284	22.5	203,154	32.0
1449	CCS Class IV	5	5	100.0	14	14	100.0	8	8	100.0	7	10	70.0	26	29	89.7	7,967	28.5	182,626	28.8
1450	**Anti-anginal medications w/in past two wks (patients w/out ACS)**																			
1451	Pts having one anti-anginal medication prescribed																2,808	42.4	90,576	48.8
1452	Pts having 2 or more anti-anginal medications prescribed																994	15.0	41,049	22.1
1453	Anti-anginal medication (pts w/ ACS)	2	5	40.0	2	14	14.3	3	8	37.5	5	10	50.0	9	29	31.0	10,875	50.7	305,229	67.8
1454	Anti-anginal medication (pts w/out ACS)																3,804	57.4	131,745	71.0
1455	Beta blockers																3,255	85.6	115,688	87.8
1456	Calcium channel blockers																724	19.0	31,883	24.2
1457	Long-acting nitrates																611	16.1	24,797	18.8
1458	Ranolazine																61	1.6	3,056	2.3
1459	Other anti-anginal medication not specified above																315	8.3	4,864	3.7
1460	**Heart failure w/in past two wks**	**0**	**5**	**0.0**	**1**	**14**	**7.1**	**0**	**8**	**0.0**	**2**	**10**	**20.0**	**3**	**29**	**10.3**	**2,257**	**8.0**	**61,392**	**9.7**

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PCI
Clinical Evaluation Leading to the Procedure
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1461	**NYHA w/in past two wks**																			
1462	Class I				0	1	0.0				0	2	0.0	0	3	0.0	256	11.4	6,886	11.3
1463	Class II				0	1	0.0				1	2	50.0	1	3	33.3	676	30.2	17,485	28.6
1464	Class III				0	1	0.0				1	2	50.0	1	3	33.3	799	35.7	21,586	35.3
1465	Class IV				1	1	100.0				0	2	0.0	1	3	33.3	510	22.8	15,151	24.8
1466	**Cardiogenic shock**																			
1467	Cardiogenic shock w/in the past 24 hrs and/or at start of PCI	1	5	20.0	2	14	14.3	2	8	25.0	2	10	20.0	5	29	17.2	1,118	4.0	17,606	2.8
1468	Cardiogenic shock w/in the past 24 hrs	1	5	20.0	2	14	14.3	2	8	25.0	2	10	20.0	5	29	17.2	799	2.8	12,610	2.0
1469	Cardiogenic shock at start of PCI	1	5	20.0	2	14	14.3	2	8	25.0	2	10	20.0	5	29	17.2	926	3.3	14,199	2.2
1470	**Cardiac arrest w/in the past 24 hrs**	**1**	**5**	**20.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**1**	**29**	**3.5**	**888**	**3.2**	**12,355**	**1.9**
1471	**Cardiomyopathy or LV systolic dysfunction**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**3**	**10**	**30.0**	**3**	**29**	**10.3**	**2,150**	**7.6**	**63,385**	**10.0**
1472	**Pre-operative evaluation before non-cardiac surgery**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**443**	**1.6**	**12,580**	**2.0**

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PCI
Procedure Indications
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1473	**PCI indication**																			
1474	Immediate PCI for STEMI	5	5	100.0	14	14	100.0	8	8	100.0	9	10	90.0	28	29	96.6	7,681	27.3	88,737	14.0
1475	PCI for STEMI (unstable, >12 hrs from Sx onset)	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	343	1.2	5,664	0.9
1476	PCI for STEMI (stable, >12 hrs from Sx onset)	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	230	0.8	3,744	0.6
1477	PCI for STEMI (stable after successful full dose lytics)	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	56	0.2	2,743	0.4
1478	Rescue PCI for STEMI (after failed full-dose lytics)	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	57	0.2	3,207	0.5
1479	PCI for high risk Non-STEMI or unstable angina	0	5	0.0	0	14	0.0	0	8	0.0	1	10	10.0	1	29	3.5	11,709	41.6	287,748	45.2
1480	Staged PCI	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	2,173	7.7	48,915	7.7
1481	Other	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	5,910	21.0	195,451	30.7
1482	**Immediate PCI - STEMI first noted:**																			
1483	First ECG	4	5	80.0	10	14	71.4	5	8	62.5	6	9	66.7	20	28	71.4	6,822	88.9	79,334	89.5
1484	Subsequent ECG	1	5	20.0	4	14	28.6	3	8	37.5	3	9	33.3	8	28	28.6	850	11.1	9,277	10.5
1485	**Non-system reason for delay in PCI for immediate PCI**																			
1486	Difficult vascular access	0	5	0.0	0	14	0.0	1	8	12.5	0	9	0.0	0	28	0.0	100	1.3	1,104	1.3
1487	Cardiac arrest and/or need for intubation before PCI	0	5	0.0	2	14	14.3	0	8	0.0	1	9	11.1	3	28	10.7	432	5.6	5,269	6.0
1488	Pt delays in providing consent for the procedure	1	5	20.0	0	14	0.0	0	8	0.0	0	9	0.0	1	28	3.6	60	0.8	639	0.7
1489	Difficulty crossing the culprit lesion during the PCI procedure	0	5	0.0	0	14	0.0	0	8	0.0	2	9	22.2	2	28	7.1	277	3.6	2,521	2.9
1490	Other	0	5	0.0	2	14	14.3	2	8	25.0	2	9	22.2	4	28	14.3	476	6.2	4,883	5.5
1491	None	4	5	80.0	10	14	71.4	5	8	62.5	4	9	44.4	18	28	64.3	6,324	82.5	74,128	83.7
1492	**Thrombolytic therapy for STEMI pts**																			
1493	Pts who received thrombolytic therapy	0			0			0			0			0			268		6,958	
1494	**Door to balloon times (excluding transfers)**																			
1495	Total number of immediate PCI procedures	5			14			8			9			28			7,303		67,309	
1496	Median	68.0			72.5			76.0			91.0			80.0			69.0		64.0	
1497	<= 90 minutes	4	5	80.0	11	14	78.6	6	8	75.0	4	9	44.4	19	28	67.9	5,816	79.6	55,669	82.7
1498	**Door to balloon times (excluding transfers and**																			

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PCI
Procedure Indications
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
	pts w/ a reason for delay)																			
1499	Total number of immediate PCI procedures	4			11			6			4			19			6,601		61,784	
1500	Median	66.0			67.0			71.5			76.0			67.0			67.0		62.0	
1501	<= 90 minutes	4	4	100.0	11	11	100.0	6	6	100.0	4	4	100.0	19	19	100.0	5,816	88.1	55,669	90.1
1502	**D2B times - Pts transferred in from another acute care facility only (excluding reason for delays)**	**0**			**0**			**0**			**0**			**0**			**317**		**18,188**	
1503	Median door to door time																72.0		83.0	
1504	Median																101.5		113.0	
1505	<= 90 minutes																112	35.3	4,801	26.4

PCI
Stress and Imaging Studies
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1506	Stress or imaging study																			
1507	Stress or imaging study performed	0	5	0.0	0	14	0.0	0	8	0.0	1	10	10.0	1	29	3.5	7,884	28.6	206,619	33.4
1508	Positive stress or imaging study	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	6,017	21.8	168,835	27.3
1509	Positive stress or imaging study w/ intermediate risk of ischemia	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	1,912	6.9	51,649	8.3
1510	Positive stress or imaging study w/ high risk of ischemia	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	1,210	4.4	31,278	5.1
1511	Proportion of elective PCI procedures with a positive antecedent stress or imaging study (suggestive of ischemia) or with a FFR Ratio of <= 0.8																2,072	56.2	70,063	58.6
1512	Positive stress or imaging study w/ high risk or extent of ischemia prior to elective PCI																760	7.8	21,148	7.6
1513	**Standard exercise stress test performed**										**1**	**1**	**100.0**	**1**	**1**	**100.0**	**676**	**8.6**	**15,583**	**7.5**
1514	Result																			
1515	Negative										0	1	0.0	0	1	0.0	100	14.8	1,836	11.8
1516	Positive										0	1	0.0	0	1	0.0	486	71.9	12,272	78.8
1517	Indeterminant										1	1	100.0	1	1	100.0	48	7.1	923	5.9
1518	Unavailable										0	1	0.0	0	1	0.0	40	5.9	544	3.5
1519	Risk or extent of ischemia for positive stress tests																			
1520	Low																36	7.4	624	5.1
1521	Intermediate																134	27.6	2,836	23.1
1522	High																99	20.4	2,212	18.0
1523	Unavailable																215	44.2	6,586	53.7
1524	**Stress echocardiogram**										**1**	**1**	**100.0**	**1**	**1**	**100.0**	**1,266**	**16.0**	**21,111**	**10.2**
1525	Result																			
1526	Negative										1	1	100.0	1	1	100.0	188	14.9	2,524	12.0
1527	Positive										0	1	0.0	0	1	0.0	964	76.2	16,892	80.0
1528	Indeterminant										0	1	0.0	0	1	0.0	80	6.3	1,296	6.1
1529	Unavailable										0	1	0.0	0	1	0.0	30	2.4	376	1.8
1530	Risk or extent of ischemia for positive stress echos																			
1531	Low																86	8.9	1,645	9.7
1532	Intermediate																264	27.4	5,342	31.6
1533	High																238	24.7	3,715	22.0

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PCI
Stress and Imaging Studies
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1534	Unavailable																375	38.9	6,175	36.6
1535	**Stress testing w/ SPECT MPI**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**5,416**	**68.5**	**163,355**	**78.5**
1536	Result																			
1537	Negative																516	9.5	15,476	9.5
1538	Positive																4,608	85.1	141,046	86.3
1539	Indeterminant																206	3.8	4,683	2.9
1540	Unavailable																74	1.4	2,046	1.3
1541	Risk or extent of ischemia for positive SPECT MPI																			
1542	Low																528	11.5	17,865	12.7
1543	Intermediate																1,514	32.9	43,800	31.1
1544	High																877	19.0	25,449	18.0
1545	Unavailable																1,685	36.6	53,764	38.1
1546	**Stress testing w/CMR**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**84**	**1.1**	**1,441**	**0.7**
1547	Result																			
1548	Negative																6	7.1	114	7.9
1549	Positive																72	85.7	1,244	86.3
1550	Indeterminant																1	1.2	43	3.0
1551	Unavailable																5	6.0	38	2.6
1552	Risk or extent of ischemia for positive CMR tests																			
1553	Low																5	6.9	159	12.8
1554	Intermediate																30	41.7	344	27.7
1555	High																15	20.8	334	26.9
1556	Unavailable																22	30.6	406	32.6
1557	**CTA**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**140**	**1.8**	**5,776**	**2.8**
1558	Results of CTA																			
1559	No disease																7	5.0	147	2.6
1560	One vessel disease																40	28.6	2,133	36.9
1561	Two vessel disease																29	20.7	1,494	25.9
1562	Three vessel disease																47	33.6	1,258	21.8
1563	Indeterminant																6	4.3	218	3.8
1564	Unavailable																11	7.9	516	8.9
1565	**Coronary calcium score**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**92**	**1.2**	**3,411**	**1.6**
1566	Calcium scores																			
1567	<=100 (none to mild)																7	7.6	397	11.6
1568	101-400 (moderate)																26	28.3	845	24.8

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PCI
Stress and Imaging Studies
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1569	>400 (extensive)																56	60.9	2,056	60.3

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PCI
Appropriate Use Criteria
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1570	**PCI Appropriate Use Criteria**																			
1571	**PCIs eligible for AUC reporting**	**5**			**14**						**10**			**29**			**28,171**		**636,415**	
1572	PCIs evaluated using AUC	5	5	100.0	14	14	100.0				10	10	100.0	29	29	100.0	24,825	88.1	538,435	84.6
1573	**Appropriate Use (Overall)**																			
1574	Appropriate (Among evaluated PCIs)	5	5	100.0	14	14	100.0				10	10	100.0	29	29	100.0	21,887	89.7	459,270	86.6
1575	Uncertain (Among evaluated PCIs)	0	5	0.0	0	14	0.0				0	10	0.0	0	29	0.0	1,792	7.4	52,940	10.0
1576	Inappropriate (Among evaluated PCIs)	0	5	0.0	0	14	0.0				0	10	0.0	0	29	0.0	718	2.9	18,056	3.4
1577	**Appropriate Use Stratified by ACS**																			
1578	**Patients with ACS (Table 1)**	**5**			**14**						**10**			**29**			**20,244**		**394,801**	
1579	Appropriate (Among evaluated PCIs)	5	5	100.0	14	14	100.0				10	10	100.0	29	29	100.0	20,041	99.0	390,636	99.0
1580	Uncertain (Among evaluated PCIs)	0	5	0.0	0	14	0.0				0	10	0.0	0	29	0.0	19	0.1	922	0.2
1581	Inappropriate (Among evaluated PCIs)	0	5	0.0	0	14	0.0				0	10	0.0	0	29	0.0	184	0.9	3,243	0.8
1582	**Patients without ACS (Table 2 and 3)**	**0**			**0**						**0**			**0**			**4,153**		**135,465**	
1583	Appropriate (Among evaluated PCIs)																1,846	44.5	68,634	50.7
1584	Uncertain (Among evaluated PCIs)																1,773	42.7	52,018	38.4
1585	Inappropriate (Among evaluated PCIs)																534	12.9	14,813	10.9
1586	**AUC Reporting Data Quality/Completeness**																			
1587	**PCIs not classifiable for AUC reporting**	**0**	**5**	**0.0**	**0**	**14**	**0.0**				**0**	**10**	**0.0**	**0**	**29**	**0.0**	**3,346**	**11.9**	**97,980**	**15.4**
1588	No Stress Test Performed																1,710	51.1	50,826	51.9
1589	Stress/Imaging Risk Of Ischemia not documented																1,326	39.6	40,530	41.4
1590	Other																310	9.3	6,624	6.8

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PCI
Medications
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1591	PCI procedure medications (w/in 24 hrs prior to and during the procedure)																			
1592	**Aspirin**	**5**	**5**	**100.0**	**14**	**14**	**100.0**	**8**	**8**	**100.0**	**10**	**10**	**100.0**	**29**	**29**	**100.0**	**23,686**	**84.6**	**560,412**	**88.7**
1593	Among pts w/ ACS (STEMI, NSTEMI or unstable angina)	5	5	100.0	14	14	100.0	8	8	100.0	10	10	100.0	29	29	100.0	18,360	85.9	400,024	89.5
1594	**Anticoagulants**	**5**	**5**	**100.0**	**14**	**14**	**100.0**	**8**	**8**	**100.0**	**10**	**10**	**100.0**	**29**	**29**	**100.0**	**17,898**	**63.6**	**369,894**	**58.2**
1595	Fondaparinux	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	583	2.1	6,299	1.0
1596	Low molecular weight heparin (any)	1	5	20.0	0	14	0.0	0	8	0.0	0	10	0.0	1	29	3.5	2,875	10.2	60,952	9.6
1597	Unfractionated heparin (any)	4	5	80.0	14	14	100.0	8	8	100.0	10	10	100.0	28	29	96.6	15,616	55.5	326,497	51.4
1598	**Direct thrombin inhibitors**		**5**			**14**			**8**			**10**			**29**		**14,962**	**53.2**	**364,634**	**57.4**
1599	Bivalirudin	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	14,662	52.1	361,693	56.9
1600	Direct thrombin inhibitor (other than bivalirudin)	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	692	2.5	6,342	1.0
1601	Pts that received bivalirudin, unfractionated heparin,and/ or other direct thrombin inhibitors administered	4	5	80.0	14	14	100.0	8	8	100.0	10	10	100.0	28	29	96.6	26,653	94.7	610,114	95.9
1602	**Glycoprotein IIb/IIIa Inhibitors (any)**	**4**	**5**	**80.0**	**13**	**14**	**92.9**	**5**	**8**	**62.5**	**4**	**10**	**40.0**	**21**	**29**	**72.4**	**10,788**	**38.4**	**175,967**	**27.7**
1603	Among pts w/ ACS (STEMI, NSTEMI or unstable angina)	4	5	80.0	13	14	92.9	5	8	62.5	4	10	40.0	21	29	72.4	9,228	43.0	147,832	32.9
1604	Among pts w/ USA/NSTEMI w/out clopidogrel administration (p64)											1			1		1,105	8.2	24,651	7.1
1605	**Thienopyridine**	**5**	**5**	**100.0**	**13**	**14**	**92.9**	**8**	**8**	**100.0**	**7**	**10**	**70.0**	**25**	**29**	**86.2**	**24,227**	**86.1**	**555,028**	**87.4**
1606	Clopidogrel	5	5	100.0	13	13	100.0	8	8	100.0	7	9	77.8	25	27	92.6	20,591	73.5	475,019	75.2
1607	Prasugrel	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	3,814	13.6	85,053	13.4
1608	Ticlopidine	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	78	0.3	1,429	0.2

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PCI
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Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1609	Procedures																			
1610	**PCI only**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**2,319**	**8.2**	**85,179**	**13.4**
1611	PCI and dx cath during same lab visit	5	5	100.0	14	14	100.0	8	8	100.0	10	10	100.0	29	29	100.0	25,657	91.1	540,061	84.9
1612	PCI w/ dx coronary angiography during same lab visit	5	5	100.0	13	14	92.9	8	8	100.0	10	10	100.0	28	29	96.6	25,238	98.4	528,974	98.0
1613	PCI w/ left heart cath during same lab visit	5	5	100.0	14	14	100.0	6	8	75.0	10	10	100.0	29	29	100.0	21,117	82.3	463,268	85.8
1614	PCI performed in conjunction w/ other procedure	0	5	0.0	1	14	7.1	0	8	0.0	2	10	20.0	3	29	10.3	4,199	14.9	111,718	17.6
1615	Repeat target vessel revascularization	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	111	0.4	3,293	0.5
1616	**Status of PCI**																			
1617	Elective	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	9,776	34.7	280,512	44.1
1618	Urgent	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	9,459	33.6	242,860	38.2
1619	Emergent	5	5	100.0	14	14	100.0	8	8	100.0	10	10	100.0	29	29	100.0	8,777	31.2	110,693	17.4
1620	Salvage	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	143	0.5	2,019	0.3
1621	**Fluoro time in minutes (excluding other procedures)**																			
1622	Count of procedures w/ using fluoro time	5	5	100.0	13	13	100.0	8	8	100.0	8	8	100.0	26	26	100.0	23,364	99.1	505,562	98.7
1623	Mean	9.8			12.3			13.5			20.2			14.2			14.1		14.0	
1624	Median	10.4			10.2			13.3			11.6			10.4			11.2		11.0	
1625	Pts w/ CABG prior to PCI																15.7		14.8	
1626	Median 1 vessel/lesion																14.7		13.4	
1627	Median >1 vessel/lesion																19.9		19.0	
1628	Pts w/out CABG prior to PCI	9.1			10.3			13.3			11.6			10.4			10.7		10.3	
1629	Median 1 vessel/lesion	9.1			9.3			13.4			9.7			9.5			9.8		9.1	
1630	Median >1 vessel/lesion				15.0			13.3			33.5			15.6			14.9		14.3	
1631	**Fluoro dose in milligrays (excluding other procedures)**	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1632	Count of procedures w/ fluoro dose in milligrays	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1633	Mean	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1634	Median	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1635	Pts w/ CABG prior to PCI	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1636	Median 1 vessel/lesion	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1637	Median >1 vessel/lesion	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*

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Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1638	Pts w/out CABG prior to PCI	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1639	Median 1 vessel/lesion	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1640	Median >1 vessel/lesion	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1641	**Contrast volume in milliliters**																			
1642	Count of procedures w/ contrast volume coded	5	5	100.0	13	13	100.0	8	8	100.0	8	8	100.0	26	26	100.0	23,881	99.6	523,140	99.7
1643	Mean	153.0			179.3			171.3			183.1			175.4			197.7		191.6	
1644	Median	180.0			170.0			185.0			200.0			180.0			185.0		180.0	
1645	Pts w/ CABG prior to PCI																200.0		195.0	
1646	Median 1 vessel/lesion																195.0		180.0	
1647	Median >1 vessel/lesion				205.0			202.5			225.0			220.0			220.0		210.0	
1648	Pts w/out CABG prior to PCI	160.0			170.0			185.0			200.0			175.0			180.0		175.0	
1649	Median 1 vessel/lesion	160.0			170.0			177.5			90.0			170.0			175.0		165.0	
1650	Median >1 vessel/lesion				205.0			202.5			225.0			220.0			220.0		210.0	
1651	**Arterial Access Site**																			
1652	Femoral	5	5	100.0	14	14	100.0	8	8	100.0	10	10	100.0	29	29	100.0	26,211	93.1	582,281	91.5
1653	Brachial	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	83	0.3	2,168	0.3
1654	Radial	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	1,853	6.6	51,580	8.1
1655	Other	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	7	0.0	178	0.0
1656	**Methods of closure for arterial access site**																			
1657	Manual compression	0	2	0.0	0	10	0.0	0	6	0.0	0	6	0.0	0	18	0.0	8,569	31.9	250,383	38.4
1658	Mechanical compression	0	2	0.0	0	10	0.0	0	6	0.0	1	6	16.7	1	18	5.6	2,699	10.1	85,960	13.2
1659	Suture	0	2	0.0	0	10	0.0	0	6	0.0	0	6	0.0	0	18	0.0	1,846	6.9	55,597	8.5
1660	Staple	0	2	0.0	0	10	0.0	0	6	0.0	0	6	0.0	0	18	0.0	29	0.1	59	0.0
1661	Sealant	2	2	100.0	10	10	100.0	6	6	100.0	5	6	83.3	17	18	94.4	10,844	40.4	186,880	28.7
1662	Patch	0	2	0.0	0	10	0.0	0	6	0.0	0	6	0.0	0	18	0.0	1,680	6.3	48,655	7.5
1663	Other, unspecified device	0	2	0.0	0	10	0.0	0	6	0.0	0	6	0.0	0	18	0.0	1,197	4.5	24,275	3.7
1664	**Mechanical ventricular support**																			
1665	Any mechanical ventricular support (IABP, LVAD or other support)	1	5	20.0	2	14	14.3	1	8	12.5	1	10	10.0	4	29	13.8	1,216	4.3	18,715	2.9
1666	Intra-aortic balloon pump	1	5	20.0	2	14	14.3	1	8	12.5	1	10	10.0	4	29	13.8	1,102	3.9	16,666	2.6
1667	In place at start of procedure	0	1	0.0	0	2	0.0	0	1	0.0	0	1	0.0	0	4	0.0	62	5.6	1,631	9.8
1668	Inserted during procedure and prior to PCI	1	1	100.0	2	2	100.0	0	1	0.0	1	1	100.0	4	4	100.0	292	26.5	4,643	27.9
1669	Inserted after start of PCI	0	1	0.0	0	2	0.0	1	1	100.0	0	1	0.0	0	4	0.0	748	67.9	10,379	62.3

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Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1670	Other mechanical ventricular support (LVAD, etc)	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	213	0.8	2,916	0.5
1671	In place at start of procedure																118	55.4	1,028	35.3
1672	Inserted during procedure and prior to PCI																50	23.5	1,369	47.0
1673	Inserted after start of PCI																45	21.1	517	17.7

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Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1674	PCI procedure findings																			
1675	**Coronary dominance**																			
1676	Left	2	5	40.0	1	14	7.1	0	8	0.0	1	10	10.0	4	29	13.8	3,209	11.8	56,987	9.3
1677	Right	3	5	60.0	12	14	85.7	7	8	87.5	9	10	90.0	24	29	82.8	21,490	78.7	507,150	82.9
1678	Mixed	0	5	0.0	1	14	7.1	1	8	12.5	0	10	0.0	1	29	3.5	2,610	9.6	48,017	7.8
1679	**Diseased vessels (including left main disease)**																			
1680	LM disease (>=50%)	1	5	20.0	1	14	7.1	0	8	0.0	0	10	0.0	2	29	6.9	1,308	4.6	40,345	6.3
1681	LM and RCA disease (triple vessel)	1	5	20.0	1	14	7.1	0	8	0.0	0	10	0.0	2	29	6.9	844	3.0	23,103	3.6
1682	LM w/out RCA disease (double vessel)	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	464	1.7	17,242	2.7
1683	**Diseased vessels (w/ or w/out LM disease)**																			
1684	Single vessel disease	2	5	40.0	5	14	35.7	6	8	75.0	6	10	60.0	13	29	44.8	15,851	56.3	341,741	53.7
1685	Double vessel disease	2	5	40.0	5	14	35.7	2	8	25.0	2	10	20.0	9	29	31.0	8,274	29.4	197,826	31.1
1686	Triple vessel disease	1	5	20.0	4	14	28.6	0	8	0.0	2	10	20.0	7	29	24.1	3,555	12.6	84,456	13.3
1687	**EF (at start of PCI)**																			
1688	Normal (EF >=50%)	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	11,846	42.1	318,681	50.1
1689	Mildly reduced (EF 40-49%)	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	2,500	8.9	68,328	10.7
1690	Moderately reduced (EF 25-39%)	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	1,675	6.0	47,319	7.4
1691	Severely reduced (EF <25%)	0	5	0.0	0	14	0.0	0	8	0.0	1	10	10.0	1	29	3.5	439	1.6	14,260	2.2
1692	**Ejection Fraction (closest to discharge)**																			
1693	Normal (EF >=50%)	0	5	0.0	6	14	42.9	5	8	62.5	3	10	30.0	9	29	31.0	14,564	52.7	321,466	51.9
1694	Mildly reduced (EF 40-49%)	0	5	0.0	5	14	35.7	2	8	25.0	2	10	20.0	7	29	24.1	3,455	12.5	73,265	11.8
1695	Moderately reduced (EF 25-39%)	0	5	0.0	2	14	14.3	1	8	12.5	2	10	20.0	4	29	13.8	2,356	8.5	50,954	8.2
1696	Severely reduced (EF <25%)	0	5	0.0	1	14	7.1	0	8	0.0	2	10	20.0	3	29	10.3	565	2.0	14,301	2.3
1697	Intraprocedure events																			
1698	**Significant dissection**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**363**	**1.3**	**8,372**	**1.3**
1699	**Perforation**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**133**	**0.5**	**2,415**	**0.4**
1700	**Number of lesions attempted**																			
1701	PCI procedures w/ one lesion attempted	4	5	80.0	10	14	71.4	4	8	50.0	7	10	70.0	21	29	72.4	21,717	77.1	458,977	72.1
1702	PCI procedures w/ two lesions attempted	0	5	0.0	3	14	21.4	4	8	50.0	2	10	20.0	5	29	17.2	5,282	18.8	138,889	21.8
1703	PCI procedures w/ three lesions attempted	1	5	20.0	1	14	7.1	0	8	0.0	1	10	10.0	3	29	10.3	969	3.4	30,962	4.9

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Line#	**Description**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**%**	**Num**	**%**
1704	PCI procedures w/ more than 3 lesions attempted	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	203	0.7	7,587	1.2
1705	**Number of procedures w/ a culprit artery identified (in pts w/ ACS)**	**5**	**5**	**100.0**	**14**	**14**	**100.0**	**8**	**8**	**100.0**	**10**	**10**	**100.0**	**29**	**29**	**100.0**	**18,824**	**88.5**	**376,414**	**84.2**

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PCI Lesion Information
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		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1706	**Lesion location**																			
1707	Number of lesions attempted in the left main coronary artery	0	7	0.0	0	19	0.0	0	12	0.0	0	14	0.0	0	40	0.0	312	0.8	15,218	1.6
1708	Number of lesions attempted in the proximal LAD	0	7	0.0	3	19	15.8	4	12	33.3	4	14	28.6	7	40	17.5	5,287	13.9	115,508	12.4
1709	Number of lesions attempted in the mid/distal LAD	3	7	42.9	3	19	15.8	1	12	8.3	3	14	21.4	9	40	22.5	8,801	24.7	222,020	25.9
1710	Number of lesions attempted in the circumflex	1	7	14.3	9	19	47.4	0	12	0.0	1	14	7.1	11	40	27.5	8,267	23.2	211,775	24.7
1711	Number of lesions attempted in the RCA	3	7	42.9	3	19	15.8	7	12	58.3	6	14	42.9	12	40	30.0	13,178	37.0	301,102	35.1
1712	Number of lesions attempted in the ramus	0	7	0.0	1	19	5.3	0	12	0.0	0	14	0.0	1	40	2.5	524	1.5	14,826	1.7
1713	**Lesion in graft**																			
1714	Not in graft	7	7	100.0	19	19	100.0	12	12	100.0	14	14	100.0	40	40	100.0	34,430	95.8	810,143	94.1
1715	Vein	0	7	0.0	0	19	0.0	0	12	0.0	0	14	0.0	0	40	0.0	1,386	3.9	47,246	5.5
1716	Left internal mammary artery (LIMA)	0	7	0.0	0	19	0.0	0	12	0.0	0	14	0.0	0	40	0.0	71	0.2	2,516	0.3
1717	Other artery	0	7	0.0	0	19	0.0	0	12	0.0	0	14	0.0	0	40	0.0	56	0.2	1,234	0.1
1718	Location in graft																			
1719	Aortic anastomosis of vein graft																253	17.0	10,595	20.9
1720	Aortic anastomosis of arterial graft																21	1.4	707	1.4
1721	Body of vein graft																857	57.5	27,464	54.2
1722	Body of arterial graft																62	4.2	1,448	2.9
1723	Distal anastomosis of vein graft																257	17.3	8,941	17.6
1724	Distal anastomosis of arterial graft																40	2.7	1,525	3.0
1725	**Chronic total occlusions**	**0**	**6**	**0.0**	**0**	**8**	**0.0**	**0**	**9**	**0.0**	**0**	**8**	**0.0**	**0**	**22**	**0.0**	**1,119**	**14.0**	**21,821**	**17.4**
1726	**Intermediate coronary stenosis**																			
1727	Lesions w/ intermediate coronary stenosis 40-70%	0	7	0.0	0	19	0.0	0	12	0.0	0	14	0.0	0	40	0.0	3,646	10.1	112,731	13.1
1728	Lesions w/ intermediate coronary stenosis 40-70% w/ no further invasive evaluation																2,665	76.3	82,580	74.5
1729	Lesions w/ intermediate coronary stenosis w/ confirmation by intravascular ultrasound (IVUS)																551	15.7	20,780	18.7

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PCI
PCI Lesion Information
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1730	Lesions w/ intermediate coronary stenosis w/ confirmation by fractional flow reserve (FFR)																312	8.9	8,978	8.1
1731	FFR ratio <= 0.75																104	3.0	3,588	3.2
1732	FFR ratio > 0.75																208	5.9	5,337	4.8
1733	**Pre-procedure TIMI flow**																			
1734	TIMI 0 - No flow/no perfusion	7	7	100.0	19	19	100.0	12	12	100.0	10	14	71.4	36	40	90.0	8,573	23.9	127,414	14.8
1735	TIMI 1 - Slow penetration w/out perfusion	0	7	0.0	0	19	0.0	0	12	0.0	2	14	14.3	2	40	5.0	5,277	14.7	72,038	8.4
1736	TIMI 2 - Partial flow/partial perfusion	0	7	0.0	0	19	0.0	0	12	0.0	2	14	14.3	2	40	5.0	7,411	20.6	160,908	18.7
1737	TIMI 3 - Complete and brisk flow/complete perfusion	0	7	0.0	0	19	0.0	0	12	0.0	0	14	0.0	0	40	0.0	14,652	40.8	498,619	58.1
1738	**Previously treated lesions**																			
1739	Previously treated lesions	0	7	0.0	0	19	0.0	0	12	0.0	2	14	14.3	2	40	5.0	3,337	9.3	89,409	10.4
1740	Previously treated timeframe																			
1741	<1 month										0	2	0.0	0	2	0.0	312	9.4	6,309	7.1
1742	1-5 months										0	2	0.0	0	2	0.0	356	10.7	11,277	12.6
1743	6-12 months										0	2	0.0	0	2	0.0	390	11.7	12,146	13.6
1744	1-2 years										1	2	50.0	1	2	50.0	440	13.2	12,515	14.0
1745	>2 years										1	2	50.0	1	2	50.0	1,517	45.5	40,099	44.9
1746	Timeframe unknown										0	2	0.0	0	2	0.0	321	9.6	6,885	7.7
1747	Previously treated w/ stent										2	2	100.0	2	2	100.0	2,975	89.3	83,422	93.5
1748	In-stent restenosis										1	2	50.0	1	2	50.0	2,377	80.0	73,664	88.4
1749	In-stent thrombosis										1	2	50.0	1	2	50.0	749	25.2	12,756	15.3
1750	Stent type																			
1751	Drug eluting stent										0	2	0.0	0	2	0.0	1,336	45.2	44,387	53.3
1752	Non-drug eluting stent										1	2	50.0	1	2	50.0	573	19.4	18,101	21.8
1753	Stent type unknown										1	2	50.0	1	2	50.0	1,049	35.5	20,724	24.9
1754	**Lesion complexity**																			
1755	Non-high/Non-C	0	7	0.0	8	19	42.1	7	12	58.3	9	14	64.3	17	40	42.5	17,584	49.0	441,544	51.3
1756	High/C	7	7	100.0	11	19	57.9	5	12	41.7	5	14	35.7	23	40	57.5	18,334	51.0	418,743	48.7
1757	**SCAI lesion classification system**																			
1758	Type I lesion (does not meet criteria for high risk lesion and patent)	0	7	0.0	5	19	26.3	2	12	16.7	5	14	35.7	10	40	25.0	15,192	42.1	405,667	47.1
1759	Type II lesion (high risk and patent)	1	7	14.3	5	19	26.3	1	12	8.3	1	14	7.1	7	40	17.5	12,625	35.0	327,150	38.0

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PCI
PCI Lesion Information
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1760	Type III lesions (does not meet criteria for high risk and occluded)	0	7	0.0	3	19	15.8	5	12	41.7	4	14	28.6	7	40	17.5	2,372	6.6	35,489	4.1
1761	Type IV lesions (high risk and occluded)	6	7	85.7	6	19	31.6	4	12	33.3	4	14	28.6	16	40	40.0	5,691	15.8	91,299	10.6
1762	**Lesion length**																			
1763	< 20 mm	4	7	57.1	9	19	47.4	7	12	58.3	9	14	64.3	22	40	55.0	23,322	66.6	548,701	64.5
1764	>= 20 mm	3	7	42.9	10	19	52.6	5	12	41.7	5	14	35.7	18	40	45.0	11,694	33.4	301,995	35.5
1765	**Thrombus present**	**2**	**7**	**28.6**	**13**	**19**	**68.4**	**6**	**12**	**50.0**	**5**	**14**	**35.7**	**20**	**40**	**50.0**	**7,554**	**21.0**	**106,731**	**12.4**
1766	**Bifurcation lesion**	**0**	**7**	**0.0**	**3**	**19**	**15.8**	**0**	**12**	**0.0**	**0**	**14**	**0.0**	**3**	**40**	**7.5**	**4,104**	**11.4**	**104,931**	**12.2**
1767	**Guidewire across lesion**	**7**	**7**	**100.0**	**19**	**19**	**100.0**	**12**	**12**	**100.0**	**14**	**14**	**100.0**	**40**	**40**	**100.0**	**35,378**	**98.3**	**848,457**	**98.5**
1768	**Post-procedure TIMI flow**																			
1769	TIMI 0 - No flow/no perfusion	0	7	0.0	0	19	0.0	0	12	0.0	1	14	7.1	1	40	2.5	397	1.1	6,593	0.8
1770	TIMI 1 - Slow penetration w/out perfusion	0	7	0.0	0	19	0.0	0	12	0.0	0	14	0.0	0	40	0.0	174	0.5	2,779	0.3
1771	TIMI 2 - Partial flow/partial perfusion	0	7	0.0	0	19	0.0	0	12	0.0	0	14	0.0	0	40	0.0	743	2.1	10,575	1.3
1772	TIMI 3 - Complete and brisk flow/complete perfusion	7	7	100.0	19	19	100.0	12	12	100.0	13	14	92.9	39	40	97.5	33,959	96.3	826,836	97.6
1773	**Devices deployed**	**7**	**7**	**100.0**	**19**	**19**	**100.0**	**12**	**12**	**100.0**	**14**	**14**	**100.0**	**40**	**40**	**100.0**	**34,660**	**98.1**	**838,427**	**98.9**
1774	**Intracoronary devices used**																			
1775	Atherectomy	0	13	0.0	0	53	0.0	0	26	0.0	0	35	0.0	0	101	0.0	75	0.1	8,048	0.4
1776	Balloon	5	13	38.5	21	53	39.6	10	26	38.5	20	35	57.1	46	101	45.5	38,138	47.7	925,351	47.9
1777	Brachytherapy	0	13	0.0	0	53	0.0	0	26	0.0	0	35	0.0	0	101	0.0	13	0.0	190	0.0
1778	Cutting balloon	0	13	0.0	0	53	0.0	0	26	0.0	0	35	0.0	0	101	0.0	988	1.2	40,149	2.1
1779	Chronic total occlusion device	0	13	0.0	0	53	0.0	0	26	0.0	0	35	0.0	0	101	0.0	38	0.1	253	0.0
1780	Embolic protection	0	13	0.0	0	53	0.0	0	26	0.0	0	35	0.0	0	101	0.0	148	0.2	9,439	0.5
1781	Embolic protection in PCI vein grafts																128	4.2	8,655	7.7
1782	Laser	0	13	0.0	0	53	0.0	0	26	0.0	0	35	0.0	0	101	0.0	2	0.0	899	0.1
1783	Stent - bare metal	5	13	38.5	15	53	28.3	9	26	34.6	6	35	17.1	26	101	25.7	10,404	13.0	206,166	10.7
1784	Stent - covered and coated	0	13	0.0	0	53	0.0	0	26	0.0	0	35	0.0	0	101	0.0	13	0.0	434	0.0
1785	Stent - drug eluting (DES)	1	13	7.7	5	53	9.4	3	26	11.5	5	35	14.3	11	101	10.9	26,862	33.6	685,714	35.5
1786	Thrombectomy	1	13	7.7	5	53	9.4	3	26	11.5	4	35	11.4	10	101	9.9	2,078	2.6	35,476	1.8
1787	Blinded	0	13	0.0	0	53	0.0	0	26	0.0	0	35	0.0	0	101	0.0	9	0.0	297	0.0
1788	**Stent usage**																			
1789	Stents per pt admission	1.2			1.4			1.5			1.1			1.3			1.4		1.4	
1790	DES per pt admission	0.2			0.4			0.4			0.5			0.4			1.0		1.1	
1791	**Overall angiographic success**																			

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PCI
PCI Lesion Information
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1792	Angiographic success for stented lesions (<=20%) (excludes CTOs)	5	5	100.0	19	19	100.0	11	11	100.0	10	10	100.0	34	34	100.0	29,889	98.1	728,696	99.1
1793	Angiographic success for non-stent devices (excludes CTOs)	2	2	100.0				1	1	100.0	3	4	75.0	5	6	83.3	3,254	72.6	80,963	77.3

PCI (all patients)
Adverse Events
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1794	Post-procedure events (all pts)																			
1795	**Any adverse event**	**0**	**5**	**0.0**	**1**	**14**	**7.1**	**0**	**8**	**0.0**	**1**	**10**	**10.0**	**2**	**29**	**6.9**	**2,744**	**9.8**	**45,711**	**7.2**
1796	Pts w/out CABG during admission	0	5	0.0	1	14	7.1	0	8	0.0	1	9	11.1	2	28	7.1	2,562	9.3	38,946	6.3
1797	**Composite:Death, emergency CABG, stroke or repeat target vessel revascularization.**	**1**	**5**	**20.0**	**0**	**14**	**0.0**	**2**	**8**	**25.0**	**1**	**10**	**10.0**	**2**	**29**	**6.9**	**817**	**3.0**	**14,328**	**2.3**
1798	**Post procedure MI (all pts)**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**1,240**	**4.4**	**13,870**	**2.2**
1799	Post procedure MI (among hospitals routinely collecting post-PCI biomarkers)																48	2.3	2,301	3.8
1800	Post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)																102	1.3	3,097	1.4
1801	Post procedure MI for pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	9	0.0	0	28	0.0	1,204	4.4	13,114	2.1
1802	**Cardiogenic shock**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**533**	**1.9**	**7,137**	**1.1**
1803	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	9	0.0	0	28	0.0	495	1.8	5,926	1.0
1804	**Heart failure**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**372**	**1.3**	**6,786**	**1.1**
1805	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	9	0.0	0	28	0.0	345	1.3	5,861	1.0
1806	**CVA/Stroke**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**62**	**0.2**	**1,404**	**0.2**
1807	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	9	0.0	0	28	0.0	58	0.2	1,196	0.2
1808	**Hemorrhagic stroke**																**18**	**29.0**	**265**	**19.0**
1809	Pts w/out CABG during admission																17	29.3	227	19.1
1810	**Cardiac tamponade**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**29**	**0.1**	**563**	**0.1**
1811	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	9	0.0	0	28	0.0	21	0.1	330	0.1
1812	**New requirement for dialysis**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**74**	**0.3**	**1,650**	**0.3**
1813	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	9	0.0	0	28	0.0	66	0.2	1,244	0.2
1814	Post-procedure bleeding (all pts)																			
1815	**Bleeding event w/in 72 hrs of the procedure**	**0**	**5**	**0.0**	**1**	**14**	**7.1**	**0**	**8**	**0.0**	**1**	**10**	**10.0**	**2**	**29**	**6.9**	**610**	**2.2**	**10,941**	**1.7**
1816	Pts w/out CABG during admission	0	5	0.0	1	14	7.1	0	8	0.0	1	9	11.1	2	28	7.1	563	2.0	9,440	1.5
1817	**Bleeding at access site w/in 72 hrs**				**0**	**1**	**0.0**				**0**	**1**	**0.0**	**0**	**2**	**0.0**	**218**	**35.7**	**3,125**	**28.6**

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PCI (all patients)
Adverse Events
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1818	Pts w/out CABG during admission				0	1	0.0				0	1	0.0	0	2	0.0	200	35.5	2,812	29.8
1819	**Hematoma at access site w/in 72 hrs**				**0**	**1**	**0.0**				**0**	**1**	**0.0**	**0**	**2**	**0.0**	**271**	**44.4**	**4,691**	**42.9**
1820	Size																			
1821	<3 cm																75	27.7	1,423	30.5
1822	3-5 cm																72	26.6	1,247	26.7
1823	>5-10 cm																63	23.3	1,130	24.2
1824	>10 cm																61	22.5	871	18.7
1825	**Retroperitoneal bleeding w/in 72 hrs**				**0**	**1**	**0.0**				**0**	**1**	**0.0**	**0**	**2**	**0.0**	**75**	**12.3**	**1,234**	**11.3**
1826	Pts w/out CABG during admission				0	1	0.0				0	1	0.0	0	2	0.0	71	12.6	1,061	11.3
1827	**GI bleed**				**1**	**1**	**100.0**				**0**	**1**	**0.0**	**1**	**2**	**50.0**	**100**	**16.4**	**1,871**	**17.1**
1828	Pts w/out CABG during admission				1	1	100.0				0	1	0.0	1	2	50.0	92	16.3	1,621	17.2
1829	**GU bleed**				**0**	**1**	**0.0**				**1**	**1**	**100.0**	**1**	**2**	**50.0**	**29**	**4.8**	**421**	**3.9**
1830	Pts w/out CABG during admission				0	1	0.0				1	1	100.0	1	2	50.0	27	4.8	358	3.8
1831	**Other bleed, not specified above**				**0**	**1**	**0.0**				**0**	**1**	**0.0**	**0**	**2**	**0.0**	**93**	**15.3**	**2,087**	**19.1**
1832	Pts w/out CABG during admission				0	1	0.0				0	1	0.0	0	2	0.0	77	13.7	1,484	15.7
1833	**Other vascular complications requiring treatment**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**136**	**0.5**	**2,821**	**0.4**
1834	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	9	0.0	0	28	0.0	110	0.4	2,127	0.3
1835	**Vascular access site injury requiring treatment or major bleeding**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**502**	**1.8**	**8,902**	**1.4**
1836	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	9	0.0	0	28	0.0	459	1.7	7,765	1.3
1837	**RBC/whole blood transfusion**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**1**	**10**	**10.0**	**1**	**29**	**3.5**	**651**	**2.3**	**17,189**	**2.7**
1838	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	1	9	11.1	1	28	3.6	541	2.0	12,214	2.0
1839	Hgb prior to transfusion <8 g/dL										0	1	0.0	0	1	0.0	193	29.7	5,982	34.9
1840	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	169	31.2	4,290	35.2

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PCI (patients with STEMI)
Adverse Events
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1841	Post-procedure events for pts w/ STEMI																			
1842	**Any adverse event**	**0**	**5**	**0.0**	**1**	**14**	**7.1**	**0**	**8**	**0.0**	**1**	**9**	**11.1**	**2**	**28**	**7.1**	**1,463**	**18.1**	**15,300**	**15.2**
1843	Pts w/out CABG during admission	0	5	0.0	1	14	7.1	0	8	0.0	1	8	12.5	2	27	7.4	1,374	17.5	12,818	13.4
1844	**Cardiogenic shock**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**9**	**0.0**	**0**	**28**	**0.0**	**405**	**5.0**	**4,305**	**4.3**
1845	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	8	0.0	0	27	0.0	382	4.9	3,693	3.9
1846	**Heart failure**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**9**	**0.0**	**0**	**28**	**0.0**	**240**	**3.0**	**3,602**	**3.6**
1847	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	8	0.0	0	27	0.0	223	2.8	3,130	3.3
1848	**CVA/Stroke**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**9**	**0.0**	**0**	**28**	**0.0**	**31**	**0.4**	**542**	**0.5**
1849	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	8	0.0	0	27	0.0	29	0.4	456	0.5
1850	**Hemorrhagic stroke**																**8**	**25.8**	**120**	**22.2**
1851	Pts w/out CABG during admission																7	24.1	103	22.7
1852	**Cardiac tamponade**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**9**	**0.0**	**0**	**28**	**0.0**	**11**	**0.1**	**165**	**0.2**
1853	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	8	0.0	0	27	0.0	7	0.1	92	0.1
1854	**New requirement for dialysis**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**9**	**0.0**	**0**	**28**	**0.0**	**35**	**0.4**	**642**	**0.6**
1855	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	8	0.0	0	27	0.0	31	0.4	456	0.5
1856	Post-procedure bleeding for pts w/ STEMI																			
1857	**Bleeding event w/in 72 hrs of the procedure**	**0**	**5**	**0.0**	**1**	**14**	**7.1**	**0**	**8**	**0.0**	**1**	**9**	**11.1**	**2**	**28**	**7.1**	**288**	**3.6**	**3,774**	**3.7**
1858	Pts w/out CABG during admission	0	5	0.0	1	14	7.1	0	8	0.0	1	8	12.5	2	27	7.4	264	3.4	3,242	3.4
1859	**Bleeding at access site w/in 72 hrs**				**0**	**1**	**0.0**				**0**	**1**	**0.0**	**0**	**2**	**0.0**	**96**	**33.3**	**968**	**25.7**
1860	Pts w/out CABG during admission				0	1	0.0				0	1	0.0	0	2	0.0	87	33.0	877	27.1
1861	**Hematoma at access site w/in 72 hrs**				**0**	**1**	**0.0**				**0**	**1**	**0.0**	**0**	**2**	**0.0**	**103**	**35.8**	**1,238**	**32.8**
1862	Size																			
1863	<3 cm																29	28.2	352	28.5
1864	3-5 cm																29	28.2	348	28.2
1865	>5-10 cm																23	22.3	309	25.0
1866	>10 cm																22	21.4	225	18.2
1867	**Retroperitoneal bleeding**				**0**	**1**	**0.0**				**0**	**1**	**0.0**	**0**	**2**	**0.0**	**37**	**12.9**	**380**	**10.1**

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PCI (patients with STEMI)
Adverse Events
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
	w/in 72 hrs																			
1868	Pts w/out CABG during admission				0	1	0.0				0	1	0.0	0	2	0.0	35	13.3	339	10.5
1869	**GI bleed**				**1**	**1**	**100.0**				**0**	**1**	**0.0**	**1**	**2**	**50.0**	**58**	**20.1**	**834**	**22.1**
1870	Pts w/out CABG during admission				1	1	100.0				0	1	0.0	1	2	50.0	52	19.7	727	22.5
1871	**GU bleed**				**0**	**1**	**0.0**				**1**	**1**	**100.0**	**1**	**2**	**50.0**	**16**	**5.6**	**183**	**4.9**
1872	Pts w/out CABG during admission				0	1	0.0				1	1	100.0	1	2	50.0	15	5.7	157	4.9
1873	**Other bleed, not specified above**				**0**	**1**	**0.0**				**0**	**1**	**0.0**	**0**	**2**	**0.0**	**60**	**20.8**	**956**	**25.4**
1874	Pts w/out CABG during admission				0	1	0.0				0	1	0.0	0	2	0.0	51	19.3	697	21.5
1875	**Other vascular complications requiring treatment**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**9**	**0.0**	**0**	**28**	**0.0**	**53**	**0.7**	**566**	**0.6**
1876	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	8	0.0	0	27	0.0	42	0.5	404	0.4
1877	**Vascular access site injury requiring treatment or major bleeding**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**9**	**0.0**	**0**	**28**	**0.0**	**206**	**2.6**	**2,384**	**2.4**
1878	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	8	0.0	0	27	0.0	187	2.4	2,091	2.2
1879	**RBC/Whole blood transfusion**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**1**	**9**	**11.1**	**1**	**28**	**3.6**	**329**	**4.1**	**5,645**	**5.6**
1880	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	1	8	12.5	1	27	3.7	276	3.5	3,801	4.0
1881	**Hgb prior to transfusion <8 g/dL**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**101**	**30.8**	**1,922**	**34.2**
1882	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	89	32.3	1,355	35.7

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PCI (patients without STEMI)
Adverse Events
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1883	Post-procedure events (pts w/out STEMI)																			
1884	**Any adverse event**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**1,272**	**6.4**	**30,342**	**5.7**
1885	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	1,183	6.0	26,090	5.0
1886	**Post procedure MI**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**585**	**2.9**	**10,926**	**2.0**
1887	Post procedure MI (among hospitals routinely collecting post-PCI biomarkers)																48	2.3	2,289	3.8
1888	Post procedure MI (among hospitals who do not routinely collecting post-PCI biomarkers)																97	1.3	3,054	1.4
1889	Post procedure MI for pts w/out CABG during admission										0	1	0.0	0	1	0.0	569	2.9	10,377	2.0
1890	**Cardiogenic shock**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**128**	**0.6**	**2,830**	**0.5**
1891	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	0	0.0	0	0.0
1892	**Heart failure**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**132**	**0.7**	**3,180**	**0.6**
1893	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	122	0.6	2,727	0.5
1894	**CVA/Stroke**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**31**	**0.2**	**862**	**0.2**
1895	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	29	0.2	740	0.1
1896	**Hemorrhagic stroke**																**10**	**32.3**	**145**	**16.9**
1897	Pts w/out CABG during admission																10	34.5	124	16.9
1898	**Cardiac tamponade**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**18**	**0.1**	**397**	**0.1**
1899	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	14	0.1	237	0.1
1900	**New requirement for dialysis**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**39**	**0.2**	**1,008**	**0.2**
1901	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	35	0.2	788	0.2
1902	Post-procedure bleeding for pts w/out STEMI																			
1903	**Bleeding event w/in 72 hrs of the procedure**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**322**	**1.6**	**7,165**	**1.3**
1904	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	299	1.5	6,196	1.2
1905	**Bleeding at access site w/in 72 hrs**																**122**	**37.9**	**2,157**	**30.1**
1906	Pts w/out CABG during admission																113	37.8	1,935	31.2

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PCI (patients without STEMI)
Adverse Events
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1907	**Hematoma at access site w/in 72 hrs**																**168**	**52.2**	**3,453**	**48.2**
1908	Size																			
1909	<3 cm																46	27.4	1,071	31.2
1910	3-5 cm																43	25.6	899	26.2
1911	>5-10 cm																40	23.8	821	23.9
1912	>10 cm																39	23.2	646	18.8
1913	**Retroperitoneal bleeding w/in 72 hrs**																**38**	**11.8**	**854**	**11.9**
1914	Pts w/out CABG during admission																36	12.0	722	11.7
1915	**GI bleed**																**42**	**13.0**	**1,036**	**14.5**
1916	Pts w/out CABG during admission																40	13.4	893	14.4
1917	**GU bleed**																**13**	**4.0**	**238**	**3.3**
1918	Pts w/out CABG during admission																12	4.0	201	3.3
1919	**Other bleed, not specified above**																**33**	**10.3**	**1,130**	**15.8**
1920	Pts w/out CABG during admission																26	8.7	786	12.7
1921	**Other vascular complications requiring treatment**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**83**	**0.4**	**2,255**	**0.4**
1922	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	68	0.3	1,723	0.3
1923	**Vascular access site injury requiring treatment or major bleeding**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**296**	**1.5**	**6,518**	**1.2**
1924	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	272	1.4	5,674	1.1
1925	**RBC/Whole blood transfusion**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**322**	**1.6**	**11,542**	**2.2**
1926	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	265	1.3	8,412	1.6
1927	**Hgb prior to transfusion <8 g/dL**																**92**	**28.6**	**4,060**	**35.3**
1928	Pts w/out CABG during admission																80	30.2	2,935	35.0

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PCI
Lab Results
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1929	Labs (all pts)																			
1930	**Proportion of elective inpts who have biomarkers collected post PCI**																**3,275**	**49.5**	**75,548**	**48.4**
1931	**PCIs w/ Cr assessed pre-procedure**	**5**	**5**	**100.0**	**14**	**14**	**100.0**	**8**	**8**	**100.0**	**10**	**10**	**100.0**	**29**	**29**	**100.0**	**26,831**	**95.2**	**597,675**	**93.9**
1932	PCIs w/ Cr assessed pre- and post-procedure (LOS >= 1 day)	4	5	80.0	12	14	85.7	8	8	100.0	7	10	70.0	23	29	79.3	23,060	81.9	518,223	81.4
1933	Acute kidney injury (Cr increase >50%) –excluding pts on dialysis pre-procedure and w/ a LOS <1 day		4			12		2	8	25.0		7			23		256	2.1	6,533	2.3
1934	**Pts w/ a pre- and post-procedure Hgb**	**5**	**5**	**100.0**	**14**	**14**	**100.0**	**8**	**8**	**100.0**	**7**	**10**	**70.0**	**26**	**29**	**89.7**	**22,169**	**80.2**	**492,704**	**79.5**
1935	Proportion of pts w/ a Hgb decrease of >5 g/dL	0	5	0.0	0	14	0.0	0	8	0.0	0	7	0.0	0	26	0.0	17	0.1	328	0.1

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PCI
Discharge Information
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1936	Discharge																			
1937	**CABG**	**1**	**5**	**20.0**	**1**	**14**	**7.1**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**2**	**29**	**6.9**	**402**	**1.5**	**7,677**	**1.2**
1938	CABG status																			
1939	Elective	0	5	0.0	1	14	7.1	0	8	0.0	0	10	0.0	1	29	3.5	61	0.2	1,225	0.2
1940	Urgent	1	5	20.0	0	14	0.0	0	8	0.0	0	10	0.0	1	29	3.5	214	0.8	4,634	0.8
1941	Emergent	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	118	0.4	1,708	0.3
1942	Salvage	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	9	0.0	101	0.0
1943	**CABG indication**																			
1944	PCI complication	0	1	0.0	0	1	0.0							0	2	0.0	44	11.0	917	12.0
1945	PCI failure w/out clinical deterioration	0	1	0.0	0	1	0.0							0	2	0.0	100	24.9	1,925	25.1
1946	Treatment of CAD w/out PCI immediately preceding CABG	0	1	0.0	0	1	0.0							0	2	0.0	60	14.9	1,393	18.2
1947	PCI/CABG hybrid procedure	1	1	100.0	1	1	100.0							2	2	100.0	198	49.3	3,422	44.7
1948	**CABG location**																			
1949	At your facility	0	1	0.0	0	1	0.0							0	2	0.0	138	34.3	7,073	92.2
1950	Transferred to other facility	1	1	100.0	1	1	100.0							2	2	100.0	264	65.7	595	7.8
1951	**Other major surgery during this admission**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**1**	**10**	**10.0**	**1**	**29**	**3.5**	**378**	**1.4**	**10,058**	**1.6**
1952	**Cardiac rehabilitation referral**	**0**	**3**	**0.0**	**0**	**11**	**0.0**	**0**	**6**	**0.0**	**0**	**6**	**0.0**	**0**	**20**	**0.0**	**13,823**	**56.1**	**338,168**	**59.3**
1953	Medications prescribed at discharge																			
1954	**Angiotensin converting enzyme (ACE) inhibitors**	**1**	**3**	**33.3**	**6**	**11**	**54.6**	**5**	**6**	**83.3**	**4**	**6**	**66.7**	**11**	**20**	**55.0**	**13,949**	**55.6**	**314,368**	**53.9**
1955	Among pts w/ EF < 40%				1	1	100.0				2	2	100.0	3	3	100.0	1,933	70.3	49,015	71.1
1956	**Angiotensin II receptor blocker (ARB)**	**0**	**3**	**0.0**	**1**	**11**	**9.1**	**1**	**6**	**16.7**	**1**	**6**	**16.7**	**2**	**20**	**10.0**	**2,484**	**9.8**	**80,783**	**13.7**
1957	Among pts w/ EF < 40%				0	1	0.0				0	2	0.0	0	3	0.0	277	10.0	8,431	12.0
1958	**ACE or ARB among pts w/ EF < 40%**																**1,346**	**75.1**	**43,255**	**79.5**
1959	**Aspirin**	**3**	**3**	**100.0**	**11**	**11**	**100.0**	**6**	**6**	**100.0**	**6**	**6**	**100.0**	**20**	**20**	**100.0**	**24,592**	**95.8**	**583,052**	**97.6**
1960	Among pts w/ ACS	3	3	100.0	11	11	100.0	6	6	100.0	6	6	100.0	20	20	100.0	18,765	96.5	415,072	97.8
1961	**Beta blockers**	**2**	**3**	**66.7**	**11**	**11**	**100.0**	**6**	**6**	**100.0**	**6**	**6**	**100.0**	**19**	**20**	**95.0**	**21,500**	**85.2**	**499,986**	**85.2**
1962	Among pts w/ Acute MI	2	3	66.7	11	11	100.0	6	6	100.0	6	6	100.0	19	20	95.0	10,488	93.0	186,386	94.5
1963	**Lipid lowering agents (any)**	**3**	**3**	**100.0**	**11**	**11**	**100.0**	**6**	**6**	**100.0**	**6**	**6**	**100.0**	**20**	**20**	**100.0**	**23,470**	**90.9**	**551,668**	**91.8**
1964	Statins	3	3	100.0	11	11	100.0	6	6	100.0	6	6	100.0	20	20	100.0	22,877	89.5	534,660	90.2
1965	Nonstatins	0	3	0.0	0	11	0.0	0	6	0.0	0	6	0.0	0	20	0.0	3,046	11.8	96,882	16.1
1966	Among pts w/ dyslipidemia	1	1	100.0	5	5	100.0	2	2	100.0	6	6	100.0	12	12	100.0	17,252	92.3	452,068	93.7
1967	**Thienopyridine**	**2**	**3**	**66.7**	**11**	**11**	**100.0**	**6**	**6**	**100.0**	**6**	**6**	**100.0**	**19**	**20**	**95.0**	**24,790**	**96.0**	**584,356**	**97.2**

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PCI
Discharge Information
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	**Description**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**%**	**Num**	**%**
1968	Among pts w/ stents	2	2	100.0	11	11	100.0	6	6	100.0	5	5	100.0	18	18	100.0	23,134	97.4	545,807	98.6
1969	**Discharge status**																			
1970	Alive	4	5	80.0	14	14	100.0	6	8	75.0	9	10	90.0	27	29	93.1	27,099	98.0	610,923	98.6
1971	Dead (unadjusted)	1	5	20.0	0	14	0.0	2	8	25.0	1	10	10.0	2	29	6.9	545	2.0	8,656	1.4
1972	Dead (unadjusted - excluding CABG and other major surgery)	1	4	25.0	0	13	0.0	2	8	25.0	1	9	11.1	2	26	7.7	516	1.9	7,652	1.3
1973	Death in lab (all pts)	0	1	0.0				0	2	0.0	0	1	0.0	0	2	0.0	87	16.0	1,102	12.7
1974	Primary cause of death	1	1	100.0				2	2	100.0	1	1	100.0	2	2	100.0	544	100.0	8,636	100.0
1975	Cardiac	0	1	0.0				1	2	50.0	0	1	0.0	0	2	0.0	380	69.9	6,346	73.5
1976	Neurologic	0	1	0.0				0	2	0.0	0	1	0.0	0	2	0.0	43	7.9	520	6.0
1977	Renal	0	1	0.0				0	2	0.0	0	1	0.0	0	2	0.0	4	0.7	86	1.0
1978	Vascular	0	1	0.0				0	2	0.0	0	1	0.0	0	2	0.0	5	0.9	111	1.3
1979	Infection	0	1	0.0				0	2	0.0	0	1	0.0	0	2	0.0	13	2.4	206	2.4
1980	Valvular	0	1	0.0				0	2	0.0	0	1	0.0	0	2	0.0	12	2.2	191	2.2
1981	Pulmonary	0	1	0.0				1	2	50.0	1	1	100.0	1	2	50.0	31	5.7	443	5.1
1982	Unknown	0	1	0.0				0	2	0.0	0	1	0.0	0	2	0.0	27	5.0	325	3.8
1983	Other	1	1	100.0				0	2	0.0	0	1	0.0	1	2	50.0	29	5.3	408	4.7
1984	**Discharge location**	**4**	**4**	**100.0**	**14**	**14**	**100.0**	**6**	**6**	**100.0**	**9**	**9**	**100.0**	**27**	**27**	**100.0**	**27,086**	**100.0**	**610,716**	**100.0**
1985	Home	2	4	50.0	9	14	64.3	6	6	100.0	5	9	55.6	16	27	59.3	24,966	92.2	585,400	95.9
1986	Extended care, transitional care or rehab facility	0	4	0.0	0	14	0.0	0	6	0.0	0	9	0.0	0	27	0.0	587	2.2	11,648	1.9
1987	Other acute care hospital	1	4	25.0	3	14	21.4	0	6	0.0	3	9	33.3	7	27	25.9	1,009	3.7	4,594	0.8
1988	Nursing home	1	4	25.0	1	14	7.1	0	6	0.0	1	9	11.1	3	27	11.1	288	1.1	5,444	0.9
1989	Hospice	0	4	0.0	0	14	0.0	0	6	0.0	0	9	0.0	0	27	0.0	47	0.2	1,000	0.2
1990	Other	0	4	0.0	1	14	7.1	0	6	0.0	0	9	0.0	1	27	3.7	117	0.4	1,320	0.2
1991	Left against medical advice (AMA)	0	4	0.0	0	14	0.0	0	6	0.0	0	9	0.0	0	27	0.0	72	0.3	1,310	0.2
1992	**Risk adjusted mortality (RAM) - all pts**																			
1993	Eligible pts (LFHS)	4			11						7			22			26,048		603,333	
1994	Observed Mortality (among eligible) (LFHS)	1			0						1			2			545		8,656	
1995	Expected Mortality (among eligible) (LFHS)	0.07			0.33						0.33			0.74			495.79		8,735.23	
1996	Observed/Expected Mortality Ratio	14.15			0.00						3.00			2.72			1.10		0.99	
1997	Risk Adjusted Mortality Rate (%)	18.23									4.18			3.90					1.42	
1998	Registry Aggregate Observed	1.29			1.51			1.55			1.39			1.43					1.43	

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PCI
Discharge Information
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
	Mortality																			
1999	Lower 95% confidence interval	0.97			0.00						0.22			0.69					1.40	
2000	Upper 95% confidence interval	48.83			10.52						13.67			10.74					1.45	
2001	**RAM for pts w/ STEMI**																			
2002	Eligible pts	4			11						6			21			7,342		96,972	
2003	Observed Mortality (among eligible)	1			0						1			2			397		5,309	
2004	Expected Mortality (among eligible)	0.07			0.33						0.30			0.70			360.87		5,262.31	
2005	Observed/Expected Mortality Ratio	14.15			0.00						3.39			2.86			1.10		1.01	
2006	Risk Adjusted Mortality Rate (%)	72.68									17.92			15.67					5.52	
2007	Registry Aggregate Observed Mortality	5.14			5.65			5.80			5.29			5.47					5.47	
2008	Lower 95% confidence interval	3.88			0.00						0.95			2.79					5.41	
2009	Upper 95% confidence interval	194.68			39.53						54.32			42.54					5.64	
2010	**RAM STEMI pts excluded**																			
2011	Eligible pts										1			1			18,706		506,361	
2012	Observed Mortality (among eligible)										0			0			148		3,347	
2013	Expected Mortality (among eligible)										0.04			0.04			134.92		3,472.92	
2014	Observed/Expected Mortality Ratio										0.00			0.00			1.10		0.96	
2015	Risk Adjusted Mortality Rate (%)																		0.64	
2016	Registry Aggregate Observed Mortality	0.58			0.69			0.73			0.65			0.66					0.66	
2017	Lower 95% confidence interval										0.00			0.00					0.62	
2018	Upper 95% confidence interval										13.66			13.97					0.66	

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PCI (all patients)
Length of Stay
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
2019	Length of stay (LOS) - all pts																			
2020	Pts w/ CABG or other major surgery	1			1						1			3			756		16,905	
2021	Pts w/out CABG or other major surgery	5			14			8			10			29			27,619		618,717	
2022	**Total LOS - all pts**																			
2023	Mean	3.2			3.2			3.5			3.7			3.4			3.2		3.1	
2024	Median	2.0			2.0			3.0			2.5			2.0			2.0		2.0	
2025	Standard deviation	3.42			3.21			2.51			3.68			3.30			8.51		9.09	
2026	**Pre-procedure LOS - all pts**																			
2027	Mean	0.2			0.0			0.1			0.1			0.1			0.8		0.8	
2028	Median	0.0			0.0			0.0			0.0			0.0			0.0		0.0	
2029	Standard deviation	0.45			0.00			0.35			0.32			0.26			7.31		7.45	
2030	**Post-procedure LOS - all pts**																			
2031	Mean	3.0			3.2			3.4			3.6			3.3			2.4		2.3	
2032	Median	2.0			2.0			2.5			2.5			2.0			1.0		1.0	
2033	Standard deviation	3.00			3.21			2.56			3.50			3.17			4.29		5.07	
2034	**Total LOS - pts w/ CABG or other major surgery**																			
2035	Mean	0.0			0.0						10.0			3.3			7.0		10.9	
2036	Median	0.0			0.0						10.0			0.0			4.5		8.0	
2037	Standard deviation													5.77			8.69		13.19	
2038	**Pre-procedure LOS - pts w/ CABG or other major surgery**																			
2039	Mean	0.0			0.0						1.0			0.3			1.3		1.7	
2040	Median	0.0			0.0						1.0			0.0			0.0		0.0	
2041	Standard deviation													0.58			2.95		7.42	
2042	**Post-procedure LOS - pts w/ CABG or other major surgery**																			
2043	Mean	0.0			0.0						9.0			3.0			5.7		9.2	
2044	Median	0.0			0.0						9.0			0.0			3.0		7.0	
2045	Standard deviation													5.20			7.97		10.74	
2046	**Total LOS - pts w/out CABG or other major surgery**																			
2047	Mean	3.2			3.2			3.5			3.7			3.4			3.2		3.0	
2048	Median	2.0			2.0			3.0			2.5			2.0			2.0		2.0	
2049	Standard deviation	3.42			3.21			2.51			3.68			3.30			8.51		9.06	

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PCI (all patients)
Length of Stay
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	**Description**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**%**	**Num**	**%**
2050	**Pre-procedure LOS - pts w/out CABG or other major surgery**																			
2051	Mean	0.2			0.0			0.1			0.1			0.1			0.8		0.8	
2052	Median	0.0			0.0			0.0			0.0			0.0			0.0		0.0	
2053	Standard deviation	0.45			0.00			0.35			0.32			0.26			7.31		7.44	
2054	**Post-procedure LOS - pts w/out CABG or other major surgery**																			
2055	Mean	3.0			3.2			3.4			3.6			3.3			2.4		2.2	
2056	Median	2.0			2.0			2.5			2.5			2.0			1.0		1.0	
2057	Standard deviation	3.00			3.21			2.56			3.50			3.17			4.28		5.02	

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PCI (patients with STEMI)
Length of Stay
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
2058	Length of stay (LOS) - pts w/ STEMI																			
2059	Pts w/ STEMI and CABG or other major surgery	1			1						1			3			373		5,459	
2060	Pts w/ STEMI and w/out CABG or other major surgery	5			14			8			9			28			8,033		100,056	
2061	**Total LOS - all pts w/ STEMI**																			
2062	Mean	3.2			3.2			3.5			3.6			3.3			3.8		4.4	
2063	Median	2.0			2.0			3.0			2.0			2.0			3.0		3.0	
2064	Standard deviation	3.42			3.21			2.51			3.88			3.35			7.18		9.25	
2065	**Pre-procedure LOS - all pts w/ STEMI**																			
2066	Mean	0.2			0.0			0.1			0.1			0.1			0.2		0.3	
2067	Median	0.0			0.0			0.0			0.0			0.0			0.0		0.0	
2068	Standard deviation	0.45			0.00			0.35			0.33			0.26			4.16		6.58	
2069	**Post-procedure LOS - all pts w/ STEMI**																			
2070	Mean	3.0			3.2			3.4			3.4			3.3			3.6		4.1	
2071	Median	2.0			2.0			2.5			2.0			2.0			3.0		3.0	
2072	Standard deviation	3.00			3.21			2.56			3.68			3.22			5.84		6.45	
2073	**Total LOS - pts w/ STEMI and CABG or other major surgery**																			
2074	Mean	0.0			0.0						10.0			3.3			6.5		11.5	
2075	Median	0.0			0.0						10.0			0.0			4.0		9.0	
2076	Standard deviation													5.77			9.55		13.40	
2077	**Pre-procedure LOS - pts w/ STEMI and CABG or other major surgery**																			
2078	Mean	0.0			0.0						1.0			0.3			0.4		0.4	
2079	Median	0.0			0.0						1.0			0.0			0.0		0.0	
2080	Standard deviation													0.58			1.61		2.24	
2081	**Post-procedure LOS - pts w/ STEMI and CABG or other major surgery**																			
2082	Mean	0.0			0.0						9.0			3.0			6.1		11.1	
2083	Median	0.0			0.0						9.0			0.0			3.0		8.0	
2084	Standard deviation													5.20			9.39		13.13	
2085	**Total LOS – pts w/ STEMI and w/out CABG or other major surgery**																			

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PCI (patients with STEMI)
Length of Stay
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
2086	Mean	3.2			3.2			3.5			3.6			3.3			3.8		4.4	
2087	Median	2.0			2.0			3.0			2.0			2.0			3.0		3.0	
2088	Standard deviation	3.42			3.21			2.51			3.88			3.35			7.16		9.19	
2089	**Pre-procedure LOS - pts w/ STEMI and w/out CABG or other major surgery**																			
2090	Mean	0.2			0.0			0.1			0.1			0.1			0.2		0.3	
2091	Median	0.0			0.0			0.0			0.0			0.0			0.0		0.0	
2092	Standard deviation	0.45			0.00			0.35			0.33			0.26			4.16		6.59	
2093	**Post-procedure LOS - pts w/ STEMI and w/out CABG or other major surgery**																			
2094	Mean	3.0			3.2			3.4			3.4			3.3			3.6		4.1	
2095	Median	2.0			2.0			2.5			2.0			2.0			3.0		3.0	
2096	Standard deviation	3.00			3.21			2.56			3.68			3.22			5.82		6.36	

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PCI (patients without STEMI)
Length of Stay
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
2097	Length of stay (LOS) for pts w/out STEMI																			
2098	Pts w/out STEMI and w/ CABG or other major surgery																382		11,442	
2099	Pts w/out STEMI and w/out CABG or other major surgery										1			1			19,581		518,584	
2100	**Total LOS - all pts w/out STEMI**																			
2101	Mean										5.0			5.0			3.0		2.8	
2102	Median										5.0			5.0			2.0		1.0	
2103	Standard deviation																8.99		9.04	
2104	**Pre-procedure LOS - all pts w/out STEMI**																			
2105	Mean										0.0			0.0			1.1		0.9	
2106	Median										0.0			0.0			0.0		0.0	
2107	Standard deviation																8.25		7.60	
2108	**Post-procedure LOS - all pts w/out STEMI**																			
2109	Mean										5.0			5.0			1.9		1.9	
2110	Median										5.0			5.0			1.0		1.0	
2111	Standard deviation																3.34		4.67	
2112	**Total LOS - pts w/out STEMI and w/ CABG or other major surgery**																			
2113	Mean																7.4		10.6	
2114	Median																5.0		8.0	
2115	Standard deviation																7.75		13.08	
2116	**Pre-procedure LOS - pts w/ STEMI and w/ CABG or other major surgery**																			
2117	Mean																2.1		2.3	
2118	Median																1.0		1.0	
2119	Standard deviation																3.64		8.82	
2120	**Post-procedure LOS - pts w/out STEMI and w/ CABG or other major surgery**																			
2121	Mean																5.4		8.3	
2122	Median																4.0		6.0	
2123	Standard deviation																6.30		9.25	
2124	**Total LOS - pts w/out STEMI and w/out CABG or other major surgery**																			

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PCI (patients without STEMI)
Length of Stay
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
2125	Mean										5.0			5.0			3.0		2.8	
2126	Median										5.0			5.0			2.0		1.0	
2127	Standard deviation																8.99		9.01	
2128	**Pre-procedure LOS - pts w/out STEMI and w/out CABG or other major surgery**																			
2129	Mean										0.0			0.0			1.1		0.9	
2130	Median										0.0			0.0			0.0		0.0	
2131	Standard deviation																8.25		7.59	
2132	**Post-procedure LOS - pts w/out STEMI and w/out CABG or other major surgery**																			
2133	Mean										5.0			5.0			1.9		1.9	
2134	Median										5.0			5.0			1.0		1.0	
2135	Standard deviation																3.33		4.64	

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ATTACHMENT XII

Greenwich Hospital's Letter of Intent to the Office of Health Care Access dated March 9, 2011 (PAMI Outcomes Limitations)

GREENWICH HOSPITAL
YALE NEW HAVEN HEALTH

March 9, 2011

Kimberly Martone
Director of Operations
Office of Health Care Access
State of Connecticut Department of Public Health
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: Docket Number 03-30148-CON, as modified by Docket Number 06-30148-MDF, Docket Number 08-30148-MDF and Docket Number 09-30148-MDF (Establishment of a Primary Interventional Cardiac Service at Greenwich Hospital)

Dear Ms. Martone:

This letter is in follow up to a phone conversation that we had earlier this year with staff of the Office of Health Care Access ("OHCA") regarding the reporting obligations of Greenwich Hospital under the above-referenced docket. Pursuant to Docket Number 09-30148-MDF, in the event that Greenwich Hospital participates in the American College of Cardiology National Cardiovascular Database (the "ACC-NCDR"), it is required to submit to OHCA, on an annual basis, any and all Executive Summary pages from the Institutional Outcomes Reports received from the ACC-NCDR. Greenwich Hospital may, however, determine not to participate in the ACC-NCDR, provided that it so notifies OHCA of its decision.

Greenwich Hospital has, since September of 2008, participated in the ACC-NCDR and has made various submissions to OHCA in compliance with Docket Number 09-30148-MDF. ACC-NCDR has, however, recently modified its database criteria to require reporting on additional measures, many of which apply to programs that provide for both primary and elective angioplasty services. In addition, the ACC-NCDR reports provide comparative benchmarking for all participating programs, and do not separately benchmark programs that provide only primary/emergency angioplasty (so-called "PAMI only programs") such as that in operation at Greenwich Hospital. As a result, the report shows an "apples to oranges" comparison of data and is not a good indication of performance for PAMI only programs such as Greenwich Hospital's program.

As a result, Greenwich Hospital's performance is benchmarked against programs that have significantly higher volumes that include elective angioplasty cases. This results in benchmarking that is skewed, can be incorrectly interpreted, and limits valid comparisons. However, at this time the ACC-NCDR data appears to be the only benchmarking data set available to hospitals. The ACC-NCDR data is not designed to be used in the public domain but rather is designed to be used as an internal document for benchmarking purposes by hospitals. The public may not be aware of the data discrepancies outlined above and, therefore, not be able to correctly either interpret the data or draw correct conclusions about a hospital's performance based on the data. Upon Greenwich Hospital's submission of the ACC-NCDR data to the Office of Health Care Access, the data becomes available to the public under Freedom of Information laws where it may be incorrectly interpreted as discussed above.

Enclosed are the Greenwich Hospital ACC-NCDR Executive Summary pages for the period from July 1, 2009 through June 30, 2010 in compliance with its obligations under Docket Number 09-30148-MDF.

<u>In light of the concerns about the data and results obtained from ACC-NCDR, Greenwich Hospital respectfully requests that the Executive Summary be qualified by the information contained in this letter and that any disclosure or other use of the Executive Summary or the data contained therein be accompanied by a copy of this letter.</u>

Thank you for your consideration. Please feel free to contact me at (203) 863-3909 should you have any questions.

Sincerely,

Nancy M. Hamson

Nancy M. Hamson
Planning Director

cc: Frank A. Corvino
Gayle Capozzalo
Nancy Levitt Rosenthal
Christopher Howes, MD
Peggy Martino

Executive Summary

CathPCI Registry®

Greenwich Hospital(187346) compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2010Q2

Section I: PCI Performance Measures

Endorsed by the National Quality Forum and appropriate for public reporting

PCI Performance Measures

Distribution of Data

10th percentile — Better → — 90th percentile

1 **PCI in-hospital risk adjusted mortality (all patients)**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
2.54		1.42	0.77

Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1979]



Note

In-hospital risk adjusted mortality for PCI is the only performance measure in the CathPCI Registry® that has been endorsed by the National Quality Forum. Such performance measures meeting the requirement for approval are intended not only for clinical quality improvement, but also may be considered for purposes of public reporting.

The "Registry Metrics" on the subsequent pages of this report are those measures that have been developed to support self assessment and quality improvement at the provider, hospital, and/or health care system level. While these metrics have not been formally developed by the American College of Cardiology/American Heart Association Task Force for Performance Measures Task Force, they may be identified as evolving measures worthy of consideration for further development into performance measures.

Any disclosure of this data should be accompanied by the Greenwich Hospital cover letter dated March 9, 2011

Executive Summary

CathPCI Registry®

Greenwich Hospital(187346) compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2010Q2

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

PCI Process Metrics

Distribution of Data

10th percentile · Better → · 90th percentile

2 **Positive stress or imaging study prior to elective PCI**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
	50.5%	52.4%	70.9%

Proportion of elective PCI procedures (excluding patients with ACS) with an antecedent stress or imaging study with a positive result (suggestive of ischemia) or with a fractional flow reserve assessed during the procedure. [Detail Line:1515]

3 **Median time to immediate PCI for STEMI patients (in minutes)**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
76.5	67.0	64.0	52.1

Your hospital's median time from hospital arrival to immediate PCI for STEMI patients in minutes. Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1504]

4 **Proportion of STEMI patients receiving immediate PCI w/in 90"**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
88.5%	87.2%	87.9%	98.4%

Proportion of STEMI patients with a time from your hospital arrival (or subsequent ECG if ST elevation first noted on subsequent ECG) to immediate PCI <=90". Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1505]

5 **Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
	76.0	86.0	57.5

Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1507]

6 **Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
	109.0	118.0	84.9

Your hospital's median time from arrival at referring facility to immediate PCI at STEMI receiving facility among transferred patients. Exclusions: Reasons for delay does not equal none. [Detail Line:1508]

7 **Median fluoro time (in minutes)**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
12.1	9.6	8.8	6.5

Inclusion criteria: PCI of one vessel/lesion. Exclusion criteria: Prior CABG, or "other" procedure during the same lab visit; PCI of >1 vessel/lesion. [Detail Line:1612]

8 **Aspirin prescribed at discharge**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
100.0%	95.3%	97.0%	99.8%

Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1941]

9 **Thienopyridine prescribed at discharge (patients with stents)**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
100.0%	97.3%	98.1%	100.0%

Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine prescribed at discharge. [Detail Line: 1950]

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NCDR® CathPCI Registry®

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Any disclosure of this data should be accompanied by the Greenwich Hospital cover letter dated March 9, 2011

Executive Summary

CathPCI Registry®

Greenwich Hospital(187346) compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2010Q2

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

10 **Lipid lowering agent prescribed at discharge (pts with dyslipidemia)**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
80.0%	90.8%	92.4%	98.0%

Proportion of patients (without a documented contraindication) prescribed a lipid lowering agent at discharge.
Inclusions: History of dyslipidemia [Detail Line:1948]

PCI Outcome Metrics — **Distribution of Data** (10th percentile … 90th percentile; better →)

11 **Vascular access site injury requiring treatment or major bleeding***

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
0.0%	1.9%	1.4%	0.0%

Your hospital's proportion of patients (excluding CABG or other surgery during same admission) with major access site related injury requiring treatment or major bleeding. [Detail Line:1818]

12 **Emergency CABG**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
0.0%	0.5%	0.3%	0.0%

Your hospital's proportion of patients having emergency CABG (at your facility or transferred to another facility). [Detail Line:1923]

13 **Post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
	3.2%	3.0%	0.7%

Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with >= 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1781]

14 **Post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
	2.0%	1.4%	0.4%

Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with < 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1782]

15 **Acute kidney injury*****

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
3.6%	1.9%	2.2%	0.9%

Your hospital's proportion of patients who had a rise of serum creatinine of > 50% over the pre-procedure baseline (excluding patients on dialysis pre-procedure).
Inclusions: >= 90% of patients with a pre and post creatinine coded; LOS >=1 day. [Detail Line:1915]

16 **Post procedure stroke**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
0.0%	0.2%	0.2%	0.0%

Your hospital's proportion of patients with stroke post procedure. [Detail Line:1788]

17 **Composite: Death, emergency CABG, stroke or repeat target vessel revascularization**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
5.7%	2.8%	2.3%	0.8%

Your hospital's proportion of patients with death, emergency CABG, stroke or repeat target vessel revascularization post procedure up to hospital discharge.
Exclusions: Staged PCI during same admission. [Detail Line:1779]

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Executive Summary

CathPCI Registry®

Greenwich Hospital(187346) compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2010Q2

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

18 **PCI In-hospital risk adjusted mortality (patients with STEMI)**

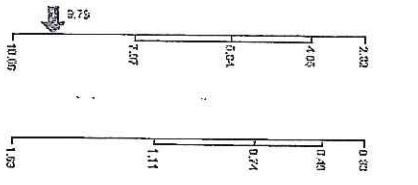
My Hospital	Vol Group R4Q	All Hosp	90th Pctl
9.78		5.51	2.82

Your hospital's PCI In-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:1988]

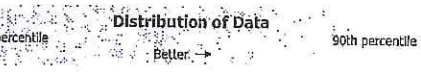
19 **PCI In-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
		0.67	0.33

Your hospital's PCI In-hospital risk adjusted mortality rate for patients with other diagnoses (not STEMI) using the NCDR® risk adjustment model. [Detail Line:1997]



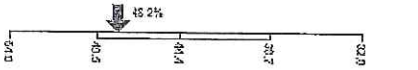
Diagnostic Cath Process Metrics



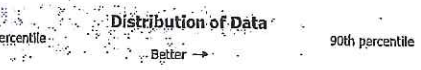
20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
48.2%	48.0%	44.2%	32.8%

Patients with an elective diagnostic cath and coronary angiography with all native coronary territories <50%
Exclusions: Patients with prior CABG, cardiac transplant evaluation; pre-op evaluation for non-cardiac surgery and diagnostic cath treatment recommendation of "other cardiac therapy without CABG or PCI". [Detail Line:1254]



Diagnostic Cath Outcomes Metrics



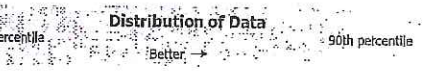
21 **Vascular access site injury requiring treatment or major bleeding***

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
0.4%	0.4%	0.3%	0.0%

Your hospital's proportion of patients with major access site related injury requiring treatment or major bleeding. [Detail Line:1303]



Utilization Metrics



22 **Median post-procedure length of stay (in days) for PCI patients with STEMI**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
2.0	3.0	3.0	1.7

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2053]



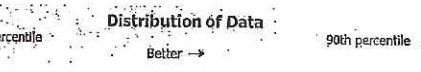
23 **Median post-procedure length of stay (in days) for PCI patients with no STEMI**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
	1.0	1.0	0.6

Your hospital's median post-procedure length of stay (in days) for PCI patients with no STEMI. [Detail Line:2092]



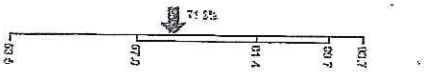
Data Quality Metrics



24 **Creatinine assessed pre and post PCI procedure**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
71.8%	78.9%	76.0%	93.7%

Proportion of PCI patients with creatinine assessed pre and post procedure. Inclusions: LOS >=1 day. [Detail Line:1914]



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Executive Summary

CathPCI Registry®

Greenwich Hospital(187346) compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2010Q2

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

Test Metrics

Distribution of Data

10th percentile | 90th percentile | Better →

25 **Test Metric: Transfusion of whole blood or RBCs**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
0.0%	2.1%	2.0%	0.0%

Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Exclusions: Patients having CABG or other major surgery during the same admission. [Detail Line:1820]



26 **Test Data Quality Metric: Biomarkers assessed post-PCI for elective inpatients**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
	51.8%	45.2%	96.0%

Proportion of elective procedures with biomarkers assessed post PCI. Inclusion criteria: LOS >= 1 day and hospital status is "not outpatient". [Detail Line:1912]



Executive Summary Footnotes

*Vascular access site injury requiring treatment or major bleeding is defined as:

1.Bleeding at access site, hematoma at access site, or retroperitoneal bleed that occur within 72 hours of the procedure. To qualify, the event must be associated with a hemoglobin drop of >3 g/dL; transfusion of whole or packed red blood cells, or a procedural intervention/surgery at the bleeding site to reverse/stop or correct the bleeding. This excludes "GI", "GU" and "Other" bleeds.

2.Major access site related injury requiring treatment includes access site occlusion, peripheral embolization, dissection, pseudoaneurysm, AV fistula requiring treatment anytime from the procedure until discharge.

**Your rate of post procedure MI cannot be reported if you only collected cardiac biomarkers on <90% of your patients who were in the hospital >=1 day.

***Your rate of acute kidney injury cannot be reported if you only collected creatinine pre and post procedure on <90% of your patients who were in the hospital >=1 day.

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ATTACHMENT XIII

Internal Revenue Service
Tax Exempt Status

Internal Revenue Service

Date: October 4, 2007

GREENWICH HOSPITAL
% CHRIS CONNOR
5 PERRYRIDGE RD
GREENWICH CT 06830-4608

Department of the Treasury
P. O. Box 2508
Cincinnati, OH 45201

Person to Contact:
Mary Holland 17-57088
Customer Service Representative
Toll Free Telephone Number:
877-829-5500
Federal Identification Number:
06-0646659

Dear Sir or Madam:

This is in response to your request of October 4, 2007, regarding your organization's tax-exempt status.

In February 1972 we issued a determination letter that recognized your organization as exempt from federal income tax. Our records indicate that your organization is currently exempt under section 501(c)(3) of the Internal Revenue Code.

Our records indicate that your organization is also classified as a public charity under sections 509(a)(1) and 170(b)(1)(A)(vi) of the Internal Revenue Code.

Our records indicate that contributions to your organization are deductible under section 170 of the Code, and that you are qualified to receive tax deductible bequests, devises, transfers or gifts under section 2055, 2106 or 2522 of the Internal Revenue Code.

If you have any questions, please call us at the telephone number shown in the heading of this letter.

Sincerely,

Michele M. Sullivan

Michele M. Sullivan, Oper. Mgr.
Accounts Management Operations 1

STATE OF CONNECTICUT
DEPARTMENT OF REVENUE SERVICES
92 Farmington Avenue, Hartford, CT 06105

TAX EXEMPTION PERMIT ISSUED UNDER THE SALES AND USE TAXES ACT

In accordance with the provisions of the Sales and Use Taxes Act and the regulations thereunder, it is hereby certified that the charitable or religious organization named below is exempt from all sales and use taxes on purchases of tangible personal property made by it for the sole and exclusive purposes of the organizations.

Duplicate

Permit No. E-0933 Date Issued 4/18/91

The Greenwich Hospital Association
Perryridge Road
Greenwich, CT 06830-4697

This permit is NOT assignable or transferrable

JAMES F. KEEHAN, Commissioner of Revenue Services

-251 (Rev. 2/90)

IRS Department of the Treasury
Internal Revenue Service

OGDEN UT 84201-0038

In reply refer to: 0441981549
Nov. 01, 2010 LTR 4168C E0
06-0646652 000000 00
00029143
BODC: TE

YALE NEW HAVEN HOSPITAL
% LAURIE CAHILL
20 YORK ST
NEW HAVEN CT 06510-3220

025077

Employer Identification Number: 06-0646652
Person to Contact: Mr. Ludlow
Toll Free Telephone Number: 1-877-829-5500

Dear Taxpayer:

This is in response to your Oct. 21, 2010, request for information regarding your tax-exempt status.

Our records indicate that you were recognized as exempt under section 501(c)(3) of the Internal Revenue Code in a determination letter issued in November 1966.

Our records also indicate that you are not a private foundation within the meaning of section 509(a) of the Code because you are described in section(s) 509(a)(1) and 170(b)(1)(A)(iii).

Donors may deduct contributions to you as provided in section 170 of the Code. Bequests, legacies, devises, transfers, or gifts to you or for your use are deductible for Federal estate and gift tax purposes if they meet the applicable provisions of sections 2055, 2106, and 2522 of the Code.

Please refer to our website www.irs.gov/eo for information regarding filing requirements. Specifically, section 6033(j) of the Code provides that failure to file an annual information return for three consecutive years results in revocation of tax-exempt status as of the filing due date of the third return for organizations required to file.

If you have any questions, please call us at the telephone number shown in the heading of this letter.

Sincerely yours,

Rita A. Leete

Rita A. Leete
Accounts Management II

IRS Department of the Treasury
Internal Revenue Service

OGDEN UT 84201-0038

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YALE NEW HAVEN HOSPITAL
% LAURIE CAHILL
20 YORK ST
NEW HAVEN CT 06510-3220

025077

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The IRS address must appear in the window. Use for payments

0441981549

BODCD-TE

Letter Number: LTR4168C
Letter Date : 2010-11-01
Tax Period : 000000

060646652

YALE NEW HAVEN HOSPITAL
% LAURIE CAHILL
20 YORK ST
NEW HAVEN CT 06510-3220

INTERNAL REVENUE SERVICE

OGDEN UT 84201-0038

060646652 20 YALE 00 2 000000 670 00000000000

ATTACHMENT XIV

State of Connecticut Department of Public Health
Hospital License

STATE OF CONNECTICUT

Department of Public Health

License No. 0045

General Hospital

In accordance with the provisions of the General Statutes of Connecticut Section 19a-493:

Greenwich Hospital of Greenwich, CT, d/b/a Greenwich Hospital is hereby licensed to maintain and operate a General Hospital.

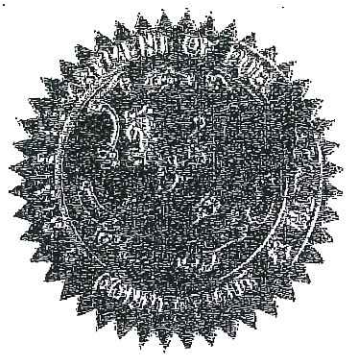
Greenwich Hospital is located at 5 Perryridge Road, Greenwich, CT 06830

The maximum number of beds shall not exceed at any time:
32 Bassinets
174 General Hospital beds

This license expires **September 30, 2013** and may be revoked for cause at any time.

Dated at Hartford, Connecticut, October 1, 2011. RENEWAL.

Satellites:
The Endoscopy Center of Greenwich Hospital, 500 West Putnam Avenue, Greenwich, CT



Jewel Mullen, MD, MPH, MPA
Commissioner

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Division of Health Systems Regulation

DEBORAH Z. WOODWORTH

JAN 30 2012

ASST. TO THE PRESIDENT

TO: Administrator
Yale-New Haven Hospital, Inc.
20 York Street
New Haven, CT 06504

FROM: Colleen Judge
Processing Technician

DATE: January 25, 2012

We are enclosing a corrected license showing a change for your facility:

( ) Change of Administrator

( ) Change of Medical Director

( ) Change of Director of Nurses

(X) Increase of bed capacity from 874 General Hospital Beds to 896 General Hospital Beds Eff: 1/11/12.

(X) Increase of bed capacity from 92 Bassinets to 112 Bassinets, effective 1/11/12.

( ) Decrease of bed capacity from _____ to _____ Eff: _____.

(X) Other change, describe below:
Added (1) Satellite – P.T. Barnum Pediatric Center located at 226 Mill Hill Avenue, Bridgeport CT 06610 effective 1/11/12.

Please note that this license is in effect only for the operation of the facility as it is now organized. This division should be notified immediately if you:

1. Change your Administrator
2. Change your Director of Nurses
3. Change your Medical Director
4. Plan to relocate
5. Plan to sell your facility
6. Plan to discontinue operation.

Any of these changes or proposed changes also require written notification to this division.

If we can be of any assistance, please do not hesitate to call the licensure office.

Phone: (860) 509-7444
Telephone Device for the Deaf (860) 509-7191
410 Capitol Avenue - MS # 12HFL
P.O. Box 340308 Hartford, CT 06134
An Equal Opportunity Employer

STATE OF CONNECTICUT

Department of Public Health

LICENSE

License No. 0044

General Hospital

In accordance with the provisions of the General Statutes of Connecticut Section 19a-493:
Yale-New Haven Hospital, Inc. of New Haven, CT d/b/a Yale-New Haven Hospital, Inc. is hereby licensed to maintain and operate a General Hospital.

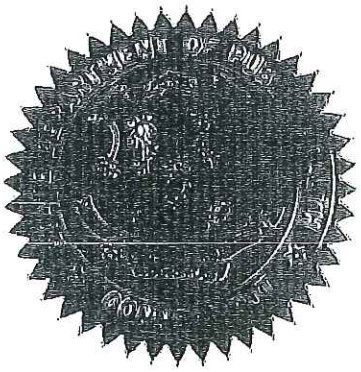
Yale-New Haven Hospital, Inc. is located at 20 York Street, New Haven, CT 06504.

The maximum number of beds shall not exceed at any time:
112 Bassinets
896 General Hospital Beds

This license expires **September 30, 2013** and may be revoked for cause at any time.
Dated at Hartford, Connecticut, October 1, 2011.

Satellites:
Hill Regional Career High School, 140 Legion Avenue, New Haven, CT
Branford High School Based Health Center, 185 East Main Street, Branford, CT
Walsh Middle School, 185 Damascus Road, Branford, CT
James Hillhouse High School Based Health Center, 480 Sherman Parkway, New Haven, CT
Weller Building, 425 George Street, New Haven, CT
Yale-New Haven Psychiatric Hospital, 184 Liberty Street, New Haven, CT
Yale-New Haven Shoreline Medical Center, 111 Goose Lane, Guilford, CT
Pediatric Dentistry Center, 860 Howard Avenue, New Haven, CT
YNHASC Temple Surgical Center, 60 Temple Street, New Haven, CT
YNHASC Women's Surgical Center, 40 Temple Street, New Haven, CT
Mauro-Sheridan School Based Health Center, 191 Fountain Street, New Haven, CT
Yale-New Haven Hospital Dental Center, 2560 Dixwell Avenue, Hamden, CT
Murphy School Based Health Center, 14 Brushy Plain Road, Branford, CT
*P.T. Barnum Pediatric Center, 226 Mill Hill Avenue, Bridgeport, CT

License Revised to Reflect:
*Increased Bassinets by 20 Beds and Increased General Beds by 22 effective 1/11/12
*Added (1) Satellite effective 1/11/12



Jewel Mullen, MD, MPH, MPA
Commissioner

ATTACHMENT XV

Financial Attachment I

12. C (i). Please provide one year of actual results and three years of projections of **Total Facility** revenue, expense and volume statistics without, incremental to and with the CON proposal in the following reporting format:

Total Facility: Description	FY 2011 Actual Results	FY 2012 Projected W/out CON	FY 2012 Projected Incremental	FY 2012 Projected With CON	FY 2013 Projected W/out CON	FY 2013 Projected Incremental	FY 2013 Projected With CON	FY 2014 Projected W/out CON	FY 2014 Projected Incremental	FY 2014 Projected With CON	FY 2015 Projected W/out CON	FY 2015 Projected Incremental	FY 2015 Projected With CON
NET PATIENT REVENUE													
Non-Government	$209,127	$226,486	$0	$226,486	$236,815	$1,520	$238,335	$247,637	$1,769	$249,406	$259,027	$2,073	$261,100
Medicare	$78,070	$81,275	$0	$81,275	$83,113	$1,364	$84,477	$84,924	$1,587	$86,511	$86,779	$1,841	$88,620
Medicaid and Other Medical Assistance	$9,813	$9,915	$0	$9,915	$9,859	$51	$9,910	$9,926	$58	$9,984	$9,959	$65	$10,024
Other Government		$0		$0	$0		$0	$0		$0	$0		$0
Total Net Patient Patient Revenue	$297,010	$317,676	$0	$317,676	$329,787	$2,935	$332,722	$342,487	$3,413	$345,900	$355,765	$3,978	$359,743
Other Operating Revenue	$18,563	$17,760	$0	$17,760	$17,938	$0	$17,938	$18,117	$0	$18,117	$18,298		$18,298
Revenue from Operations	$315,573	$335,436	$0	$335,436	$347,725	$2,935	$350,660	$360,604	$3,413	$364,017	$374,063	$3,978	$378,041
OPERATING EXPENSES													
Salaries and Fringe Benefits	$164,310	$156,863	$0	$156,863	$163,295	$518	$163,813	$170,069	$604	$170,673	$177,201	$709	$177,910
Professional / Contracted Services	$36,873	$55,158		$55,158	$50,599		$50,599	$51,834		$51,834	$53,215		$53,215
Supplies and Drugs	$49,000	$53,490	$0	$53,490	$55,410	$1,835	$57,245	$57,403	$2,140	$59,543	$59,471	$2,513	$61,984
Bad Debts	$9,270	$11,714		$11,714	$12,330		$12,330	$12,977		$12,977	$13,660		$13,660
Other Operating Expense	$27,142	$30,933		$30,933	$33,555		$33,555	$35,065		$35,065	$36,265		$36,265
Subtotal	$286,595	$308,158	$0	$308,158	$315,189	$2,353	$317,542	$327,348	$2,744	$330,092	$339,812	$3,222	$343,034
Depreciation/Amortization	$18,906	$20,177		$20,177	$22,000		$22,000	$22,000		$22,000	$22,000		$22,000
Interest Expense	$425	$404		$404	$437		$437	$419		$419	$400		$400
Lease Expense				$0			$0			$0			$0
Total Operating Expense	$305,926	$328,739	$0	$328,739	$337,626	$2,353	$339,979	$349,767	$2,744	$352,511	$362,212	$3,222	$365,434
Gain/(Loss) from Operations	$9,647	$6,697	$0	$6,697	$10,099	$582	$10,681	$10,837	$669	$11,506	$11,851	$756	$12,607
Plus: Non-Operating Revenue	($3,625)	$168		$168	$78		$78	$22		$22	$1		$1
Revenue Over/(Under) Expense	$6,022	$6,865	$0	$6,865	$10,177	$582	$10,759	$10,859	$669	$11,528	$11,852	$756	$12,608
FTEs	1613	1509	0.00	1509	1515	4.5	1520	1521	5.2	1526.2	1527	5.9	1532.9
*Volume Statistics:	38	38	0	38	38	158	196	38	179	217	38	204	242

Provide projected inpatient and/or outpatient statistics for any new services and provide actual and projected inpatient and/or outpatient statistics for any existing services which will change due to the proposal.

ATTACHMENT XVI

Financial Attachment II

12.C(ii). Please provide **three** years of projections of incremental revenue, expense and volume statistics **attributable to the proposal** in the following reporting format:

Type of Service Description	Angioplasty
Type of Unit Description:	cases
# of Months in Operation	12

FY _2013_____ **FY Projected Incremental** Total Incremental Expenses: **$2,352,146**	(1)	(2) Rate	(3) Units	(4) Gross Revenue Col. 2 * Col. 3	(5) Allowances/ Deductions	(6) Charity Care	(7) Bad Debt	(8) Net Revenue Col.4 - Col.5 -Col.6 - Col.7	(9) Operating Expenses Col. 1 Total * Col. 4 / Col. 4 Total	(10) Gain/(Loss) from Operations Col. 8 - Col. 9
Total Facility by Payer Category:										
Medicare		$93,257	64	$5,968,448	$ 4,604,359.21			$1,364,089	$952,768	$411,321
Medicaid		$93,257	9	$839,313	$788,467			$50,846	$133,983	($83,137)
CHAMPUS/TriCare		$93,257		$0	$0			$0	$0	$0
Total Governmental			73	$6,807,761	$5,392,827	$0	$0	$1,414,934	$1,086,751	$328,183
Commericial Insurers		$93,257	77	$7,180,789	$5,661,119			$1,519,670	$1,146,299	$373,371
Uninsured		$93,257	8	$746,056	$0	$746,056		$0	$119,096	($119,096)
Total NonGovernment		$93,257	85	$7,926,845	$5,661,119	$746,056	$0	$1,519,670	$1,265,395	$254,275
Total All Payers		$93,257	158	$14,734,606	$11,053,945	$746,056	$0	$2,934,605	$2,352,146	$582,459

12.C(ii). Please provide **three** years of projections of incremental revenue, expense and volume statistics **attributable to the proposal** in the following reporting format:

Type of Service Description: Angioplasty
Type of Unit Description: cases
# of Months in Operation: 12

FY 2014_____ **FY Projected Incremental** Total Incremental Expenses: **$2,744,716** **Total Facility by Payer Category:**	(1)	(2) Rate	(3) Units	(4) Gross Revenue Col. 2 * Col. 3	(5) Allowances/ Deductions	(6) Charity Care	(7) Bad Debt	(8) Net Revenue Col.4 - Col.5 -Col.6 - Col.7	(9) Operating Expenses Col. 1 Total * Col. 4 / Col. 4 Total	(10) Gain/(Loss) from Operations Col. 8 - Col. 9
Medicare		$100,252	73	$7,318,396	$ 5,731,328.64			$1,587,067	$1,119,353	$467,714
Medicaid		$100,252	10	$1,002,520	$944,895			$57,625	$153,336	($95,711)
CHAMPUS/TriCare		$100,252	0	$0	$0			$0	$0	$0
Total Governmental			83	$8,320,916	$6,676,224	$0	$0	$1,644,692	$1,272,690	$372,003
Commericial Insurers		$100,252	87	$8,721,924	$6,953,379			$1,768,545	$1,334,024	$434,521
Uninsured		$100,252	9	$902,268	$0	$902,268		$0	$138,002	($138,002)
Total NonGovernment		$100,252	96	$9,624,192	$6,953,379	$902,268	$0	$1,768,545	$1,472,026	$296,518
Total All Payers		$100,252	179	$17,945,108	$13,629,603	$902,268	$0	$3,413,237	$2,744,716	$668,521

12.C(ii). Please provide **three** years of projections of incremental revenue, expense and volume statistics **attributable to the proposal** in the following reporting format:

Type of Service Description	cases									
Type of Unit Description:										
# of Months in Operation	12									
FY _2015	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
FY Projected Incremental		Rate	Units	Gross Revenue Col. 2 * Col. 3	Allowances/ Deductions	Charity Care	Bad Debt	Net Revenue Col.4 - Col.5 -Col.6 - Col.7	Operating Expenses Col. 1 Total * Col. 4 / Col. 4 Total	Gain/(Loss) from Operations Col. 8 - Col. 9
Total Incremental Expenses:	**$3,221,898**									
Total Facility by Payer Category:										
Medicare		$107,770	83	$8,944,910	$7,104,405			$1,840,505	$1,310,870	$529,634
Medicaid		$107,770	11	$1,185,470	$1,120,814			$64,656	$173,730	($109,074)
CHAMPUS/TriCare		$107,770	0	$0	$0			$0	$0	$0
Total Governmental			94	$10,130,380	$8,225,220	$0	$0	$1,905,160	$1,484,600	$420,560
Commericial Insurers		$107,770	99	$10,669,230	$8,596,412			$2,072,818	$1,563,568	$509,250
Uninsured		$107,770	11	$1,185,470	$0	$1,185,470		$0	$173,730	($173,730)
Total NonGovernment		$107,770	110	$11,854,700	$8,596,412	$1,185,470	$0	$2,072,818	$1,737,298	$335,520
Total All Payers		$107,770	204	$21,985,080	$16,821,632	$1,185,470	$0	$3,977,978	$3,221,898	$756,080

ATTACHMENT XVII

Assumptions

Greenwich Hospital

Assumptions

Net Revenue Rate Increases	FY 2012	FY 2013	FY 2014	FY 2015
1) Government	0.0 - 2.0%	0.0 - 2.0%	0.0 - 2.0%	0.0 - 2.0%
2) Non-Government	3.0 - 5.0%	3.0 - 5.0%	3.0 - 5.0%	3.0 - 5.0%

	FY 2012	FY 2013	FY 2014	FY 2015
EXPENSES				
Salaries and Fringe Benefits	3.0%	3.0%	3.0%	3.0%
Non-Salary				
1) Medical and Surgical Supplies	3.5%	3.5%	3.5%	3.5%
2) Pharmacy and Solutions	3.0%	3.0%	3.0%	3.0%
3) Malpractice Insurance	5.0%	5.0%	5.0%	5.0%
4) Professional and Contracted Services	2.5%- 3.0%	2.5%- 3.0%	2.5%- 3.0%	2.5%- 3.0%
5) All Other Expenses	3 - 7%	3 - 7%	3 - 7%	3 - 7%

	FY 2012	FY 2013	FY 2014	FY 2015
FTEs				
1) Total estimated FTEs-before new program	1,509	1,515	1,521	1,527

Other

In Addition, Greenwich Hospital currently is responsible to pay $1.8 million for medical staff 24/7 coverage at the hospital.

There are no capital expenditures budgeted, therefore no additional depreciation expense is assumed.

Public Notice Affidavit

The Greenwich Time

000007

Greenwich Time

MASON INC.
23 AMITY ROAD
BETHANY CT 06524

GREENWICH TIME
1455 East Putnam Avenue
Old Greenwich, CT 06870
Telephone: 203-330-6208
Fax: 203-384-1158
Legal.notices@scni.com

Public Notice

Pursuant to section 19a-638 of Connecticut General Statutes, Yale-New Haven Hospital will submit the following Certificate of Need application:

Applicant(s): Yale-New Haven Hospital
Greenwich Hospital
Address: 5 Perryridge Road
Town: Greenwich
Proposal: Establish and Operate an Elective Angioplasty Program at Greenwich Hospital
Estimated Total Project Cost/Expenditure: $0

GREENWICH TIME
CERTIFICATE OF PUBLICATION

I, Sarah Hussey
Being duly sworn, depose and say that I am a Representative in the employ of SOUTHERN CONNECTICUT NEWSPAPERS, INC., Publisher of *The Advocate* and *Greenwich Time*, that a LEGAL NOTICE as stated below was published in the GREENWICH TIME.

Subscribed and sworn to before me on this 7.th Day of December, A.D. 2011.

Pamela E. Caluori
Pamela Caluori/Notary Public

My commission expires on January 2013

PO Number

Publication	Ad Number	Ad Caption	
Greenwich Time	0001710001-01	Public Notice	Pursuant tc

Publication Schedule

12/1/2011, 12/2/2011, 12/3/2011

Filing Fee

000009

OFFICE OF HEALTH CARE ACCESS

REQUEST FOR NEW CERTIFICATE OF NEED

FILING FEE FORM

APPLICANT: Yale-New Haven Hospital and Greenwich Hospital PROJECT TITLE: Establish and Operate an Elective Angioplasty Program at Greenwich Hospital DATE: February 14, 2012	FOR OHCA USE ONLY: DATE INITIAL 1. Check logged (Front desk) _____ _____ 2. Check rec'd (Clerical/Cert.) _____ _____ 3. Check correct (Superv.) _____ _____ 4. Check logged (Clerical/Cert).) _____ _____

NEW CERTIFICATE OF NEED APPLICATION	
TOTAL FEE DUE:	**$500.00**

ATTACH HERE CERTIFIED OR CASHIER'S CHECK ONLY (Payable to: Treasurer, State of Connecticut)

Bank of America

Cashier's Check

No. 1482632

Notice to Purchaser - In the event this check is lost, misplaced or stolen, a sworn statement and 90-day waiting period will be required prior to replacement. This check should be negotiated within 90 days.

Date DECEMBER 29, 2011

30-1/1140
NTX

Banking Center YALE NEW HAVEN HOSPITAL

0021178 00002 0001482632

ELECTIVE ANGIOPLASTY AT GH

Remitter (Purchased By)

$ **500.00**

Pay **FIVE HUNDRED DOLLARS AND 00 CENTS**

To The Order Of **TREASURER, STATE OF CONNECTICUT**
****

Margaret M Hickey

Authorized Signature

07-14-3774B 06-2005

Bank of America, N.A.
San Antonio, Texas

VOID AFTER 90 DAYS

⑈1482632⑈ ⑆114000019⑆ 00164100554 5⑈

THE ORIGINAL DOCUMENT HAS REFLECTIVE WATERMARK ON THE BACK

THE ORIGINAL DOCUMENT HAS REFLECTIVE WATERMARK ON THE BACK

Hospital Affidavits

Yale-New Haven Hospital
Greenwich Hospital

AFFIDAVIT

Applicant: **Yale-New Haven Hospital**

Project Title: **Establish and Operate an Elective Angioplasty Program at Greenwich Hospital**

I, **Marna P. Borgstrom, CEO**, of **Yale-New Haven Hospital** being duly sworn, depose and state that **Yale-New Haven Hospital's** information submitted in this Certificate of Need Application is accurate and correct to the best of my knowledge.

Marna P B
Signature

2/10/12
Date

Subscribed and sworn to before me on 2/10/12

Jacalyn D Gonzalez
Notary Public/Commissioner of Superior Court

My commission expires: 03/31/12

My Commission Expires 03/31/2

AFFIDAVIT

Applicant: Greenwich Hospital

Project Title: Establish and Operate an Elective Angioplasty Program at Greenwich Hospital

I, Frank A. Corvino, President and CEO of Greenwich Hospital being duly sworn, depose and state that information submitted in this Certificate of Need Application is accurate and correct to the best of my knowledge.

Signature

1-26-12
Date

Subscribed and sworn to before me on 1/26/12

Jacalyn D. Bryles

Notary Public/Commissioner of Superior Court

My commission expires: 3/31/16

My Commission Expires 03/31/2016

State of Connecticut
Office of Health Care Access
Certificate of Need Application

Instructions: Please complete all sections of the Certificate of Need ("CON") application. If any section or question is not relevant to your project, a response of "Not Applicable" may be deemed an acceptable answer. If there is more than one applicant, identify the name and all contact information for each applicant. OHCA will assign a Docket Number to the CON application once the application is received by OHCA.

Docket Number: TBD

Applicant(s): Yale-New Haven Hospital and Greenwich Hospital

Contact Person: Jean Ahn

Contact Person's Title: System Director, Planning & Business Development

Contact Person's Address: Yale-New Haven Hospital, Planning & Business Development
20 York Street (Howe 3), New Haven, CT 06504

Contact Person's Phone Number: 203-688-2609

Contact Person's Fax Number: 203-688-5013

Contact Person's Email Address: jean.ahn@ynhh.org

Project Town: Greenwich, CT

Project Name: Establish and Operate an Elective Angioplasty Program at Greenwich Hospital

Statute Reference: Section 19a-638, C.G.S.

Estimated Total Capital Expenditure: $0

1. Project Description: Establishment of Cardiac Services

Please provide a narrative detailing the proposal.

Greenwich Hospital and Yale-New Haven Hospital, both members of Yale New Haven Health System, propose to build upon the successful Primary Angioplasty program (PAMI) at Greenwich Hospital, which serves as a satellite of the Yale-New Haven Heart and Vascular Center, and which received permanent approval status from the Office of Health Care Access in July 2008 after completion of a three-year demonstration project. This proposal seeks to add elective angioplasty to the other cardiac services provided at Greenwich Hospital as part of the Yale-New Haven Heart and Vascular Center. The addition of elective angioplasty to a community hospital setting represents a national trend in cardiac services that has occurred over the past several years. Certain interventional cardiac services, including elective angioplasty, are no longer exclusively the province of academic medical centers and large teaching hospitals, but are being appropriately expanded to smaller community hospitals with comparable results. The addition of elective angioplasty to Greenwich Hospital's continuum of high quality cardiac services would be in keeping with similar expansions in numerous other states, and would permit the Hospital to more fully utilize and sustain its high quality infrastructure.

Angioplasty is an interventional procedure performed in the cardiac catheterization laboratory that is used to open blocked or narrowed coronary arteries due to coronary heart disease, thereby improving blood flow to the heart. In most cases, it is performed on an elective basis (and called elective angioplasty), although certain patients require a primary (emergency) angioplasty if they are experiencing a certain type of myocardial infarction. In most cases, a stent is placed in the patient's artery during the procedure in order to reduce the likelihood of future blockage in that artery. Elective angioplasty frequently relieves symptoms of coronary heart disease such as angina (chest pain) and shortness of breath. It is a relatively low-risk procedure that does not require general anesthesia and is one of the most common cardiac procedures.

Elective angioplasty services at Greenwich Hospital will complement cardiac services currently provided at the Hospital and will be a part of the integrated Yale-New Haven Heart & Vascular Center supported administratively and clinically by Yale-New Haven Hospital (YNHH). The clinical and operational infrastructure to provide a high quality full-service cardiac program already exists, and will be enhanced by the ability to offer elective angioplasties. Greenwich Hospital is already performing angioplasty on more acutely ill patients through its primary angioplasty program and the staff and physicians are well prepared to perform elective angioplasty for less acute patients. The proposed Greenwich Hospital program will be included in the existing satellite cardiology program of the Yale-New Haven Heart & Vascular Center, and as it does today with the primary angioplasty program, will follow the YNHH clinical safety and quality protocols, credentialing processes and operational policies and procedures. The Medical Director of the cardiac services program at Greenwich Hospital is appointed by the Yale University School of Medicine (YSM) Department of Cardiology and is a member of the YSM's interventional cardiology faculty. In addition, the privileged medical staff is associated with either YSM Department of Cardiology, members of which currently practice at Greenwich Hospital as part of the existing primary angioplasty program or are members

of the Greenwich Hospital medical staff with privileges in performing angioplasties. All associated physicians will utilize the lab in accordance with pre-established clinical protocols and quality standards.

2. **Clear Public Need**

   a. Explain why there is a clear public need for the proposal. Provide evidence that demonstrates this need.

   Approved Docket Number (DN) 08-30148-MDF demonstrated clear public need for emergency angioplasty services at Greenwich Hospital. The current proposal expands upon DN 08-30148-MDF to demonstrate that the same population, from which the Hospital's primary angioplasty patients originate, also have a clear need for access to their provider of choice for high quality elective angioplasty services.

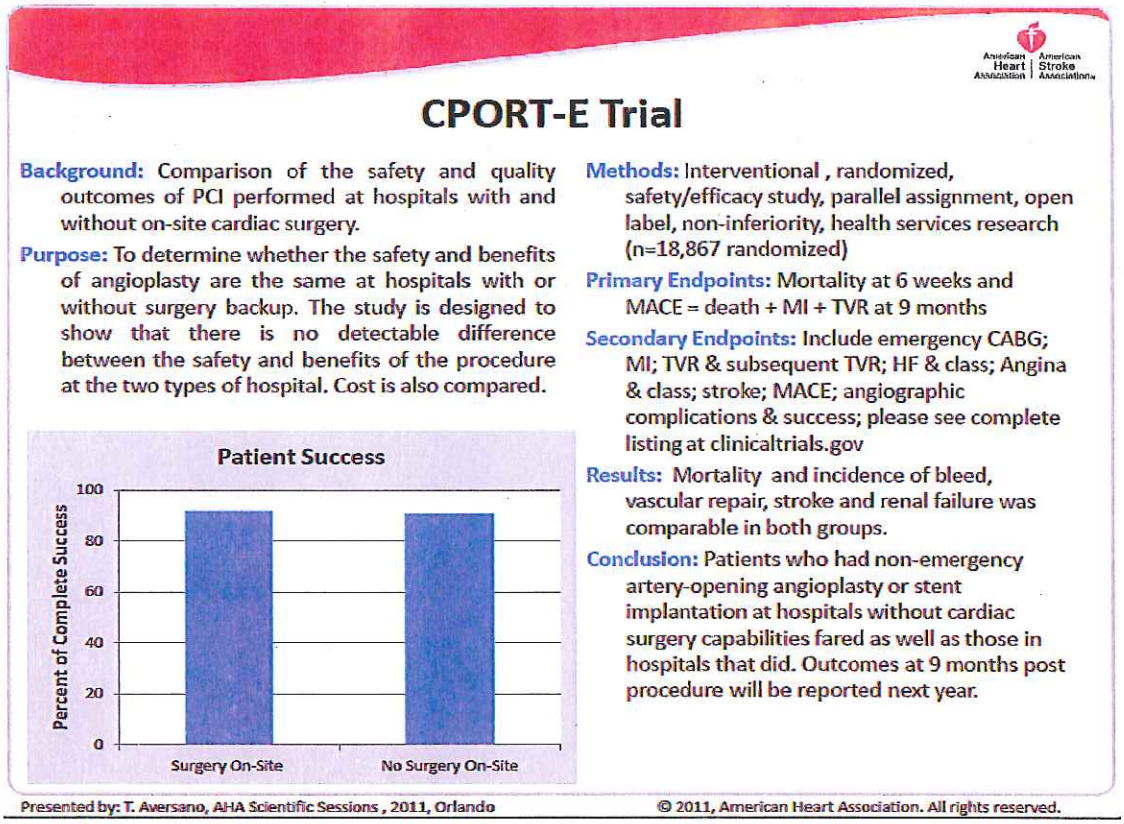
   Clear public need for the proposal is supported by the following three key factors:
   - **Local access to elective angioplasty care at Greenwich Hospital is needed and appropriate:**
   - **Greenwich Hospital must address the cost-effectiveness of angioplasty services; and**
   - **The proposed program will improve the quality of care of elective angioplasty services provided to Greenwich Hospital service area patients.**

   These factors will be described in more detail below.

   <u>Local access to elective angioplasty care at Greenwich Hospital is needed and appropriate</u> as supported by the following three key factors:
   - **Recent clinical guidelines and studies demonstrate the safety and efficacy of elective angioplasty programs without cardiac surgery back-up;**
   - **National and local trends that demonstrate improved access to elective angioplasty; and**
   - **The historical lack of access for elective angioplasty for patients who seek care at Greenwich Hospital.**

   Recent Clinical Guidelines & Studies Demonstrate the Safety and Efficacy of Elective Angioplasty without Cardiac Surgery Back-Up
   The most recent American College of Cardiology/American Heart Association/ Society for Cardiac Angiography and Intervention (ACC/AHA/SCAI) PCI guidelines released on November 7, 2011 represent a significant change in the recommendation level regarding elective angioplasty in hospitals without cardiac surgery programs. The new guidelines assign a class IIB recommendation, which means the benefit is greater than or equal to the risk, for elective angioplasty without cardiac surgery back-up.

Recent studies and publications indicate that standalone elective angioplasty can be safely performed with positive outcomes. The first major study, assessing outcomes of patients undergoing angioplasty at centers with and without surgical back-up, found comparable results at both types of facilities. Preliminary results from the CPORT-E trial led by Dr. Thomas Aversano at Johns Hopkins University were released in mid-November 2011. In this large multi-center study, nearly 14,000 patients were randomly assigned to have elective angioplasty at a hospital with onsite surgical capability, and approximately 4,500 patients were randomly assigned to have elective angioplasty at a hospital without surgical backup. The death rate after six weeks was the same for each group, and neither group of patients was more likely to need emergency cardiac surgery. A summary slide of study results presented in November 2011 at an American Heart Association conference is shown below.



An American Heart Association (AHA) news release summarizing the CPORT-E study's findings, included as Attachment I, stated that "Patients who had non-emergency artery-opening angioplasty or stent implantation at experienced hospitals without on-site heart surgery capabilities fared no worse than those in surgery-equipped hospitals" and also noted the following:

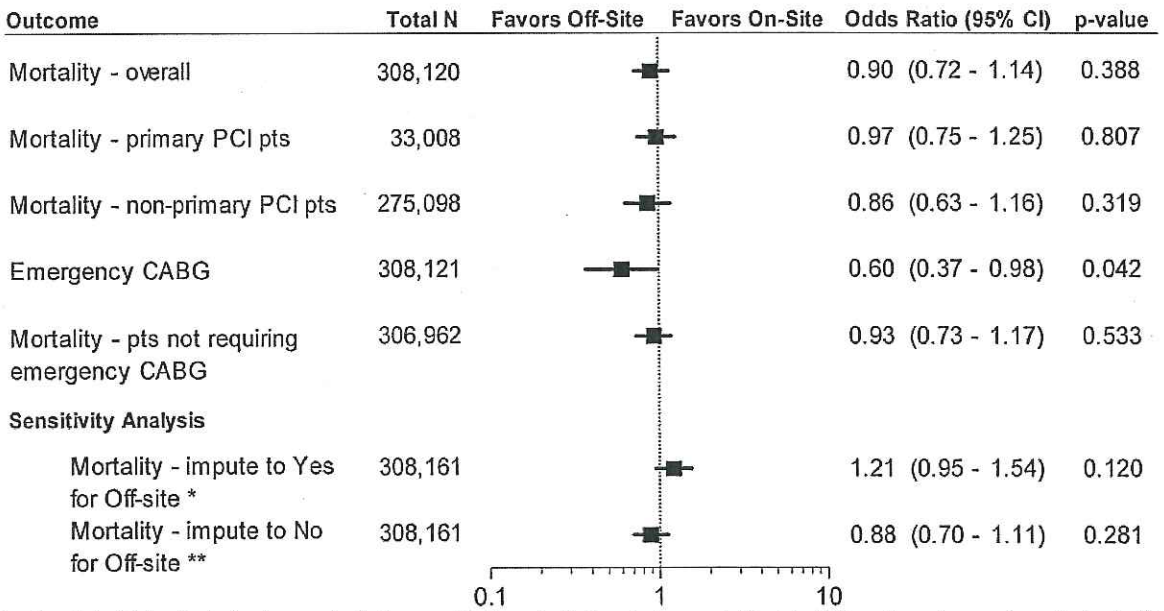
- **Patients who had non-emergency artery-opening angioplasty or stent implantation at hospitals without heart surgery capabilities fared as well as those in hospitals that did; and**
- **Both groups of patients had less than a 1 percent death rate.**

Interestingly, before results from the CPORT-E study were available, some states (such as New Jersey) that had hospitals participating in the study legislated that these hospitals that had started elective angioplasty programs on the study protocol, could continue their elective angioplasty programs even though the protocol has completed enrollment.

In a separate article, Param Puneet Singh, MD, et al (2011), published '*Outcomes of Nonemergent Percutaneous Coronary Intervention With and Without Onsite Surgical Backup: a Meta Analysis.*' The meta-analysis suggests that there is no difference in outcome with regard to risk of nonfatal myocardial infarction, need for emergency coronary artery bypass grafting, and the risk of death in patients undergoing elective angioplasty in hospitals with and without on-site cardiac surgery backup (see Attachment II).

The National Cardiovascular Data Registry (NCDR, 2009) evaluated the national experience for angioplasty without surgery onsite. The NCDR studied programs that already perform these procedures. Data from 60 hospitals and approximately 8,700 patients who had angioplasty at centers without on-site cardiac surgery ("offsite centers") were compared to 405 hospitals and approximately 300,000 patients at centers with cardiac surgery on-site ("onsite centers"). One notable finding was that after risk adjustment there were no mortality differences between off- and on-site facilities among total angioplasty patients, primary angioplasty patients, non-primary angioplasty patients, or patients who did not require emergency surgery (see chart below). In fact, there were higher risk-adjusted odds of emergency surgery in on-site angioplasty centers.

Risk-Adjusted Analysis of Outcomes



Odds ratio plot of risk-adjusted outcomes, including sensitivity analysis for missing mortality data. Odds ratio: outcomes for patients at off-site (vs. on-site) facilities, adjusting for within site correlations and potential confounding variables. *Worst case scenario: all patients with missing mortality data were considered to have died. **Best case scenario: all patients with missing mortality data were considered as alive. CABG _ coronary artery bypass graft surgery; CI = confidence interval; PCI = percutaneous coronary intervention; pts = patients.

Source: Kutcher, M, et.al, Percutaneous Coronary Interventions in Facilities Without Cardiac Surgery On Site: A Report from the National Cardiovascular Data Registry (NCDR), Journal of the American College of Cardiology, Volume 54, No. 1, June 30, 2009, pgs. 16 - 24

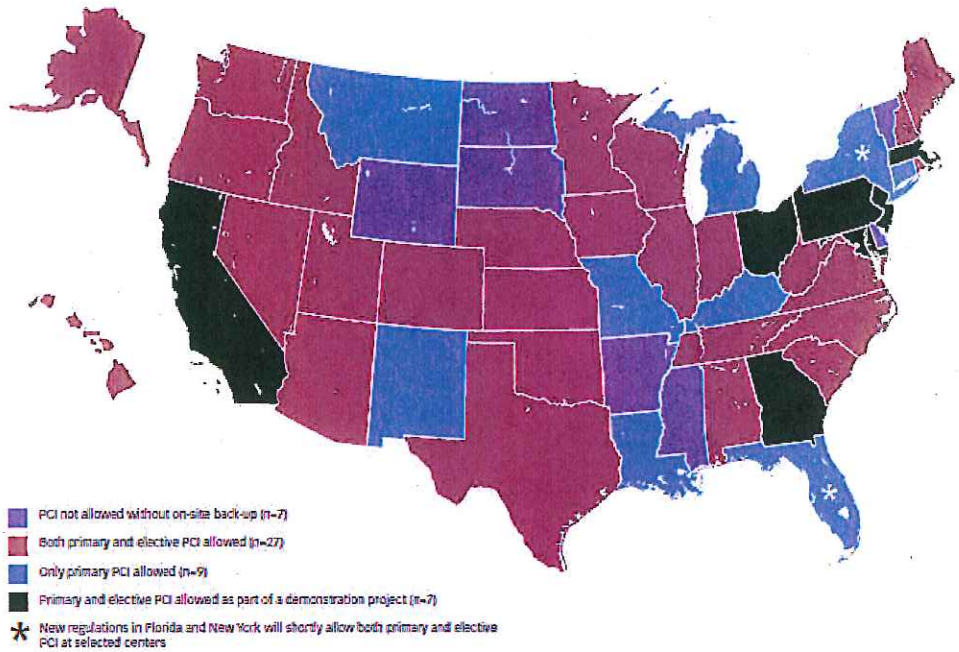
Despite lower annual angioplasty procedural volumes and more patients presenting with myocardial infarction (MI) subsets, off-site angioplasty facilities reporting to the NCDR Cath PCI Registry had similar rates of procedural success, morbidity, emergency surgery, and risk-adjusted mortality when compared with on-site angioplasty centers. Another potentially important observation is that on-site surgery did not necessarily confer an advantage for the rare patient that did require emergent surgery. In cases that required emergency surgery, off-site angioplasty centers had similar observed procedure success, morbidity, emergency cardiac surgery rates and mortality. (See Attachment III)

National and Local Trends Demonstrate Improved Access to Elective Angioplasty

In the past several years, the interventional cardiology field has experienced a significant expansion of services. Health Care Advisory Board research shows that as of 2009, 34 states allowed elective angioplasty to be performed without surgical backup, including New York, Pennsylvania, New Hampshire and Maine; seven of the 34 states allowed it as part of a demonstration project. In New York, ten hospitals have been granted approval to provide elective angioplasty without on-site cardiac surgery, including White Plains Hospital in White Plains. In January 2011, California enacted a six site "pilot" program for elective angioplasty without on-site cardiac surgery.

The map below, by the Health Care Advisory Board, shows the states that allow percutaneous coronary intervention without onsite cardiac surgical back-up as of 2009.

Figure 1: Status of Percutaneous Coronary Intervention without On-site Cardiac Surgical Back-up in the US



There are now only seven states (Arkansas, Delaware, Mississippi, North Dakota, South Dakota, Vermont, and Wyoming) where neither primary nor elective percutaneous coronary intervention (PCI) is allowed without on-site surgery. Legislation is pending in California to allow a carefully monitored demonstration project of elective PCI without on-site back-up. Primary PCI without on-site surgery is allowed in Washington, but not elective PCI. However, Washington has a liberal definition of emergency PCI such that patients with acute coronary syndromes and non-ST segment elevation myocardial infarction who have stabilized are allowed to undergo PCI at facilities without on-site surgery. Florida and New York both have rule changes pending to allow both primary and elective PCI at selected facilities without on-site surgery. Modified from Dehmer et al., 2007.[10]

Source: Dehmer, Gregory, J., Percutaneous Coronary Intervention without On-site Surgical Back-up, US Cardiology, 2009, Vol. 6 (1), pages 69-74

Since this map was published in 2009, both New York and Florida have allowed elective angioplasty without onsite surgical backup, as the footnote indicates.

Significantly, of the 34 states that allow standalone elective angioplasty, 28 require Certificate of Need regulatory approval, including New York. The majority of states permit both primary and elective angioplasty. Based on the new ACC/AHA/SCAI guidelines, the CPORT-E trial results and other recently published studies, one would expect elective angioplasty without cardiac surgery back-up to continue to expand.

An additional indication of the reduced level of risk of elective angioplasty and the routine nature of the procedure is the trend towards performing the procedure on an outpatient basis. This practice occurs throughout the country, including Connecticut. The percentage of inpatient angioplasty in Connecticut has declined each year from 98.9% in FY 2008 to 89.6% in the latest CHIME data from FY 2011.

The Historical Lack of Access for Elective Angioplasty for Patients who Seek Care at Greenwich Hospital

Since Fiscal Year 2008, 272 patients came to Greenwich Hospital and needed elective angioplasty but could not access this service. Limits placed on access to this routine cardiac procedure required these patients to be transferred to another facility, in some cases outside Connecticut. Due to existing physician referral patterns, the majority of these 246 patients were transferred to Yale-New Haven Hospital, as shown in the table below. An additional 26 patients were discharged and referred for elective angioplasty at a future time.

Number of Patients Discharged Directly from GH to Another Institution for Elective Angioplasty

Fiscal Year	Yale-New Haven Hospital	Westchester Medical Center	Cornell	Columbia	Stamford	West Haven VA	Total Transfers	Number of Patients Discharged Home and Referred for Elective Angioplasty in the Future	Total Cases
2008	44	1	0	0	0	0	45	9	54
2009	71	0	1	1	1	0	74	5	79
2010	51	0	2	0	1	0	54	10	64
2011	53	0	2	1	0	1	57	2	59
2012*	16	0	0	0	0	0	16	0	16
Totals	**235**	**1**	**5**	**2**	**2**	**1**	**246**	**26**	**272**

*Number of transfers to another institution between October 1, 2011 and December 31, 2011

Source: Greenwich Hospital Cardiology Department

Therefore, in total since FY 2008, 272 patients sought invasive cardiac care at Greenwich Hospital but could not access the necessary services in their local community. As a result of this lack of access, there are several adverse patient implications. First, the lack of access to elective angioplasty at Greenwich Hospital means that these patients received two invasive procedures instead of one since their diagnostic cardiac catheterization was performed at Greenwich Hospital and a

subsequent angioplasty was performed at a second facility. This results in increased risk for infection, delays in receiving the care required, and additional costs for a second procedure. Second, patients who were medically fragile, were subjected to transport to another facility. Third, transferring patients to another facility creates an unnecessary stressful and uncomfortable situation for patients and family. Fourth, transferring to another facility is an increased stress for the patients and their families with regard to transportation. For some, in Greenwich Hospital's greater service area, transportation outside the service area is problematic.

Greenwich Hospital Must Address the Cost-Effectiveness of Angioplasty Services
As previously described, service area residents who obtain a cardiac catheterization at Greenwich Hospital and require a subsequent angioplasty procedure must undergo two invasive procedures at two institutions. This practice increases the costs of care to patients and payers and ultimately to the health care system as a whole. Patients have to incur the additional out of pocket costs for the second procedure as well as additional transportation costs for themselves and possibly also family members. With patients receiving two procedures at two separate institutions, payers have increased expenses for the care provided to patients. Eliminating a second invasive cardiac procedure would improve the cost-effectiveness of angioplasty services for service area residents.

Primary angioplasty is a critically needed, lifesaving service that the Hospital provides to the community. Greenwich Hospital made significant investments in its primary angioplasty program in order to provide a necessary service to its service area, however, the costs of operating such a small program impede the Hospital's efforts to provide cost-effective care. An agreement is in place with the Yale School of Medicine to provide 24/7 coverage at the Hospital so that a highly skilled interventional cardiologist is always either on-site or in close proximity should a patient be in need of primary angioplasty. Greenwich Hospital is responsible for paying $1.78 million per year to the Yale School of Medicine to provide physician staffing for the primary angioplasty program. While this physician model is an essential component of the primary angioplasty program, it results in significant staffing costs to cover approximately 40 primary angioplasty cases treated at the Hospital each year. Allowing these same physicians to also perform elective angioplasty at Greenwich Hospital would be a cost-effective and efficient approach and would reduce the costs per case from the current arrangement. Since the current physician staffing covers 24/7, no additional physician expense is required to add elective angioplasty. Therefore this proposal represents a cost-effective solution to angioplasty services in Greenwich Hospital's service area.

The Proposed Program will Improve the Quality of Care of Elective Angioplasty Services Provided to Greenwich Hospital Service Area Patients
Greenwich Hospital's partnership with clinical faculty from the Yale School of Medicine and its membership in the Yale New Haven Health System will improve the quality of elective angioplasty services to Greenwich Hospital service area residents. As previously noted, service area residents who present to or desire elective angioplasty treatment at Greenwich Hospital are subjected to transfer to another Connecticut hospital and a second invasive procedure or may receive their care at a

New York hospital. The transfer process, additional procedures, and transportation out-of-state do not constitute high quality service or a positive patient experience. The term elective angioplasty is misleading as patients may have unstable, acute coronary symptoms, yet must be called elective since they do not meet the criteria for emergency angioplasty for STEMI. The proposed program will allow service area residents to remain in the local community and obtain elective angioplasty services from some of the nation's leading interventional cardiologists.

Greenwich Hospital's partnership with the clinical faculty from the Yale School of Medicine (YSM) has been a key factor in the success of its primary angioplasty program. The program is staffed by some of the nation's leading interventional cardiologists, who maintain a busy clinical practice, and many of whom perform angioplasty procedures far in excess of the minimum national standards each year. These clinicians are familiar with the Hospital's medical staff and operations. They also bring with them the procedures, clinical protocols and safety standards that are in place at Yale-New Haven Heart and Vascular Center, one of the Northeast's and nation's leading programs. In addition, the interventional cardiologists from YSM currently perform elective angioplasty procedures both at Yale-New Haven Hospital and at the West Haven VA, and are highly skilled in performing the procedure, with demonstrated outcomes that attest to their excellent quality. In fact, these same physicians are providing care to the majority of patients who currently must be transferred from Greenwich Hospital to Yale New Haven Hospital to receive elective angioplasty. Providing elective angioplasty at Greenwich Hospital will allow patients to receive the same high quality care from the same physicians without having to incur the stress of transfers and second procedures.

Greenwich Hospital has been a member of Yale New Haven Health System (YNHHS) for over twelve years. As Yale New Haven Health System has evolved, it has expanded the degree of clinical integration among its corporate members (Bridgeport Hospital, Greenwich Hospital, Yale-New Haven Hospital, and Northeast Medical Group). This clinical integration, which brings significant benefits, including consistent approaches towards clinical quality and safety practices, staffing and training, information systems, knowledge sharing and best practices, is expected to continue. Quality and outcomes will be predictable across YNHHS sites because identical care management and clinical protocols will be followed.

In addition, YNHHS is in the process of implementing the Epic common electronic medical record. This will have a major impact on YNHHS' ability to better coordinate care and services as well as easily implement and monitor best practice policies and procedures among its members, as there will be a shared medical record among all three hospitals and its clinicians. There will be a seamless flow of information within YNHHS and other providers/settings including community physicians. Providers at one site will be able to access information on a patient's visit to a different System hospital. For example, patients that are treated at both Greenwich Hospital and Yale-New Haven Hospital will share a common medical record, allowing clinicians at both sites to have 24/7 access to the most up-to-date clinical information on patients. Such integration would benefit the small number of angioplasty patients that may have to be transferred to YNHH but were also treated at Greenwich Hospital. The

implementation of Epic and the corresponding changes in System-wide processes will also facilitate the easy capture and analysis of data to support performance improvement, outcomes management, public reporting and transparency. Epic will help ensure that regulations and organizational policies and procedures regarding security, privacy and compliance are met. This will enable the Yale-New Haven Heart and Vascular Center to continue to monitor and develop all appropriate standards, protocols, policies, procedures and quality assessments which will be followed by Greenwich Hospital in providing angioplasty services to patients.

Conclusion of Public Need

Based on all of the above factors, the proposed elective angioplasty program at Greenwich Hospital, as a satellite of the Yale-New Haven Heart and Vascular Center, will be an appropriate, cost-effective, high quality program that is consistent with clinical guidelines, recent research and the approach currently being followed in many other states and at many other hospitals. Greenwich Hospital is well-prepared to embark on this project given the existing and proposed infrastructure and the program's success in treating more acutely ill patients with primary angioplasty. The program would be part of the Yale-New Haven Heart and Vascular Center, therefore it would comply with its rigorous standards and requirements, and provide patients with the ability to receive elective angioplasty locally at Greenwich Hospital, where they can benefit from high quality care and continuity, and avoid the complications and stress of transfer.

b. Provide the following regarding the proposal's location:

i. The rationale for choosing the proposed service location;

Greenwich Hospital is a progressive institution offering a wide range of medical, surgical, diagnostic and preventive programs with outstanding results. The Hospital currently provides diagnostic cardiac services including echocardiography, nuclear cardiac imaging, stress testing, cardiac CT angiography, and diagnostic cardiac catheterization. In addition, Greenwich Hospital offers interventional cardiac services to provide primary angioplasty for acute myocardial infarction (MI) patients pursuant to the Hospitals' authorization to provide primary angioplasty service under OHCA CON approval (DN 08-30148-MDF). The Hospital also has a cardiac rehabilitation program with inpatient and outpatient components for post-hospital follow-up care. A detailed list of services is below:

Ambulatory BP monitor	Arterial Doppler (PVR)
Cardiac Rehabilitation	Diagnostic Cardiac Catheterization
EKG Stress tests	Electrical Cardioversions
Peripheral angiography/intervention	Event Loop Recorder Implant
Electrophysiology Study	Holter monitor (24 and 48 hour)
Fetal Echocardiograms	Intravascular Ultrasound of Coronary/ Fractional Flow Reserve
Implantable Cardiac Defibrillator	Percutaneous Coronary Intervention in the event of an MI Alert
Nuclear Stress Tests	Permanent/Temporary Pacemakers
Pericardiocentesis	Trans-esophageal Echocardiograms (with bubbles)
Pharmacological Stress Echocardiograms (Dobutamine)	Trans-esophageal Echocardiograms (without bubbles)
Trans-thoracic Echocardiograms	Stress Echocardiograms

Greenwich Hospital is a logical location for the proposed elective angioplasty program for a multitude of reasons. The facility, physicians, staff and equipment required to provide elective angioplasty services are already in place at Greenwich Hospital. The Greenwich Hospital cardiac services program, which offers high quality diagnostic cardiac catheterization and primary angioplasty, is already a satellite under the medical direction of the Yale-New Haven Heart and Vascular Center, and employs a YSM medical director as well as YSM medical staff available 24 hours per day, 7 days per week. The Hospital is a longstanding member of Yale New Haven Health System, which will allow it to benefit from continued System-wide clinical integration, collaboration and sharing of best practices.

Patients prefer to be treated locally, close to their residence and family members. For patients in the Greenwich Hospital service area, the option to receive elective angioplasty care at their local hospital, namely Greenwich Hospital, is not available to them. Referring physicians prefer to send a patient in need of interventional cardiology to a facility that can perform both diagnostic cardiac catheterization and elective angioplasty to avoid the need for the patient to be transferred and be re-catheterized if an angioplasty is required. As a result, these patients often bypass Greenwich Hospital entirely although the Hospital is fully equipped to provide services and is an excellent local option for patients.

The lack of elective angioplasty at Greenwich Hospital results in disruptive care for patients. Under the current arrangement, Greenwich Hospital patients have to be transferred to other hospitals for elective angioplasty procedures even though experienced YSM interventional cardiologists and catheterization lab support staff are onsite and available 24 hours every day to provide the needed care at Greenwich Hospital. The vast majority of patients are transferred to Yale-New Haven Hospital, where they are treated by the same physicians from whom they would have received the same care at Greenwich Hospital if Greenwich Hospital was approved to provide elective angioplasty.

In light of these considerations, as well as the previously mentioned trends in many states to allow elective angioplasty without on-site surgery, Greenwich Hospital is an appropriate location for the proposed program.

ii. The service area towns and the basis for their selection;

The primary and secondary service area towns represent those communities which comprise 85% of Greenwich Hospital's inpatient volume. They include:

Connecticut Towns
Darien, Greenwich, New Canaan, Norwalk, Stamford, Weston, Westport and Wilton.

New York Towns
Armonk, Bedford, Bedford Hills, Harrison, Hartsdale, Katonah, Larchmont, Mamaroneck, Mount Kisco, Mount Vernon, New Rochelle, Port Chester, Pound Ridge, Purchase, Rye, Scarsdale, South Salem, West Harrison and White Plains.

The Hospital and its physicians treat many patients with heart disease who live in these service area towns and the proposed elective angioplasty program would serve to provide better access to, and coordination of, cardiac care.

iii. The population to be served, including specific evidence such as incidence, prevalence, or other demographic data that demonstrates need;

Incidence of Cardiovascular Disease
Major cardiovascular disease was the leading cause of death in Connecticut according to Department of Public Health Crude and Age-Adjusted Mortality Rate data for 2006-2008. According to the Connecticut Department of Public Health most recently published *Connecticut Resident Hospitalizations, 2009* report, diseases of the circulatory system totaled 58,853 and diseases of the heart totaled more than 40,000 discharges. There were more than 6,300 discharges for acute myocardial infarction (AMI). As shown in the Table H-5 below, diseases of the heart were the leading causes of hospitalizations for all ages combined, as well as for ages 65 and older in 2009.

Table H-5
CONNECTICUT RESIDENT HOSPITALIZATIONS, 2009
Leading Causes of Hospitalization (Numbers of Hospitalizations) by Age and Sex[a]

Sex	Rank	Age group (Years)						
		0-4	5-14	15-24	25-44	45-64	65+	All ages
Both sexes	1	Respiratory (3,053)	Mental (1,890)	Mental (4,741)	Mental (10,308)	Digestive (12,592)	Heart (27,430)	Heart (40,484)
	2	Injury/Poisoning (619)	Respiratory (1,433)	Injury/Poisoning (2,265)	Digestive (7,437)	Heart (10,902)	Respiratory (19,692)	Digestive (38,952)
	3	Endocrine[c] (503)	Digestive (1,082)	Digestive (2,244)	Injury/Poisoning (4,948)	Mental (10,649)	Digestive (15,138)	Respiratory (36,804)
	4	Digestive (459)	Injury/Poisoning (809)	Respiratory (982)	Genitourinary (3,284)	Musculoskeletal (9,630)	Injury/Poisoning (13,634)	Injury/Poisoning (30,873)
	5	Infectious (372)	Anemias/Blood (326)	Endocrine[c] (631)	Respiratory (2,964)	Respiratory (8,680)	Genitourinary (10,684)	Mental (30,160)
	6	Nervous (354)	Endocrine[c] (315)	Genitourinary (622)	Musculoskeletal (2,945)	Injury/Poisoning (8,598)	Musculoskeletal (10,660)	Musculoskeletal (23,905)
	7	Skin (290)	Nervous (311)	Anemias/Blood (586)	Endocrine[c] (2,894)	Neoplasms[b] (7,928)	Neoplasms[b] (8,371)	Genitourinary (20,495)
	8	Genitourinary (286)	Musculoskeletal (236)	Infectious (469)	Neoplasms[b] (2,483)	Genitourinary (5,401)	Infectious (8,246)	Neoplasms[b] (19,212)
	9	Anemias/Blood (208)	Genitourinary (218)	Nervous (421)	Heart (1,883)	Endocrine[c] (5,002)	Cerebrovascular (6,865)	Endocrine[c] (15,222)
	10	Neoplasms[b] (85)	Skin (211)	Musculoskeletal (391)	Infectious (1,456)	Infectious (3,566)	Endocrine[c] (5,877)	Infectious (14,312)

Source: Connecticut Department of Public Health Hospitalization Statistics:
http://www.ct.gov/dph/cwp/view.asp?a=3132&q=397512&dphNav=|46941|&dphNav_GID=1601

[a] See Appendix and Table H-1 for corresponding diagnostic groups by ICD-9 CM codes.

[b] Includes both benign and malignant neoplasms.

[c] Endocrine, nutritional, metabolic, and immunologic disorders, including diabetes mellitus and volume depletion (dehydration).

According to the Connecticut Department of Public Health Office of Health Care Access' report 'The Burden of Cardiovascular Disease in Connecticut 2010 Surveillance Report' Executive Summary (included as Attachment IV):

- **Cardiovascular diseases (CVDs) are a great public health concern. CVD account for about one-third of all Connecticut resident deaths. Coronary Heart Disease (CHD), cerebrovascular disease (stroke) and heart failure (HF) are the main types, accounting for 48%, 15% and 8% respectively of all CVD deaths.**
- **Cardiovascular disease accounted for about 33% (9,351) of all Connecticut resident deaths in 2008, as shown in the table below.**

Connecticut Resident Deaths, 2008

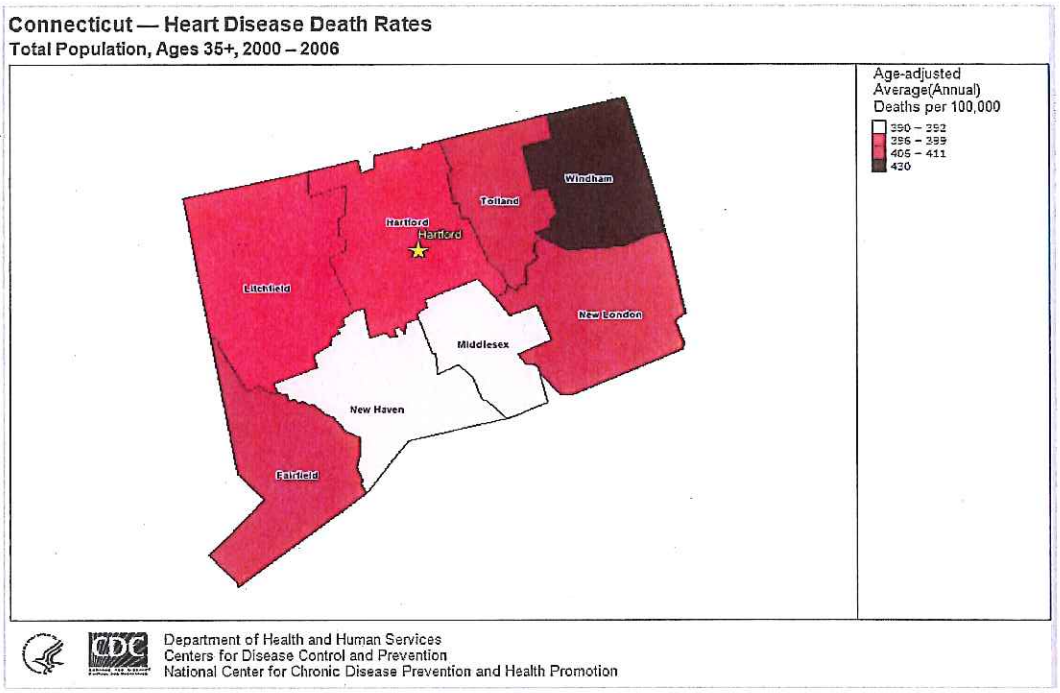
Cause of Death	Number of Deaths	Percent of Deaths
All Causes	28,749	100%
Cardiovascular Disease	9,351	33%
Cancer	6,765	24%
Chronic Liver Respiratory Disease	1,494	5%
Unintentional Injury	1,362	5%
Alzheimer's Disease	831	3%
Pneumonia and Influenza	688	2%
Diabetes	618	2%

Source: Connecticut Department of Public Health Office of Health Care Access; The Burden of Cardiovascular Disease in Connecticut 2010 Surveillance Report, March 2011

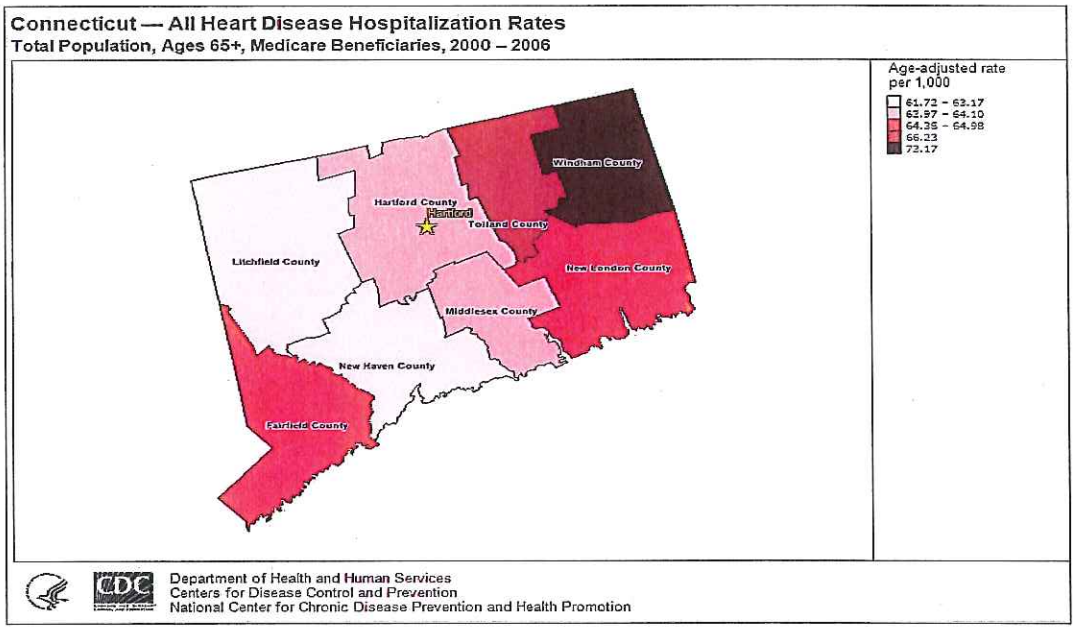
- **About $2.2 billion was billed for CVD hospitalizations in Connecticut in 2008. Approximately 34% of CVD charges are for CHD, 12% for stroke and 12% for HF. CVD also incurs enormous indirect costs.**
- **About 18% of all hospital discharges in Connecticut are due to CVD. Approximately 26% of CVD hospitalizations are due to CHD, 12% to stroke and 18% to HF (2008 data).**

The following maps show the heart disease death rate in Connecticut by county for 2000 – 2006. Fairfield County's heart disease death rate was higher than the rates in New Haven, Middlesex, Hartford and Litchfield Counties. Between 2000 and 2006, Fairfield County had the third highest 65+ heart disease hospitalization rate per 1,000 age-adjusted and spatially smoothed in Connecticut.

Heart Disease Death Rates Map



Heart Disease Hospitalization Rates Map



Service Area Demographics

The following table shows population projections for Greenwich Hospital's Connecticut and New York service area towns. The total service area will consist of over 370,000 people in Connecticut and 440,000 people in New York, of whom approximately 43% are over age 45. Because of Greenwich Hospital's location on the border of Connecticut and New York, it attracts a significant number of New York residents, who constitute a sizable proportion of the Hospital's patient population.

The proportion of Greenwich Hospital's service area patients who are over age 45 and the patients over age 65 are projected to increase between 2011 and 2016, as shown in the population table below. Both the risk and rate of heart disease increase with age, as does the corresponding need for interventional cardiology services.

Population Projections
Greenwich Hospital Service Area

Area & Age Cohort Service Area	2000	2011	2016	% Change 2000 - 2011	% Change 2011 - 2016
0-44	486,078	463,790	454,100	-4.6%	-2.1%
45-54	110,947	131,685	123,671	18.7%	-6.1%
55-64	75,351	101,043	115,399	34.1%	14.2%
65-74	56,212	60,212	72,416	7.1%	20.3%
75-84	37,209	37,304	37,086	0.3%	-0.6%
85+	14,641	18,174	19,883	24.1%	9.4%
Total	780,438	812,208	822,555	4.1%	1.3%
Ages 45+	294,360	348,418	368,455		
Ages 65+	108,062	115,690	129,385		
% 45+	37.7%	42.9%	44.8%		
% 65+	13.8%	14.2%	15.7%		

Source: Claritas

iv. How and where the proposed patient population is currently being served;

Patients from the Greenwich Hospital service area that require elective angioplasty currently go to another hospital in either Connecticut or New York to receive these services. This includes patients who receive a diagnostic cardiac catheterization at Greenwich Hospital and who subsequently require elective angioplasty as well as Greenwich Hospital primary angioplasty patients who have coronary artery disease in other vessels and require a subsequent elective angioplasty. The vast majority of these patients are transferred to Yale-New Haven Hospital and some are treated at White Plains Hospital, Columbia, Cornell and Westchester Medical Center.

Some physicians who currently utilize Greenwich Hospital services to provide care to their patients are often reluctant to direct their patients to the Greenwich Hospital cardiac catheterization lab if there is a clinical suspicion that the patient may require

angioplasty. Currently Greenwich Hospital can only address the culprit lesion for patients in need of emergency angioplasty.

As a satellite of a leading academic medical center's nationally recognized cardiac program, the Greenwich Hospital elective angioplasty program would extend the quality, safety and leading clinical advances of the Yale-New Haven Heart and Vascular Center to its patients and community. The proposed program will adhere to the same rigorous clinical, operator and institutional criteria and monitoring as the YNHH program. Consequently, the program will assure high quality outcomes, care continuity, state-of-the-art, easily accessible and high quality care.

v. All existing providers (**name, address, services provided**) of the proposed service in the towns listed above and in nearby towns;

Stamford Hospital, located at 30 Shelburne Road, Stamford CT 06904 and White Plains Hospital, located at 41 E. Post Road, White Plains, New York 10601 offer elective angioplasty in the service area.

vi. Describe existing referral patterns in the area to be served by the proposal; and

Patients are referred to Greenwich Hospital's cardiology program by their internist or cardiologist. Current referral patterns are with cardiologists within the service area and on the medical staff of Greenwich Hospital. Currently, the cardiologists (including interventional cardiologists) on the medical staff at Greenwich Hospital have practices located in Greenwich, CT (55%), Westchester County, NY (13%) and Stamford, CT (11%). The YSM physicians practicing at the Greenwich Hospital location are included in the Greenwich, CT statistics above.

vii. The effect of the proposal on existing providers, explaining how current referral patterns will be affected by the proposal.

The vast majority of patients who must be transferred from Greenwich Hospital to another hospital for elective angioplasty are sent to Yale-New Haven Hospital. Therefore, a significant proportion of the Greenwich Hospital proposed program volume will represent cases that would previously have been transferred to Yale-New Haven Hospital. This reduction in volume at Yale-New Haven Hospital has been agreed to by clinical and administrative leadership and will not negatively impact Yale-New Haven Hospital's cardiac services.

Recent discussions with the Hospital's current physician referral sources indicate that they support the provision of elective angioplasty at Greenwich Hospital, as it will allow their patients to receive their interventional cardiac care at Greenwich Hospital. Letters of support from members of the Greenwich Hospital medical staff attest to physicians' endorsement of the proposed program and are included in Attachment V.

c. Explain why the proposal will not result in an unnecessary duplication of existing or approved health care services.

The proposal will not result in unnecessary duplication of existing or approved health care services. The facility, physicians, staff and equipment required to provide elective angioplasty services are already in place at Greenwich Hospital for the primary angioplasty service.

d. The record in this docket will include, in addition to other materials, the American College of Cardiology/American Heart Association (ACC/AHA) practice guidelines. The Applicants may submit any comments in response to this evidence, which they deem appropriate.

Please see Attachment VI. Knowledge and processes related to elective angioplasty continue to evolve. As previously noted, increasing and significant evidence exists for elective angioplasty programs at facilities without on-site surgical backup. The November 7, 2011 updated ACC/AHA/SCAI angioplasty guidelines have upgraded the recommendation level for elective angioplasty programs without cardiac surgery back-up. Greenwich Hospital and Yale-New Haven Hospital adhere to these guidelines, which are incorporated into relevant policies and procedures.

e. If applicable to the proposal (e.g. establishment of cath lab without a cardiac surgical program), provide a copy of a signed agreement between the Applicant and a tertiary care facility. Identify patient selection guidelines, the process and protocols involved in the transfer of a patient requiring cardiac surgery, and joint quality assurance reviews and joint training.

A copy of the signed agreement between Greenwich Hospital and YNHH can be found in Attachment VII. The agreement addresses patient selection, emergency transfer, joint quality assurance and training.

f. Has the Applicant held any discussions with the local emergency medical service ("EMS") regarding the proposed service? Describe.

Greenwich Hospital had discussions with the Greenwich Emergency Services (GEMS) and the Emergency Medical Services companies servicing Port Chester, Rye and Harrison, New York about the proposed program, and received favorable responses from all parties.

3. Projected Volume

a. In table format, provide historical volumes (three full years and the current year-to-date) for each Applicant by service; by zip code; by inpatient/outpatient; and by unique physician identifier as applicable to the proposal.

<u>Volume by Service and Inpatient/Outpatient</u>
Historical volume for Greenwich Hospital primary angioplasties is shown in the table below.

Total Greenwich Hospital Primary Angioplasty Cases

	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012*
Total Angioplasty	40	40	32	38	15
Note: All angioplasties are inpatient					

*Note: Actual Q1 volume (October – December); annualized volume would equal 60
Sources: CHIME and Greenwich Hospital Department of Cardiology

Volume by ZIP Code

Historical volume for Greenwich Hospital primary angioplasties is shown in Attachment VIII

Volume by Unique Physician Identifier

Historical volume for Greenwich Hospital primary angioplasties broken out by unique physician identifier is shown in the table below.

Total Greenwich Hospital Primary Angioplasty Cases by Unique Physician Identifier

	Angioplasty by Unique Physician Identifier				
MD	**FY 2008**	**FY 2009**	**FY 2010**	**FY 2011**	**FY 2012***
A	1	0	0	0	0
B	1	1	1	0	0
C	1	0	0	0	1
D	2	3	0	0	0
E	0	1	1	1	0
F	2	0	0	0	0
G	14	17	15	18	7
H	0	2	1	0	0
I	2	0	3	4	0
J	17	16	11	12	7
K	0	0	0	3	0
Total	**40**	**40**	**32**	**38**	**15**

*Note: Actual Q1 volume (October – December); annualized volume would equal 60
Sources: CHIME and Greenwich Hospital Department of Cardiology

b. If applicable, for the most recently completed fiscal year, identify the number of:

i. Patients with a diagnosis of ST-segment elevation acute myocardial infarction (AMI) that presented at the Hospital's emergency room

In FY 2011, there were 57 patients that presented to Greenwich Hospital's emergency department who triggered an MI Alert with a suspected diagnosis of ST-segment elevation acute myocardial infarction.

ii. Doses of thrombolytic medication, issued through its pharmacy, to patients with a diagnosis of AMI.

In FY 2011, there were zero doses of thrombolytic medication issued through the pharmacy to patients with diagnosis of AMI. In acute MI, thrombolytics are typically only used if emergency angioplasty cannot be done in a timely manner. Greenwich Hospital did not use thrombolytics for acute MI during the past year because the Hospital brought these patients to the cardiac catheterization lab in a timely fashion, which is the clinically preferred treatment for patients.

c. In table format, provide projected volumes (three full years) for each Applicant by service; by inpatient/outpatient; and by unique physician identifier as applicable to the proposal.

The tables below provides historical and three full years of projected volumes by inpatient/outpatient.

Due to the unscheduled nature of primary angioplasty cases and the scheduling rotation for the interventional cardiologists, it is difficult to project future volumes by unique physician identifier.

CON Elective Angioplasty Volume Projections

Angioplasty Volumes at Greenwich Hospital
Historical and Projected Volumes

Volumes	FY08 Actual	FY09 Actual	FY10 Actual	FY11 Actual	Year 1	Year 2	Year 3
Primary Angioplasty Cases	40	40	32	38	38	38	38
Elective Angioplasty Cases To Be Performed at GH (currently sent to other facilities)	0	0	0	0	53	53	53
Elective Angioplasty Cases Transferred or Referred to Another Facility	54	79	64	59	0	0	0
New Referred Angioplasty Cases from Physicians	NA	NA	NA	NA	105	126	151
Total	94	119	96	97	196	217	242
Variance					99	21	25

Source: CHIME database, GH Cardiology Department, YNHH statistics, telephone survey of physicians

Volumes	Year 1	Year 2	Year 3
Inpatient Angioplasties (89.6%)	176	194	217
Outpatient Angioplasties (10.4%)	20	23	25
Total	196	217	242

Source: CHIME database

d. Provide a detailed description of all assumptions used in the derivation/calculation of the projected volumes.

The angioplasty projections include primary angioplasty cases currently treated at the Hospital and elective angioplasty cases currently not treated at the Hospital.

Greenwich Hospital currently provides primary angioplasty to patients that meet the criteria for care. For the past several fiscal years, this volume has remained fairly stable. In FY11, the Hospital had 38 primary angioplasty cases. This is the same number as the four year average number of cases. This volume was projected to remain stable over the next several years. In the first quarter of FY12, the Hospital provided 15 primary angioplasties which would project to 60 annual primary angioplasties. To be conservative, projections were based on the last several fiscal years where 12 months of data was available for each year.

While the Hospital does not provide elective angioplasty at this time, there are patients who present to the Hospital each year that require elective angioplasty. These patients are either transferred or referred to another facility for care. The number of transfers or referrals for the past four fiscal years has been 54, 79, 64 and 59 respectively. Over the past four fiscal years, on average there had been 64 patients per year either transferred or referred to another facility for care. With the approval of this application, Greenwich Hospital would be able to provide elective angioplasty to the majority of these patients and thus save the patients an unnecessary transfer or referral to another facility. These patients are already part of the Greenwich Hospital physician referral patterns established at the Hospital that would continue when the Hospital is approved to provide elective angioplasty care. However, there is a small portion of patients that would need to be transferred or referred to another facility even if Greenwich Hospital was approved to provide elective angioplasty.

In the CPORT E trial, (discussed elsewhere in the CON) of patients who underwent primary angioplasty, 12% were excluded from randomization after consenting to the study, representing the subgroup who would be transferred to another facility. In reviewing the cases in FY09-11 that were either transferred or referred for care to another facility, it was felt that some of the cases would have been transferred or referred even if Greenwich Hospital was approved to provide elective angioplasty. These percentages for FY09-11 were respectively 12%, 16% and 22% for a three year average of 16.6%. For the projection of elective angioplasty at Greenwich Hospital, the conservative estimate of 16.6% was used, i.e. 83.4% of patients who had been transferred or referred to another facility in the past would be able to receive care at Greenwich Hospital. This percentage applied to the average of 64 patients per year transferred or referred to another facility yielded 53 patients in Year 1 who would be able to stay and receive their care at Greenwich Hospital. Again, to be conservative, this volume was projected to remain stable over the next several years.

Because Greenwich Hospital does not currently provide elective angioplasty services, physicians are reluctant to send their patients for cardiac catheterizations to the Hospital in case the patient will require an elective angioplasty and then have to be

transferred or referred to another facility. The Hospital conducted a telephone survey of cardiologists currently on the Hospital's medical staff. The cardiologists were asked to estimate the number of additional patients they might send to Greenwich Hospital for cardiac catheterizations if the Hospital received approval to offer elective angioplasty. In addition, some internal medicine physicians send patients directly for cardiac catheterizations to a hospital instead of to a cardiologist. The Hospital conducted a survey of the large internal medicine practices on the medical staff. These physicians were also asked to estimate the number of additional patients they might send to Greenwich Hospital.

Lastly, the cardiology practice that is part of the YNHHS cardiology program at Greenwich Hospital estimated the number of patients each year that they send directly to Yale-New Haven for cardiac catheterizations instead of to Greenwich Hospital. These patients numbered 25, 22, 21 and 25 in FY08-11 respectively for an average of 24 per year. These patients would use Greenwich Hospital if the Hospital provided elective angioplasty services. Based on the information above, 257 additional cardiac catheterizations were estimated to be sent to Greenwich Hospital for care if the Hospital provided elective angioplasty services. The surveyed physicians who indicated they would send additional cardiac catheterizations have practices located in Greenwich, Connecticut or in Westchester County, New York.

In order to estimate the number of angioplasties resulting from the additional cardiac catheterizations, the ratio of angioplasties to cardiac catheterizations was analyzed. Since primary angioplasties and elective angioplasties have the same codes, it was not possible to separate them into two categories so angioplasty volume includes both primary and elective angioplasty cases. Angioplasty volume and cardiac catheterization volume includes both inpatient and outpatient cases. New York angioplasty and cardiac catheterization outpatient historical volumes were not available from the state of New York for CY08 and for CY11 only the first five months of inpatient and outpatient data was available. Therefore, CY11 New York data was flat line projected to estimate the entire year.

The ratios of angioplasties to cardiac catheterizations were determined for Greenwich Hospital (35.4%), Yale-New Haven Hospital (45.3%), the state of Connecticut (36.3%) and the Greenwich Hospital service area (41.2%). The Greenwich Hospital average included patients transferred or referred to another facility. While the program at Greenwich Hospital will follow all of the policies, procedures and guidelines of the Yale-New Haven Heart and Vascular Center, the New Haven facility is a tertiary hospital and may see a higher rate of angioplasty/sicker patients. To be conservative, an average ratio (41.0%) of the Yale-New Haven Hospital ratio and state of Connecticut ratio was used to estimate the number of angioplasties resulting from the cardiac catheterizations. The 41.0% ratio was applied to the 256 potential angioplasties to yield an estimated 105 new referred angioplasty cases to Greenwich Hospital in Year 1 from cardiologists on the Hospital medical staff who would previously have sent the cases either to Yale-New Haven Hospital or a New York hospital. It is expected that this volume would increase 21 and 25 angioplasties respectively in Years 2 and 3 as the Greenwich Hospital program becomes established. The increases would represent less than 1 angioplasty per year from each of the

cardiologists on the medical staff of Greenwich Hospital. Since the patients will be referred by the cardiologists on the Greenwich Hospital medical staff, it is expected that the majority of patients will be from New York or Greenwich, Connecticut. The increase in volume results from several factors including the addition of New York interventional cardiologists who currently do not practice at Greenwich Hospital but have referral relationships with the cardiologists on the Hospital medical staff, increased physician comfort with elective angioplasty care at the Hospital and patient preference for the high quality care offered at Greenwich Hospital.

In FY11, inpatient angioplasties were 89.6% of total angioplasties according to the latest available data from the CHIME database. This percentage was used to estimate the distribution of angioplasties at Greenwich Hospital in Years 1, 2 and 3.

e. Provide a copy of any articles, studies, or reports that support the statements made in this application justifying need for the proposal, along with a brief explanation regarding the relevance of the selected articles.

In addition to previous studies and reports referenced, Attachment IX contains some additional supporting materials. Key points from each document are summarized below.

Document/Article	Key Points
Atlantic Cardiovascular Patient Outcomes Research Trial presentation	**"In hospitals without on-site cardiac surgery that complete a formal PCI development program, adhere to C-PORT participation requirements, and whose outcomes are monitored, non-primary PCI is safe and associated with similar rates of adverse events including mortality"**
American Heart Association /American Stroke Association CPORT-E Trial Summary	**Summarizes results of CPORT-E Trial: "Patients who had non-emergency artery-opening angioplasty or stent implantation at hospitals without cardiac surgery capabilities fared as well as those in hospitals that did."**
2011 ACC/AHA/SCAI Guideline for Percutaneous Coronary Intervention	**Provides additional explanation and documentation of the 2011 guidelines and shows classification of recommendations and levels of evidence.**
The Advisory Board Daily Briefing On-site Surgery Not Necessary to Perform Elective PCI, November 18, 2010	**Summary of Atlantic CPORT-E Trial. Conclusion "The findings ultimately may prompt regulatory changes that could effectively decouple PCI and open heart surgery, allowing more flexibility for hospitals pursuing a regionalization strategy."**

f. Please identify the number of physicians that will be providing coverage for the proposed program. Explain whether the physicians will be full time with the proposed program or also providing coverage at other hospitals.

Physician coverage for the proposed elective angioplasty program will be similar to the existing 24/7 coverage for the primary angioplasty program. Coverage will be provided by privileged medical staff associated with either YSM Department of Cardiology, members of which currently practice at Greenwich Hospital as part of the existing primary angioplasty program, or members of the Greenwich Hospital medical staff with privileges in performing angioplasties. At this time, coverage will be provided by eleven interventional cardiologists from the Yale School of Medicine. At least one physician will be full time at Greenwich Hospital weekdays and on call nights and weekends. The on call physician will be in close proximity to Greenwich Hospital for immediate response to the Hospital during nights and weekends. When on call, the physician will only be covering Greenwich Hospital. The members of the YSM Section of Interventional Cardiology also provide coverage at Yale-New Haven Hospital, the West Haven VA and Lawrence & Memorial Hospital's primary angioplasty program.

4. Quality Measures

a. Submit a list of all key professional, administrative, clinical, and direct service personnel related to the proposal. Attach a copy of their Curriculum Vitae.

Please see Attachment X for copies of Curriculum Vitae.

<u>Greenwich Hospital</u>

- **Frank Corvino, President and CEO**
- **Eugene Colucci, CFO**
- **Quinton Friesen, Executive Vice President and COO**
- **Marc Kosak, Vice President, Administration**
- **Christopher Howes, M.D., Medical Director of PAMI Program and Interventional Cardiology at Greenwich Hospital, Assistant Professor of Medicine, Yale School of Medicine**

<u>Yale-New Haven Hospital</u>

- **Marna P. Borgstrom, Chief Executive Officer**
- **Richard D'Aquila, President and Chief Operating Officer**
- **James Staten, Senior Vice President, Finance and CFO**
- **Thomas Leary, Vice President, Physician Development**
- **Michael Simons, M.D., Chief, Section of Cardiovascular Medicine**
- **Henry Cabin, M.D., Associate Section Chief of Cardiology**
- **Francine LoRusso, RN, Director, Patient Services, Heart and Vascular Center**

b. Explain how the proposal contributes to the quality of health care delivery in the region.

The current population served through Greenwich Hospital's primary angioplasty program is limited to patients that present on an emergent basis with ST segment

elevation MI or new onset left bundle branch block. This proposal would provide local access to patients requiring interventional cardiology services on an elective and urgent basis as well as the emergent patients who currently have access to these services. Patients from the Greenwich Hospital service area that require elective angioplasty are currently required to go to another hospital to receive these services, which adds additional stress for patients and their families, particularly unnecessary due to the presence of highly qualified interventional cardiologists and staff available onsite. The facility, physicians, staff and equipment required to provide elective angioplasty services are already in place at Greenwich Hospital. As discussed in the public needs section, the current practice of transferring patients who require elective angioplasty has potential negative implications to patient care quality and safety. As well, the majority of these patients are transferred to Yale-New Haven Hospital, where they are treated by the same physicians from whom they would have received the same care at Greenwich Hospital if Greenwich Hospital was approved to provide elective angioplasty.

Greater System-wide clinical integration, through the proposed closer integration of Greenwich Hospital's cardiac services with the Yale-New Haven Heart & Vascular Center and partnership with the Yale School of Medicine will have a positive impact on the quality of health care delivery in the region. The Yale-New Haven Heart & Vascular Center will provide medical and clinical direction, education, training and management and oversight to ensure the delivery of the highest quality care. In addition, the use of the Epic common electronic medical record and combining best practices at both campuses to enhance clinical quality and patient safety through standardized procedures and practices.

<u>Greenwich Hospital's High Quality Cardiac Program</u>
The most recent ACC/AHA/SCAI guidelines have and will continue to guide Greenwich Hospital in the operation of its angioplasty program. A copy of the guidelines is attached (Attachment VI).

Greenwich Hospital participates in the National Cardiovascular Data Registry NCDR – CathPCI Registry®. Launched by the American College of Cardiology (ACC) in 1995, the "ACC National Cardiovascular Data Registry: (ACC-NCDR™) is a result of the ACC's exploration of various strategies for collecting and implementing clinical data in order to improve cardiovascular care. This database includes the implanted cardiac defibrillator registry as well as a heart catheterization registry (which further breaks down to both diagnostic and interventional procedures). The information gathered from this database allows the ACC to set benchmarks that enable facilities to see where they are deficient and therefore improve upon performance. There are currently 1,380 sites that participate in the catheterization registry.

In addition, both the primary angioplasty program, which has been in place at Greenwich Hospital since 2005, and the diagnostic cardiac catheterization laboratory, have achieved outcomes that are consistent with many larger tertiary facilities. For the four quarters ending mid-2011, 100% of STEMI patients received immediate angioplasty within 90 minutes, which meets/exceeds national standards for this measure. Other strong clinical outcomes of the Greenwich Hospital primary

angioplasty program, for the four quarters ending mid-2011, are shown in the following table.

National Cardiovascular Data Registry Institutional Outcomes
Executive Summary
Greenwich Hospital
Rolling Four Quarters Ending 2011 Q2

Section II: Quality Metrics			
Metric	Greenwich Hospital	All Hospitals 50th Percentile	All Hospitals 90th Percentile
PCI Process Metrics			
Median time to immediate PCI for STEMI patients (in minutes)	67.0	63.1	50.4
Proportion of STEMI patients receiving immediate PCI within 90"	100%	91.4%	100%
Proportion of patients with aspirin prescribed at discharge	100%	98.2%	99.9%
Proportion of patients with thienopyridine prescribed at discharge	100%	99.1%	100%
Statins prescribed at discharge	100%	91.5%	97.3%
Utilization Metrics			
Median post-procedure length of stay (in days) for PCI patients with STEMI	2.0	2.7	1.7

Source: National Cardiovascular Data Registry® – CathPCI Registry® - Executive Summary – Greenwich Hospital Compared to Rolling Four Quarters for All Hospitals Ending 2011Q2. Aggregation Date: September 30, 2011 Published Date: October 19, 2011

The ACC-NCDR database has limitations on the comparative use of its angioplasty data. However, at this time the ACC-NCDR data is the only benchmarking data set available to hospitals. The ACC-NCDR reports provide comparative benchmarking for all participating programs, and do not separately benchmark programs that provide only primary angioplasty such as Greenwich Hospital. As a result, the report shows an "apples to oranges" comparison of data. Greenwich Hospital's performance is benchmarked against programs that have significantly higher volumes that include elective angioplasty cases. As well, primary angioplasty cases tend to be more medically unstable in comparison to elective angioplasty cases. Greenwich Hospital contacted NCDR but the organization was not able to provide the Hospital with data listed separately for primary versus elective angioplasty. Greenwich Hospital's most recent complete ACC-NCDR report is included as Attachment XI. A letter from Greenwich Hospital to the Office of Health Care Access dated March 9, 2011 that discusses the limitations of comparing Greenwich Hospital's primary angioplasty outcomes with larger programs that offer elective angioplasty, is included as Attachment XII.

Even given the limitations of the angioplasty data, it is clear that Greenwich Hospital is providing essential cardiac care to patients with strong results. An elective angioplasty program is a logical and cost-efficient extension of the existing diagnostic cardiac catheterization and primary angioplasty program infrastructure, and would be

performed by many of the same expert physicians and staff, and in the same dedicated laboratories, as the existing programs.

c. Identify the Standard of Practice Guidelines that will be utilized in relation to the proposal. Attach copies of relevant sections and briefly describe how the Applicant proposes to meet each of the guidelines.

American College of Cardiology - Please see Attachment VI for the 2011 ACC/AHA/SCAI Guidelines and the 2007 SCAI Expert Consensus Document.

Quality and safety standards for the elective angioplasty program are paramount. As with the primary angioplasty program, the Hospital will continue to be part of the Yale-New Haven Heart and Vascular Center and will continue to draw on the collective clinical resources and experience of the Center and comply with all standards, protocols, policies, procedures and quality assessments. Yale-New Haven Heart and Vascular Center staff will continue to provide clinical oversight, educational training and quality review services to ensure high quality outcomes. The medical direction for the program will continue to be provided by the appointed YSM interventional cardiologist. All of this ensures one standard of care across the Yale New Haven Health System and the highest possible angioplasty care provided at Greenwich Hospital. The clinical experience gained from the additional volume of the elective angioplasty program will serve to further improve the clinical competency of the program staff.

Greenwich Hospital will meet the guidelines through clinical policies and procedures, medical staff credentialing and quality assurance processes. In addition, it is important to note that the interventional cardiology clinical faculty from the Yale School of Medicine, who will perform the majority of elective angioplasty procedures at Greenwich Hospital, are highly skilled with considerable experience in this procedure. At the various sites where these physicians practice (including Yale-New Haven Hospital, Greenwich Hospital, the West Haven VA and Lawrence & Memorial Hospital), they performed more than the guideline recommended procedures in Fiscal Year 2011.

5. Organizational and Financial Information

a. Identify the Applicant's ownership type(s) (e.g. Corporation, PC, LLC, etc.).

The ownership type is Corporation.

b. Does the Applicant have non-profit status?

☒ Yes (Provide documentation) ☐ No

Please see Attachment XIII for documentation of non-profit status.

c. Provide a copy of the State of Connecticut, Department of Public Health license(s) currently

held by the Applicant and indicate any additional licensure categories being sought in relation to the proposal.

Please see Attachment XIV for copies of licenses.

d. Financial Statements

i. If the Applicant is a Connecticut hospital: Pursuant to Section 19a-644, C.G.S., each hospital licensed by the Department of Public Health is required to file with OHCA copies of the hospital's audited financial statements. If the hospital has filed its most recently completed fiscal year audited financial statements, the hospital may reference that filing for this proposal.

Copies of both YNHH's and GH's audited financial statements for FY 2010 are currently on file with OHCA.

ii. If the Applicant is not a Connecticut hospital (other health care facilities): Audited financial statements for the most recently completed fiscal year. If audited financial statements do not exist, in lieu of audited financial statements, provide other financial documentation (e.g. unaudited balance sheet, statement of operations, tax return, or other set of books.)
Not applicable.

e. Submit a final version of all capital expenditures/costs as follows:

Table 2: Proposed Capital Expenditures/Costs

Medical Equipment Purchase	**$ 0**
Imaging Equipment Purchase	
Non-Medical Equipment Purchase	
Land/Building Purchase *	
Construction/Renovation **	
Other Non-Construction (Specify)	
Total Capital Expenditure (TCE)	**$ 0**
Medical Equipment Lease (Fair Market Value) ***	
Imaging Equipment Lease (Fair Market Value) ***	
Non-Medical Equipment Lease (Fair Market Value) ***	
Fair Market Value of Space ***	
Total Capital Cost (TCC)	**$ 0**
Total Project Cost (TCE + TCC)	**$ 0**
Capitalized Financing Costs (Informational Purpose Only)	
Total Capital Expenditure with Cap. Fin. Costs	**$ 0**

* If the proposal involves a land/building purchase, attach a real estate property appraisal including the amount; the useful life of the building; and a schedule of depreciation.
** If the proposal involves construction/renovations, attach a description of the proposed building work, including the gross square feet; existing and proposed floor plans; commencement date for the construction/
*** If the proposal involves a capital or operating equipment lease and/or purchase, attach a vendor quote or invoice; schedule of depreciation; useful life of the equipment; and anticipated residual value at the end of the lease or loan term.

Not applicable. There are no capital costs associated with the proposal.

f. List all funding or financing sources for the proposal and the dollar amount of each. Provide applicable details such as interest rate; term; monthly payment; pledges and funds received to date; letter of interest or approval from a lending institution.

Not applicable. The proposal does not include any incremental capital costs; therefore, no funding or financing is required.

g. Demonstrate how this proposal will affect the financial strength of the state's health care system.

This proposal will result in lower costs resulting from a decrease in patient transfers and a second procedure for some patients. Through the fuller use of its existing angioplasty infrastructure at Greenwich Hospital, including physicians and staff, more efficient care and enhanced patient quality and safety will result. The facility, physicians, staff and equipment required to provide elective angioplasty services are already in place at Greenwich Hospital.

6. Patient Population Mix: Current and Projected

a. Provide the current and projected patient population mix (based on the number of patients, not based on revenue) with the CON proposal for the proposed program.

Table 3: Patient Population Mix

	Current** FY ***	Year 1 FY ***	Year 2 FY ***	Year 3 FY ***
Medicare*	40.5%	40.5%	40.5%	40.5%
Medicaid*	5.4%	5.4%	5.4%	5.4%
CHAMPUS & TriCare				
Total Government	**45.9%**	**45.9%**	**45.9%**	**45.9%**
Commercial Insurers*	48.7%	48.7%	48.7%	48.7%
Uninsured	5.4%	5.4%	5.4%	5.4%
Workers Compensation				
Total Non-Government	**54.1%**	**54.1%**	**54.1%**	**54.1%**
Total Payer Mix	**100.0%**	**100.0%**	**100.0%**	**100.0%**

* Includes managed care activity.
** New programs may leave the "current" column blank.
*** Fill in years. Ensure the period covered by this table corresponds to the period covered in the projections provided.

b. Provide the basis for/assumptions used to project the patient population mix.

The current population mix for the current cases performed at the hospital was utilized in the projections.

7. Financial Attachments I & II

a. Provide a summary of revenue, expense, and volume statistics, without the CON project, incremental to the CON project, and with the CON project. **Complete Financial Attachment I.** (Note that the actual results for the fiscal year reported in the first column must agree with the Applicant's audited financial statements.) The projections must include the first three full fiscal years of the project.

Please see Attachment XV.

b. Provide a three year projection of incremental revenue, expense, and volume statistics attributable to the proposal by payer. **Complete Financial Attachment II.** The projections must include the first three full fiscal years of the project.

Please see Attachment XVI.

c. Provide the assumptions utilized in developing **both Financial Attachments I and II** (e.g., full-time equivalents, volume statistics, other expenses, revenue and expense % increases, project commencement of operation date, etc.).

Please see Attachment XVII.

d. Provide documentation or the basis to support the proposed rates for each of the FYs as reported in Financial Attachment II. Provide a copy of the rate schedule for the proposed service(s).

Rates for the proposed service will be approximately the same as the current service.

e. Provide the minimum number of units required to show an incremental gain from operations for each fiscal year.

Each additional incremental case produces an incremental gain.

f. Explain any projected incremental losses from operations contained in the financial projections that result from the implementation and operation of the CON proposal.

No incremental losses from operations are anticipated.

g. Describe how this proposal is cost effective.

The proposed elective angioplasty program maximizes use of the existing high-cost infrastructure of the primary angioplasty program and permits existing and available highly qualified expert physicians and staff to perform both primary and elective angioplasties for which they have been trained and are qualified to perform. In addition, as noted above, through System-wide integration, coordination of care practices and standardization, more cost effectiveness and evidence-based care will be provided.

ATTACHMENTS

ATTACHMENT I

American Heart Association (AHA)
Late-Breaking News Trial Report
November 14, 2011

American Heart Association.
Learn and Live

Elective angioplasty patients can fare well in experienced hospitals with no heart surgery capabilities

American Heart Association Late-Breaking Clinical Trial Report - Abstract: 18558 - EMBARGOED UNTIL 8AM ET November 14, 2011

Study Highlights:

- Patients who had non-emergency artery-opening angioplasty or stent implantation at hospitals without heart surgery capabilities fared as well as those in hospitals that did.
- Both groups of patients had less than a 1 percent death rate.

ORLANDO, FLA., Nov. 14, 2011 — Patients who had non-emergency artery-opening angioplasty or stent implantation at experienced hospitals without on-site heart surgery capabilities fared no worse than those in surgery-equipped hospitals, according to late-breaking research presented at the American Heart Association's Scientific Sessions 2011.

In a study from the Cardiovascular Patient Outcomes Research Team (CPORT), researchers randomly assigned 13,995 patients to have their procedure done at a hospital with cardiac surgery capabilities and 4,523 patients at hospitals without.

The death rate after six weeks was almost the same for each group — just under 1 percent, researchers said. Furthermore, neither group were more likely to need emergency heart bypass surgery.

If emergency surgery was required at a hospital without on-site surgery, the patient was transferred urgently.

The American College of Cardiology Foundation/American Heart Association guidelines have recommended that elective angioplasty and stent implantation be done at hospitals with cardiac surgery facilities in the same building in case emergency surgery is needed.

In this study, emergency surgery was needed for 20 of the 13,995 patients undergoing procedures at hospitals without on-site surgery and 10 of the 4,523 patients treated at hospitals with surgery available.

However, the need for emergency surgery during these procedures has plummeted over the last few decades, said Thomas Aversano, M.D., the study's lead researcher and associate professor of medicine at Johns Hopkins Medical Institutions in Baltimore, Md.

"In the 1980s, the need for cardiac surgery was high; 5 percent to 7 percent of these cases could require emergency open heart or bypass surgery," Aversano said. "The cardiac operating room was kept open in the event a complication requiring surgery occurred. Now it's one in 500 or one in 1,000. It's very uncommon."

In this carefully structured study, the 60 hospitals without cardiac surgery capabilities had to be able to annually perform at least 200 angioplasties or stent implantations, also called percutaneous coronary interventions or PCI. The physicians doing the procedures were required to be performing more than 75 PCI cases annually. All centers underwent a formally developed PCI program.

Some states restrict hospitals from performing these procedures without on-site surgery, except for an emergency, Aversano said.

"We do not support the spread of angioplasty to every hospital in the United States," he said. "However, it can be burdensome and costly for all medical centers to have cardiac surgery capabilities. And it doesn't make sense to create more surgical programs just to support the angioplasty programs."

He said regional healthcare planners can use the data from the study to make informed decisions about which hospitals should have PCI capability, with the aim of improving quality, improving access and lowering costs.

The study provides only short-term results, but early next year, researchers will have data revealing how patients fared nine months after the procedure. They said this will be important in assessing the overall effect of these two systems of care on ultimate patient outcomes.

Co-authors are the C-PORT investigators.
Disclosures are here: http://newsroom.heart.org/pr/aha/document/Disclosures_for_LBCT.xlsx.
The participating medical centers funded the study.

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Statements and conclusions of study authors that are presented at American Heart Association scientific meetings are solely those of the study authors and do not necessarily reflect association policy or position. The association makes no representation or warranty as to their accuracy or reliability. The association receives funding primarily from individuals; foundations and corporations (including pharmaceutical, device manufacturers and other companies) also make donations and fund specific association programs and events. The association has strict policies to prevent these relationships from influencing the science content. Revenues from pharmaceutical and device corporations are available at www.heart.org/corporatefunding.

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AHA News Media in Dallas: (214) 706-1396
AHA News Media Office, Nov. 12-16, at the
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For public inquiries: (800) AHA-USA1 (242-8721)

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ATTACHMENT II

American Journal of Therapeutics
Outcomes of Nonemergent Percutaneous Coronary Intervention With and Without On-site Surgical Backup: A Meta-Analysis

American Journal of Therapeutics 18, e22–e28 (2011)

Outcomes of Nonemergent Percutaneous Coronary Intervention With and Without On-site Surgical Backup: A Meta-Analysis

Param Puneet Singh, MD,* Mukesh Singh, MD, Updesh Singh Bedi, MD, Sasikanth Adigopula, MD, Sarabjeet Singh, MD, Vamsi Kodumuri, MD, Janos Molnar, MD, Aziz Ahmed, MD, Rohit Arora, MD, and Sandeep Khosla, MD

Despite major advances in percutaneous coronary intervention (PCI) techniques, the current guidelines recommend against elective PCI at hospitals without on-site cardiac surgery backup. Nonetheless, an increasing number of hospitals without on-site cardiac surgery in the United States have developed programs for elective PCI. Studies evaluating outcome in this setting have yielded mixed results, leaving the question unanswered. Hence, a meta-analysis comparing outcomes of nonemergent PCI in hospitals with and without on-site surgical backup was performed. A systematic review of literature identified four studies involving 6817 patients. Three clinical end points were extracted from each study and included in-hospital death, myocardial infarction, and the need for emergency coronary artery bypass grafting. The studies were homogenous for each outcome studied. Therefore, the combined relative risks (RRs) across all the studies and the 95% confidence intervals (CIs) were computed using the Mantel-Haenszel fixed-effect model. A two-sided alpha error less than 0.05 was considered to be statistically significant. Compared with facilities with on-site surgical backup, the risk of in-hospital death (RR, 2.7; CI, 0.6–12.9; $P = 0.18$), nonfatal myocardial infarction (RR, 1.3; CI, 0.7– 2.2; $P = 0.29$), and need of emergent coronary artery bypass grafting (RR, 0.46; CI, 0.06– 3.1; $P = 0.43$) was similar in those lacking on-site surgical backup. The present meta-analysis suggests that there is no difference in the outcome with regard to risk of nonfatal myocardial infarction, need for emergency coronary artery bypass grafting, and the risk of death in patients undergoing elective PCI in hospitals with and without on-site cardiac surgery backup.

Keywords: onsite backup surgery, percutaneous coronary intervention

INTRODUCTION

Percutaneous coronary interventions (PCI) were introduced for the first time in 1977 by Andreas Gruntzig.[1] Since then, many technologic and pharmacologic advances in PCI have been made. Steerable guidewires, coronary artery stents,[2] and new antiplatelet therapies have improved the success rate of PCI procedures and significantly reduced the risk of per-procedural complications needing urgent cardiac surgery. Recent studies have shown that the need for emergency cardiac surgery is now as low as 0.3% to 0.6%.[2,3] As a result, the number of procedures has increased worldwide,[4] and an increasing proportion of procedures are performed at centers without surgical backup.[5,6] Despite major advances in PCI technique, the current American College of Cardiology/American Heart Association/-Society of Cardiovascular Angiography and Intervention 2005 guidelines[7] for PCI recommend against elective PCI at hospitals without on-site cardiac surgery (Class III indication). Acknowledging this trend, the Society for Cardiovascular Angiography and Interventions recently issued an expert consensus statement that provides practice standards for elective PCI at hospitals

Department of Cardiology, Chicago Medical School, Rosalind Franklin University of Medicine & Science, North Chicago, IL.
**Address for correspondence: Department of Cardiology, Chicago Medical School, Rosalind Franklin University of Medicine & Science, North Chicago, IL 60064. E-mail: drparamsingh@gmail.com*

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without on-site cardiac surgery.[8] Because of the conflicting literature on this subject, the question about safety of elective PCI at centers without surgical backup remains unanswered. Hence, a meta-analysis comparing outcomes of nonemergent or elective PCI in hospitals with and without on-site surgical backup was performed.

METHODS

We performed this review in accordance with the Quality of Reporting of Meta-analysis statement and the Consolidated Standards of Reporting Trials Group recommendations.[9]

Literature search

A systematic review of the medical literature was performed to identify studies evaluating the efficacy or adverse outcomes of combination therapy in patients with congestive heart failure, acute myocardial infarction, or high-risk diabetes mellitus. Eligible studies were identified by searching MEDLINE (January 1966–December 2008), EMBASE (January 1980–December 2006), the Cochrane Library (Controlled Trials Register and Database of Systematic Reviews, all years), the National Institute of Health Clinical Trials (http://www.clinicaltrials.gov), and the U.S. Food and Drug Administration web sites (http://www.FDA.gov) and relevant bibliographies.

Study selection

There was a written protocol with explicit inclusion and exclusion criteria, which was followed for all articles that were screened. All titles and abstracts from the results of our computerized search were reviewed by the authors for potential inclusion in our study. We also searched for relevant review articles and their bibliographies for articles. In addition to our computerized search, we manually reviewed the reference list of all retrieved articles to complete our search for randomized, controlled trials comparing outcome of PCI with and without surgical backup. Study selection process is outlined in Figure 1.

Studies were excluded if they did not meet the inclusion criteria. Those studies that were not done in human subjects, not randomized, published in nonpeer-reviewed journals, or with inadequate follow up were excluded from our analysis.

End points and definitions

Three clinical end points were extracted from each study and included: in-hospital death, nonfatal myocardial infarction (MI), and need for emergency coronary artery bypass surgery (CABG). End point definitions were those used in the individual trials. Death was defined as in-hospital mortality from any cause. MI was defined as enzymatic and electrocardiographic changes consistent with MI. Emergency CABG surgery was defined as unplanned surgical revascularization within 48 hours of PCI. All end points were assessed at the end of follow up of the trial.

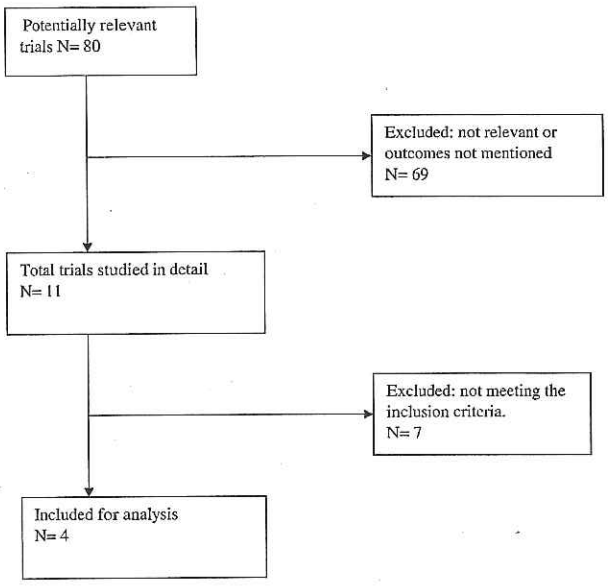

FIGURE 1. Trial selection and inclusion flow diagram.

Data extraction

The two authors (PS, MS) independently screened the titles and abstracts for eligibility. Full articles were retrieved for all titles for which abstracts were not available and for all abstracts that appeared to potentially fulfill the inclusion and exclusion criteria. It was decided that if there was a conflict between the two authors, then the study in question would be brought to the panel of all authors where the decision would be made for its inclusion. Data extraction was done independently by two authors. Each author tabulated important trial characteristics and assessed methodological quality (jaded score), including patient demographics such as age, study population, sample size diabetes, hypertension, and angiographic characteristics.

Statistical analysis

The statistical analysis was performed with the Comprehensive Meta-Analysis software package (Version CM 2.2; Biostat, Englewood, NJ). We calculated odds ratio for each study outcome to allow for pooling of similar outcomes. All the results are reported as the pooled odds ratio with 95% confidence interval (CI). Chi square test

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Table 1. Results of heterogeneity analysis.

End Point	Q-value	df (Q)	*P* Value	I-squared	Result
In-hospital death	3.4	1	0.067	70.2	Homogenous
Nonfatal myocardial infarction	1.4	3	0.707	0.0	Homogenous
Emergency coronary artery bypass graft	2.0	1	0.155	50.7	Homogenous

was used to assess heterogeneity. The studies were homogenous for each outcome studied (Table 1). Therefore, the combined relative risks (RRs) across all the studies and the 95% CIs were computed using the Mantel-Haenszel fixed-effect model. A two-sided alpha error less than 0.05 was considered to be statistically significant.

Role of funding source

The funding source had no role in the design, conduct, or reporting of the study or in the decision to submit the manuscript for publication.

RESULTS

Data synthesis and study characteristics

Figure 1 represents the trial selection and inclusion flow diagram. After the initial search based as described previously, a total of 80 articles was considered as potentially relevant. After the title and abstract review, 69 of the 80 were excluded because they were not randomized, non-English trials, or did not meet our inclusion criteria. From the remaining 11, seven were excluded after full text review because there was inadequate follow up, the outcomes measured were different, or the study characteristics did not meet our inclusion criteria. Our search of abstracts from conference proceedings of the American College of Cardiology, American Heart Association, European Society of Cardiology, and Heart Failure Society of America did not reveal any additional studies that satisfied our inclusion and exclusion criteria. Our meta-analysis included the remaining four randomized, controlled trials involving 6817 patients.[10–13]

Baseline characteristics

Table 2 summarizes the study population characteristics of all the studies included for the analysis. All four studies were large randomized, controlled trials with adequate follow up. Mean duration of follow up was 31 months. Mean age of patients enrolled was 64 years. Allocation sequence generation and concealment were adequately described in all four studies. All the studies had two arms comparing the outcome of patients undergoing elective PCI at two centers with and without on-site cardiac surgery backup. In-hospital death and need for emergency surgery as outcomes were reported in two studies,[12,13] whereas non-fatal MI was reported in all four studies included in this meta-analysis.[10–13]

Clinical outcomes

Angiographic characteristics of patients in the included studies are given in Table 3. The outcomes measured in our analysis were in-hospital death, nonfatal MI, and need for emergent CABG.

In-Hospital Death

Compared with hospitals with surgical capability, there was no difference in the risk of in-hospital death in patients undergoing elective PCI at centers without surgical back up (RR, 2.7; CI, 0.6–12.9; $P = 0.18$) (Fig. 2).

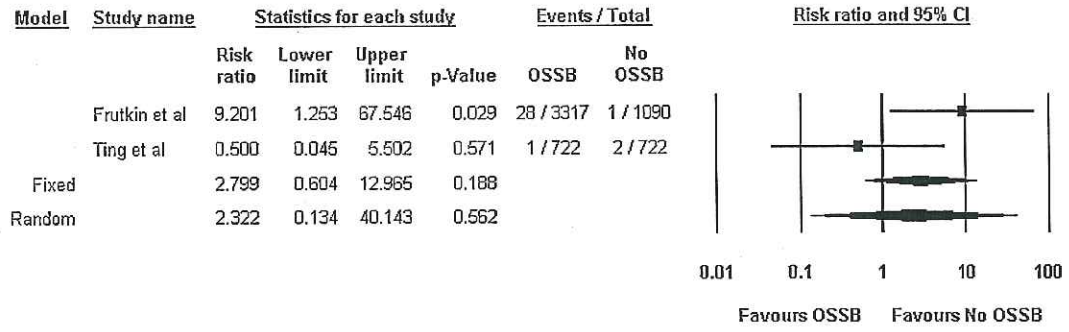

FIGURE 2. Risk of in-hospital death with on-site surgical backup versus no backup.

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Table 2. General characteristics of the patient population in studies included in meta-analysis.

Characteristics		Dellavalle, 1995	Melberg, 2006	Frutkin, 2008	Ting, 2006
N	SB	154	304	3317	722
	NSB	174	305	1090	722
Age	SB	55 ± 12	58 ± 10	66 ± 13	64.9 ± 12.5
	NSB	64 ± 18	59 ± 10	66 ± 12	64.9 ± 12.7
Females	SB	37 (24%)	61 (20%)	1129 (34%)	246 (34%)
	NSB	33 (19%)	64 (21%)	300 (27.5%)	218 (30%)
Prior MI	SB	72 (47%)	39	1320 (40%)	273 (39%)
	NSB	108 (62%)	39	319 (29%)	248 (34%)
Prior PCI	SB	15 (9.1%)	9	1583 (48%)	245 (34%)
	NSB	30 (17.2%)	6	477 (44%)	244 (34%)
Prior stroke/TIA	SB	—	—	603 (18%)	80 (11%)
	NSB	—	—	163 (15%)	69 (10%)
Prior CABG	SB	1 (0.6%)	6	728 (22%)	84 (12%)
	NSB	5 (2.7%)	5	220 (20%)	74 (10%)
PVD	SB	—	—	421 (13%)	72 (10%)
	NSB	—	—	125 (11%)	86 (12%)
DM	SB	—	5	110 (34%)	170 (24%)
	NSB	—	9	310 (28%)	176 (24%)
HTN	SB	—	25	2527 (76%)	480 (69%)
	NSB	—	24	820 (75%)	496 (69%)
CKD	SB	—	—	193 (6%)	18 (2%)
	NSB	—	—	29 (3%)	18 (3%)
CHF	SB	—	—	346 (10%)	38 (5%)
	NSB	—	—	65 (6%)	39 (5%)
LVEF less than 40%	SB	—	—	374 (19%)	92 (13%)
	NSB	—	—	59 (9%)	74 (10%)

MI, myocardial infarction; PCI, percutaneous coronary intervention; TIA, transient ischemic attack; CABG, coronary artery bypass grafting; PVD, peripheral vascular disease; DM, diabetes mellitus; HTN, hypertension; CKD, chronic kidney disease; CHF, congestive heart failure; LVEF, left ventricular ejection fraction; SB, on-site surgical backup group; NSB, no on-site surgical backup group.

Nonfatal Myocardial Infarction

The risk of nonfatal MI was similar in both groups of patients without any significant difference (RR, 1.3; CI, 0.7–2.2; $P = 0.29$) (Fig. 3).

Need for Emergent Coronary Artery Bypass Grafting

The risk for need for emergent CABG did not differ between the patients undergoing PCI at centers with and without surgical backup (RR, 0.46; CI, 0.06–3.1; $P = 0.43$) (Fig. 4).

DISCUSSION

Our meta-analysis shows that there is no difference in the incidence of in-hospital mortality, nonfatal MI, and

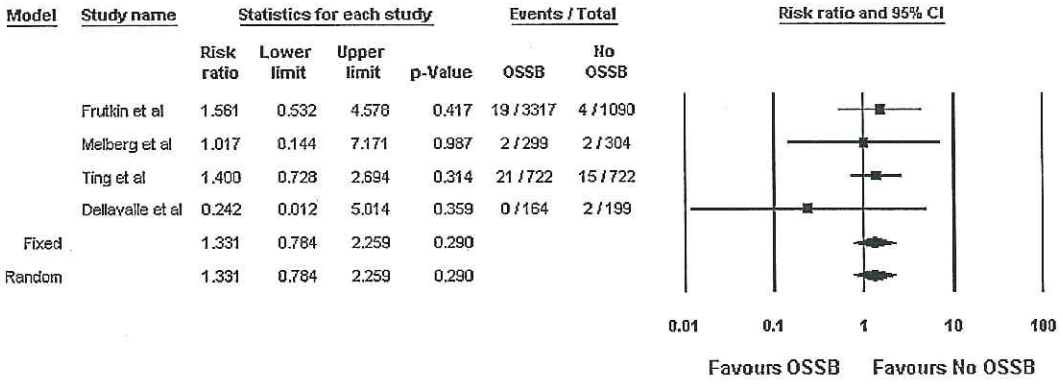

FIGURE 3. Risk of nonfatal myocardial infarction with on-site surgical backup versus no backup.

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Table 3. Angiographic characteristics of patients in studies included in the meta-analysis.

Characteristics	Dellavalle		Melberg, 2006		Frutkin		Ting, 2006	
	SB	NSB	SB	NSB	SB	NSB	SB	NSB
Extent of disease								
SVD	98 (60%)	139 (70%)	39	39	999 (30%)	299 (27%)	—	—
DVD	56 (34%)	44 (22%)	35	37	1079 (33%)	356 (33%)	423 (62%)	429 (61%)
TVD	10 (6%)	16 (8%)	26	24	1231 (37%)	434 (40%)		
Type of PCI								
SV	131 (80%)	179 (90%)	—	—	2244 (68%)	773 (71%)	646 (90%)	636 (88%)
MV	33 (20%)	20 (10%)	—	—	852	282 (26%)	75 (10%)	86 (12%)
LM	3 (2%)	0	—	—	27 (0.8%)	4 (0.4%)	—	—
VG	1 (0.5%)	4 (2%)	—	—	263 (8%)	60 (6%)	22 (3%)	24 (3%)
No. of stents placed	—	—	—	—	1.7 ± 1.3	1.8 ± 1.1	1.3 ± 0.9	1.5 ± 1.0

SB, on-site surgical backup group; NSB, no on-site surgical backup group; SVD, single-vessel disease; DVD, double-vessel disease; TVD, triple-vessel disease; SV, single vessel; MV, multiple vessel; LM, left main; VG, venous graft.

the need for emergency CABG in patients undergoing PCI at centers with and without surgical backup (Fig. 5). Overall, of 6817 patients in all four studies, total in-hospital deaths were 32 (0.47%). In the group with no surgical backup, in-hospital mortality was 0.13% (three of 2315 patients died), whereas in the group with on-site surgical backup, the in-hospital mortality rate was 0.6% (29 of 4502 patients died).

The purpose of cardiac surgical backup for PCI is to provide emergent hemodynamic support and revascularization to salvage complications that cannot be addressed by catheter-based techniques. PCI can be complicated by life-threatening hemodynamic and ischemic emergencies that can be addressed only by the availability of emergency cardiac surgery. The role of on-site cardiac surgical backup is twofold: on-site cardiac surgical backup provides prompt availability of cardiac surgical support in the event of a hemodynamic or ischemic emergency and on-site cardiac surgical backup is a surrogate for an institution's overall capability to provide a highly experienced and promptly available team to respond to a catheterization laboratory emergency.[14] Technical improvements in PCI instruments and techniques have led to the concept that the requirement for emergency cardiac surgery is sufficiently rare that PCI can be performed safely without on-site surgery. This has led to the development of elective angioplasty programs without on-site surgical coverage.

Cardiac surgical backup for PCI has evolved from a formal surgical standby in the 1980s to an informal arrangement of first-available operating room and, in some cases, off-site surgical backup.[15–21] With the advent of intracoronary stenting, there has been a decrease in the need for emergency CABG ranging between 0.4% and 2%.[2,3,21–28] Not surprisingly, emergency CABG surgery for a patient with an occluded or dissected coronary artery is associated with a higher mortality than elective surgery.[21,29–34] Emergency procedures are also associated with high rates of perioperative infarction and less frequent use of

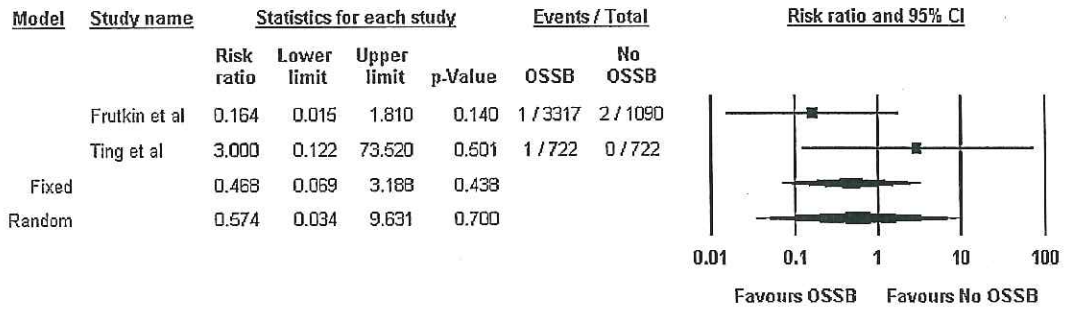

FIGURE 4. Risk of emergency coronary artery bypass graft with on-site surgical backup versus no backup.

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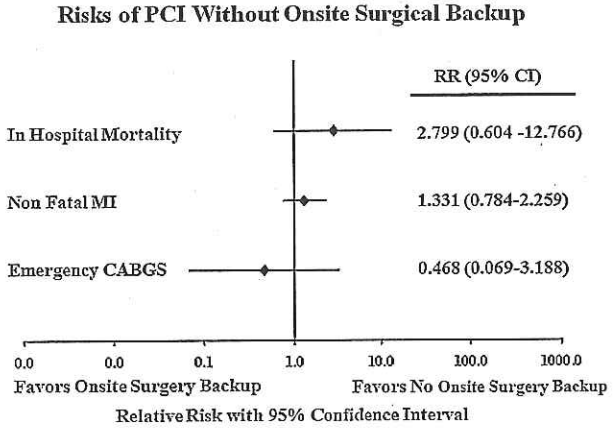

FIGURE 5. Summary figure.

arterial conduits. Complex coronary artery disease intervention, hemodynamic instability, and prolonged time to reperfusion are contributing factors to the increased risk of emergency bypass surgery.

A recently published report from analysis of National Cardiovascular Data Registry showed findings similar to our meta-analysis. This National Cardiovascular Data Registry data analysis showed that off-site PCI centers had similar observed procedure success, morbidity, emergency cardiac surgery rates, and mortality in cases that required emergency surgery. The risk-adjusted mortality rates in off-site PCI facilities were comparable to those of PCI centers that had cardiac surgery on-site regardless of whether PCI was performed as primary therapy for ST-elevation MI or in a nonprimary setting.[35]

Like with any meta-analysis, our analysis has limitations inherent to such analysis. Meta-analyses have inherent methodological limitations in that summary data are pooled from studies of different designs. The study population used in all the trials, although being somewhat similar, is not exactly the same. Although we detected no significant heterogeneity, a meta-analysis cannot replace large, well-conducted randomized trials as evidence for and against an intervention.

Our meta-analysis adds to the current body of literature on PCI by considering between study heterogeneity, bias, consistency of outcomes among studies and inclusion of large recent studies. This meta-analysis shows that there is no difference in the outcome with regard to risk of nonfatal MI, need for emergency CABG, and the risk of death in patients undergoing elective PCI in hospitals with and without on-site cardiac surgery backup.

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ATTACHMENT III

Journal of the American College of Cardiology
News from the NCDR – Percutaneous Coronary Interventions in Facilities without Cardiac Surgery On Site: A Report from the National Cardiovascular Data Registry (NCDR)

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News from the NCDR

NCDR™ National Cardiovascular Data Registry

Percutaneous Coronary Interventions in Facilities Without Cardiac Surgery On Site: A Report From the National Cardiovascular Data Registry (NCDR)

Michael A. Kutcher, MD,* Lloyd W. Klein, MD,† Fang-Shu Ou, MS,‡ Thomas P. Wharton, JR, MD,§ Gregory J. Dehmer, MD,‖ Mandeep Singh, MD, MPH,¶ H. Vernon Anderson, MD,# John S. Rumsfeld, MD, PHD,** William S. Weintraub, MD,†† Richard E. Shaw, PHD,‡‡ Matthew T. Sacrinty, MPH,* Albert Woodward, PHD, MBA,§§ Eric D. Peterson, MD, MPH,‡ Ralph G. Brindis, MD, MPH,‖‖ on behalf of the National Cardiovascular Data Registry (NCDR)

Since the introduction of percutaneous coronary intervention (PCI) in 1977 by Andreas Gruntzig (1), the presence of cardiac surgery backup on site has been a recommended practice to treat the potential of life-threatening complications. As a result of major improvements in technology and pharmacology, the need for emergency cardiac surgery is now infrequent (0.3% to 0.6%) (2,3). Moreover, primary PCI has been accepted as superior to fibrinolytic therapy for ST-segment elevation myocardial infarction (STEMI) (4). These developments have provided the justification for some hospitals without cardiac surgery to develop PCI programs based on a strategy to provide more rapid care for STEMI (5,6) and to increase the availability of PCI to patients in geographically underserved areas.

Favorable outcomes for primary PCI performed in facilities without cardiac surgery backup on site have been reported (7–9). In addition, smaller observational studies have extended this concept to both primary and elective PCI (10–14), and even PCI limited to elective cases (15). However, there are few large studies that have directly compared the procedural outcomes of both primary and elective PCI at facilities without cardiac surgery on site with those that have traditional surgery on site (16–18). Because of the conflicting literature on this subject, the American College of Cardiology (ACC), American Heart Association (AHA), and Society for Cardiovascular Angiography and Interventions (SCAI) 2005 PCI guidelines continue to designate primary PCI a Class IIb indication (may be considered), and elective PCI a Class III indication (not recommended) when performed at facilities without surgical backup on site (19). The 2007 PCI guideline focused update did not address or change these designations (20). Despite

From the *Wake Forest University School of Medicine, Winston-Salem, North Carolina; †Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois; ‡Duke Clinical Research Institute, Durham, North Carolina; §Exeter Hospital, Exeter, New Hampshire; ‖Texas A&M University College of Medicine, Scott & White HealthCare, Temple, Texas; ¶Mayo Clinic, Rochester, Minnesota; #University of Texas Health Science Center, Houston, Texas; **Denver VA Medical Center, Denver, Colorado; ††Christiana Health Care System, Newark, Delaware; ‡‡Sutter Pacific Heart Centers, San Francisco, California; §§National Cardiovascular Data Registry, Washington, DC; and ‖‖Northern California Kaiser Permanente, San Francisco, California. Data analysis was performed by the Duke Clinical Research Institute with funding from the National Cardiovascular Data Registry. Drs. Kutcher and Klein perform percutaneous coronary intervention (PCI) at facilities that have on-site cardiac surgery. Dr. Wharton is a consultant to Corazon, The Heart and Vascular Experts, and performs PCI at a facility that does not have on-site cardiac surgery. Dr. Dehmer is Chief, Division of Cardiology, Texas A&M College of Medicine, Scott & White HealthCare, which includes facilities that have on-site cardiac surgery and facilities that do not. Dr. Singh performs PCI at Mayo Clinic facilities that have on-site cardiac surgery and facilities that do not. Dr. Anderson performs PCI at a facility that has on-site cardiac surgery.

these classifications, the number of PCI programs in the U.S. without surgery on site has increased significantly over the past several years (21). Recently, a SCAI expert panel outlined practical consensus principles for PCI performed at facilities without surgery on site, while not specifically encouraging or endorsing this practice (22).

The National Cardiovascular Data Registry (NCDR) was established by the ACC to proactively monitor and assess the clinical practice of cardiology in the U.S. (23). The NCDR CathPCI Registry, cosponsored by the ACC and SCAI, offers its participant institutions data field definitions, uniform data entry, secure transmission requirements, a data quality program, and risk-adjustment algorithms (24–26). Therefore, this registry provides an excellent resource of comparative data, in a relative contemporary clinical setting, to address the controversy over PCI at facilities without surgical backup on site.

Abbreviations and Acronyms

ACC = American College of Cardiology
AHA = American Heart Association
CABG = coronary artery bypass graft surgery
IABP = intra-aortic balloon pump
MI = myocardial infarction
NSTEMI = non–ST-segment myocardial infarction
PCI = percutaneous coronary intervention
SCAI = Society for Cardiovascular Angiography and Interventions
STEMI = ST-segment elevation myocardial infarction

Methods

Study population. Clinical characteristics and in-hospital outcomes were assessed in consecutive PCI cases reported to the NCDR CathPCI Registry from January 1, 2004, to March 30, 2006. Standardized NCDR version 3.04 definitions and data fields were used by all participating sites (27). The analysis cohort consisted of 308,161 patients from 465 PCI-capable facilities. Of these, 8,736 patients had PCI performed at 60 institutions in which it was verified there was no surgical backup on site within the buildings or campus that constituted the facility (off-site facility). The remaining 299,425 patients underwent PCI at 405 facilities that had cardiac surgery on site (on-site facility). Off-site PCI facilities comprised 13% of sites and 3% of patients in the NCDR CathPCI Registry during the study period.

Definitions. The primary outcomes for analysis were the incidence of emergency surgery and in-hospital death from all causes after PCI. Emergency surgery was defined as coronary artery bypass graft (CABG) surgery performed after PCI in which there was evidence of active ischemia or mechanical dysfunction (emergency), or if the patient required cardiopulmonary resuscitation en route to the operating room or before anesthesia (emergent/salvage). Secondary outcomes included procedure success, total complications (any general, bleeding, or vascular complications), and reperfusion time in cases of primary PCI for STEMI.

Off-site data clarification. During initial analysis, variations in 2 data fields unique to off-site PCI programs were noted. The field "CABG during this admission" permitted entry of only 1 category. In off-site centers, there was a disproportionately low incidence of "emergency" surgery, but a proportionately large number of patients "transferred for CABG" entered in this field. In addition, "transfer" patients could be counted as "alive" in the data field "discharge status" from an off-site center, but this opened the potential that a subsequent death after emergency surgery at the outside surgical center may not have been captured.

To resolve these issues, we conducted a data clarification project. Off-site centers with specific data points in question were queried to clarify whether a "transfer for CABG" data point was for elective or emergency surgery, and to verify the eventual survival at the off-site surgical center. This effort also provided an opportunity to gather additional information by a Capabilities Survey to reaffirm a true off-site status and to assess organization, staffing, and logistics. All of the off-site programs were invited to fill out the survey form, even those sites in which data clarification was not necessary.

Of the 8,736 patients undergoing PCI in off-site centers, 172 (2%) patients from 43 sites required data clarification regarding transfer surgery or mortality status. Of these 43 sites, 38 (88%) sites were able to clarify CABG status and/or mortality information for 154 of the 172 (90%) patients. For the 18 patients (0.2% of 8,736) whose transfer or mortality data were not clarified, if CABG status was uncertain, the original record entry was used for the CABG status-related analysis. If the subsequent mortality at the receiving surgery center could not be clarified, these patients were not included in the analysis of observed or risk-adjusted mortality.

Statistical analysis. Data analysis was performed by the Duke Clinical Research Institute. For descriptive analyses, institutional comparisons between off- and on-site PCI centers were made based on hospital characteristics. Comparisons between patients were made based on clinical characteristics, treatment profiles, procedural details, and clinical outcomes. These aggregates were further divided and analysis performed in patients who underwent primary PCI as first-line therapy for reperfusion in the presence of STEMI, and to the remainder of patients who underwent PCI in a nonprimary setting. Continuous variables are presented as mean with SD or as frequencies with percentages in each pre-specified category. Categorical variables are expressed as frequencies with percentages. To test for independence of patients' baseline characteristics, in-hospital care patterns and outcomes with respect to off-site versus on-site centers, the Wilcoxon rank-sum test was used for continuous variables, and the Pearson chi-square test was used for categorical variables.

A multivariable logistic regression model was then used to estimate the risk-adjusted association between on-site versus off-site PCI center surgical status and primary outcomes. Variables adjusted to mortality in-

cluded age, sex, insulin-treated diabetes mellitus, hypercholesterolemia, hypertension, dialysis, cerebrovascular disease, chronic lung disease, peripheral vascular disease, congestive heart failure, prior CABG, prior PCI, prior myocardial infarction (MI), cardiogenic shock at presentation, MI status (STEMI, non–ST-segment myocardial infarction [NSTEMI], and no MI), pre-operative intra-aortic balloon pump (IABP), PCI status (rescue, emergent, urgent, and elective), subacute thrombosis in a major artery, any treated lesion in left main artery, any treated lesion with pre-procedure stenosis 100%, any treated lesion with pre-procedure Thrombolysis In Myocardial Infarction (TIMI) flow grade 0, any treated lesion with high/C risk characteristics (see definition, bottom legend, Table 1), and total number of lesions treated. Variables adjusted to emergency CABG included cardiogenic shock, MI status (STEMI, NSTEMI, and no MI), pre-operative IABP, PCI status (rescue, emergent, urgent, and elective), and any treated left main artery lesion.

The Generalized Estimate Equation method (28) was applied to account for within-hospital clustering, considering patients at the same hospital are more likely to have similar responses relative to patients in other hospitals (i.e., within-center correlation for response). This method produces estimates comparable to those from ordinary logistic regression, but estimated variances are adjusted for the correlation of outcomes within each hospital.

Because not all off-site PCI center patient mortality data could be clarified, a sensitivity analysis was performed. This analysis utilized the same multivariable logistic regression model but imputed data to either of the following: patients with missing mortality data were considered either as all had died (worst scenario) or as all were alive (best scenario) on discharge.

Results

Institutional characteristics. Institutional characteristics are shown in Table 2. Compared with on-site centers, off-site PCI facilities had smaller bed capacity, were more likely to be located in nonurban areas, and had lower annual total PCI and primary PCI volume ($p < 0.001$). Overall, 43 (72%) of the off-site programs performed <200 total PCIs per year, and only 3 sites (5%) had >400 cases, suggesting that it was unlikely the outcomes were preferentially influenced by a few large-volume centers. The recommended volume standard of 36 or more primary PCIs per year (19) was achieved by 42% of the off-site programs compared with 80% of the on-site centers ($p < 0.001$).

Off-site capabilities survey. The survey (Table 3) was completed by 53 of the 60 off-site PCI facilities (88%). Approximately one-quarter of the centers had travel distances >40 miles and transit times (estimated driving or flight) >30 min. This information also reaffirmed that these were true off-site programs and did not have surgery back-up nearby in the next building. Full 24-h, 7-day coverage for PCI was provided by 92% of the sites. Both primary and elective PCI were performed in 79% of the centers, and none of the programs performed only elective PCI. Descriptive demographics regarding the organization of technical staff, interventional cardiologists, and transpor-

Table 1 Clinical Characteristics by PCI Status

	All PCI Patients			Primary PCI Patients			Nonprimary PCI Patients		
Characteristic	Off-Site (n = 8,736)	On-Site (n = 299,425)	p Value	Off-Site (n = 1,934)	On-Site (n = 31,099)	p Value	Off-Site (n = 6,802)	On-Site (n = 268,312)*	p Value
Age, yrs, mean ± SD	63.5 ± 12	64.1 ± 12	<0.001	61.2 ± 13	60.6 ± 13	0.194	64.2 ± 12	64.4 ± 12	0.062
Male	5,817 (67)	198,656 (66)	0.639	1,384 (72)	21,958 (71)	0.371	4,433 (65)	176,688 (66)	0.243
Previous MI >7 days	2,285 (26)	87,521 (29)	<0.001	327 (17)	5,440 (17)	0.509	1,958 (29)	82,077 (31)	0.001
Previous CHF	839 (9.6)	30,953 (10.3)	0.026	80 (4)	1,442 (5)	0.308	759 (11)	29,510 (11)	0.675
Diabetes	2,534 (29)	95,160 (32)	<0.001	361 (19)	6,514 (21)	0.016	2,173 (32)	88,642 (33)	0.058
Previous renal failure	367 (4)	15,868 (5)	<0.001	56 (3)	1,033 (3)	0.308	311 (4.6)	14,835 (5.5)	<0.001
Cerebrovascular disease	817 (9)	33,865 (11)	<0.001	105 (5)	2,165 (7)	0.010	712 (10)	31,700 (12)	<0.001
Peripheral vascular disease	895 (10)	35,519 (12)	<0.001	123 (6)	2,019 (6)	0.818	772 (11)	33,500 (12)	0.005
Hypertension	6,226 (71)	225,404 (75)	<0.001	1,069 (55)	18,275 (59)	0.002	5,157 (76)	207,120 (77)	0.007
Dyslipidemia	5,827 (67)	220,220 (74)	<0.001	974 (50)	17,432 (56)	<0.001	4,853 (71)	202,780 (76)	<0.001
Previous PCI	2,711 (31)	105,133 (35)	<0.001	321 (17)	5,254 (17)	0.735	2,390 (35)	99,875 (37)	<0.001
Previous CABG	1,068 (12)	56,815 (19)	<0.001	99 (5)	1,810 (6)	0.199	969 (14)	55,000 (21)	<0.001
Lesion characteristics									
≥2 lesions in laboratory visit	2,503 (29)	99,309 (33)	<0.001	478 (25)	8,463 (27)	0.048	2,025 (30)	90,843 (34)	<0.001
Segment in SVG	396 (5)	20,644 (7)	<0.001	55 (3)	989 (3)	0.657	341 (5)	19,675 (7)	<0.001
High-risk C lesion†	3,426 (39)	123,207 (41)	<0.001	1,106 (57)	18,933 (61)	0.001	2,320 (34)	104,270 (39)	<0.001

Data are n (%) unless otherwise indicated. *14 patients not included due to missing value for variable "Acute PCI." †High risk C lesion includes any of the following: diffuse (length >20 mm), excessive tortuosity of proximal segment, extremely angulated segments >90 degrees, total occlusions >3 months old and/or bridging collaterals, inability to protect major side branches, and degenerated vein grafts with friable lesions.

CABG = coronary artery bypass grafting; CHF = congestive heart failure; MI = myocardial infarction; PCI = percutaneous coronary intervention; SVG = saphenous vein graft.

tation modalities are further outlined in Table 3. Of note, 81% of the off-site programs reported that their interventional operators also rotated and performed PCI at on-site facilities.

Clinical characteristics. Clinical characteristics are shown in Table 1. In aggregate, on-site PCI centers generally treated patients with more risk factors and performed a greater percentage of PCI in multiple-lesion (33% vs. 29%, $p < 0.001$), saphenous vein graft (7% vs. 5%, $p < 0.001$), and higher lesion-risk cases (41% vs. 39%, $p = 0.001$). This difference was more pronounced in patients who underwent nonprimary PCI. In contrast, off-site facilities had a greater incidence of patients who had a clinical presentation of STEMI or NSTEMI (41% vs. 29%, $p < 0.001$) (Fig. 1).

Observed unadjusted procedural outcomes. Observed unadjusted procedural outcomes are shown in Table 4. Off-site facilities had slightly higher aggregate procedural success (94% vs. 93%, $p = 0.010$), predominantly due to higher success rates in nonprimary PCI cases. Aggregate total complications were similar in both off- and on-site facilities (6.5% vs. 6.3%), but off-site programs tended to have more bleeding events, and on-site more vascular complications. Off-site programs had fewer total complications in primary PCI (11.6% vs. 13.4%, $p = 0.029$) and had lower general (2.6% vs. 3.3%, $p = 0.001$) and vascular (0.8% vs. 1.1%, $p = 0.017$) complication rates in nonprimary PCI patients compared with on-site facilities.

In the overall PCI cohort, there was no significant difference in the incidence of emergency CABG surgery (0.3% vs. 0.4%, $p = 0.271$) or mortality with emergency CABG (13.6% vs. 12.8%, $p = 0.907$) between off- and on-site facilities, respectively. There was no difference in either of these variables when the analysis was stratified into primary PCI and nonprimary PCI patients. Although the unadjusted aggregate mortality rate was higher in off-site facilities (1.7% vs. 1.2%, $p < 0.001$) and appeared to be confined to patients who did not require emergency surgery, this difference did not persist when stratified by primary or nonprimary PCI. This increased unadjusted aggregate mortality was most likely due to a higher proportion of primary PCI patients (22% vs. 10%, $p < 0.001$) and STEMI and NSTEMI presentations (41% vs. 29%, $p < 0.001$) in off-site compared with on-site programs, respectively.

Primary PCI reperfusion times in nontransferred patients were significantly shorter in off-site PCI centers (mean 2.1 ± 5.1 h, median 1.4 h) compared with on-site (mean 2.6 ± 8.4 h, median 1.5 h, $p < 0.001$). These "reperfusion times" were defined as the time of arrival at the facility to the time of first treatment device deployment (27). Although both groups followed the same definition, these data were collected before there were major national quality

Table 2 Institutional Characteristics

Variable	Off-Site (n = 60)	On-Site (n = 405)	p Value
Number of CMS-certified beds			
Median	198	371	<0.001
Mean ± SD	212 ± 109	403 ± 188	
<200	31 (52%)	40 (10%)	<0.001
≥200 and <400	27 (45%)	178 (44%)	
≥400	2 (3%)	185 (46%)	
Location/community type			
Rural	21 (35%)	67 (17%)	<0.001
Suburban	24 (40%)	115 (28%)	
Urban	15 (25%)	223 (55%)	
Average annual PCI volume			
Median	134	612	<0.001
Mean ± SD	166 ± 138	745 ± 551	
<200	43 (72%)	23 (6%)	<0.001
≥200 and <400	14 (23%)	98 (24%)	
≥400	3 (5%)	284 (70%)	
Average annual primary PCI volume			
Median	32	66	<0.001
Mean ± SD	35 ± 22	78 ± 52	
≥36	25 (42%)	324 (80%)	<0.001

Two sites had missing Centers for Medicare and Medicaid Services (CMS) bed data. Primary percutaneous coronary intervention (PCI) indicates PCI performed as first-line therapy for reperfusion in the presence of ST-segment elevation myocardial infarction (STEMI), and does not include rescue or facilitated PCI or PCI for non-STEMI.

Table 3 Off-Site Capabilities Survey

Characteristic	Off-Site (n = 53)
Average travel distance to surgical facility, miles	
Mean ± SD	36 ± 59
<10	11 (21%)
≥10 and <20	18 (34%)
≥20 and <40	11 (21%)
≥40	13 (25%)
Average transit time to surgical facility, min	
Mean ± SD	25 ± 17
<10	4 (8%)
≥10 and <20	16 (30%)
≥20 and <30	19 (36%)
≥30	14 (26%)
Predominant transportation mechanism	
Ground ambulance	28 (53%)
Helicopter	11 (21%)
Fixed wing aircraft	1 (2%)
Combination of ground or air	13 (25%)
Dedicated staff and facilities for PCI	
24 h, 7 days a week	49 (92%)
Daytime during weekdays only	3 (6%)
Variable time frames	1 (2%)
Type of PCI provided	
Only primary PCI for acute MI	11 (21%)
Both primary PCI and elective PCI	42 (79%)
Only elective PCI	0 (0%)
Catheterization laboratory staff experience*	
Work only at off-site PCI center	41 (77%)
Rotate between off- and on-site PCI centers	11 (21%)
Interventional operators at facility	
Mean ± SD	5 ± 4
1	5 (9%)
2 to 3	18 (34%)
4 to 5	11 (21%)
6 or more	19 (36%)
Interventional operators' experience*	
Work only at off-site PCI center	9 (17%)
Rotate between off- and on-site PCI centers	43 (81%)

*One site did not respond.
Abbreviations as in Table 1.

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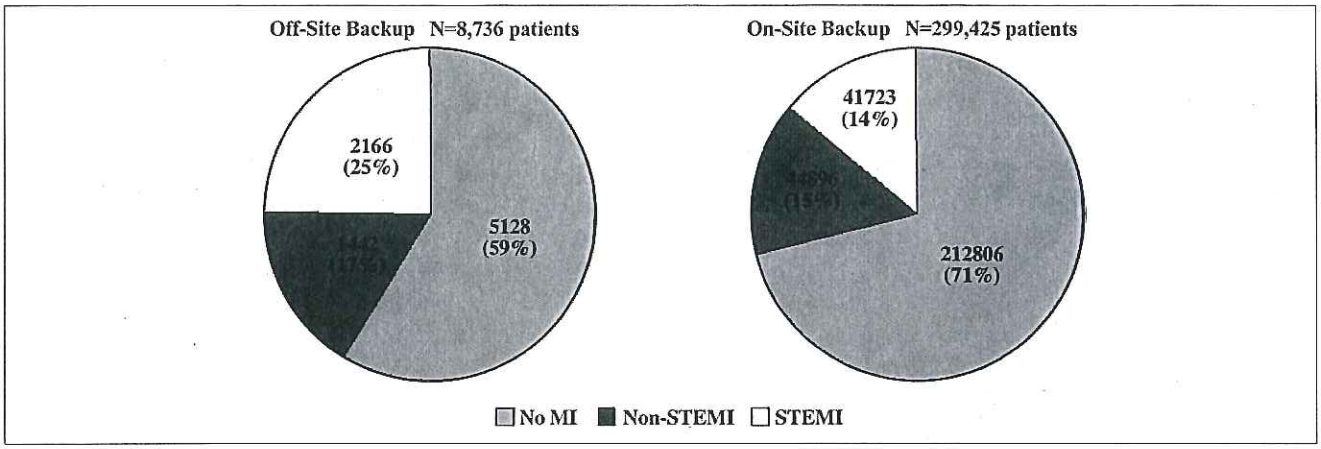
Figure 1 MI Presentation Status

Pie charts showing the relative distribution of myocardial infarction (MI) presentation within centers with on- or off-site surgical backup. **Blue areas** indicate no MI; **purple areas** indicate non–ST-segment elevation myocardial infarction (non-STEMI); **yellow areas** indicate STEMI. $p < 0.001$.



improvement initiatives and attention to the detailed measurements of true "door-to-balloon" times. Therefore, these times do not reflect the current door-to-balloon standards.

Risk-adjusted outcomes. After risk adjustment, there were no mortality differences between off- and on-site facilities among total PCI patients, primary PCI patients, nonprimary PCI patients, or patients who did not require emergency surgery (Fig. 2). There was a higher risk-adjusted odds of emergency surgery in on-site PCI centers (odds ratio: 0.60 [95% confidence interval: 0.37 to 0.98], $p = 0.042$).

A sensitivity analysis was performed comprising models that imputed missing mortality from off-site centers to 2 potential scenarios. Although the point estimate changed from 0.88 to 1.21, the confidence intervals surrounding these estimates were not statistically significant between off- and on-site facilities under either of these extreme assumptions.

Discussion

This study represents the largest and most comprehensive clinical comparison of PCI centers in the U.S. with and without cardiac surgery support on site. Despite lower annual PCI procedural volumes and more patients presenting with MI subsets, off-site PCI facilities reporting to the NCDR CathPCI Registry had similar rates of procedural success, morbidity, emergency surgery, and risk-adjusted mortality when compared with on-site PCI centers. These results persisted whether PCI was performed as primary therapy for STEMI or in a less urgent nonprimary PCI setting. In addition, the off-site Capabilities Survey in this study provided more descriptive information than has been previously reported in the literature regarding the organization and logistics of established off-site PCI programs.

It is important to contrast this study with the few large comparative reports in the literature. Wennberg et al. (16) found no difference in risk-adjusted mortality for primary PCI at facilities without surgery backup on site, but an increase in mortality for nonprimary/rescue PCI, particularly at very low-volume programs (<50 Medicare PCIs per year). Although their study had more hospitals without surgery on site (n = 178) and similar patient volumes (n = 8,168), the time period was from 1999 to 2001, and the data were derived from coded admission/discharge billing diagnoses confined to the Medicare population. In contrast, our study was based on well-defined contemporary clinical parameters and included clarification of ambiguous transfer data from the off-site PCI programs. We found no significant difference for risk-adjusted mortality between centers with and without surgery on site, in either primary or nonprimary PCI patients.

Ting et al. (17) previously reported comparable acute and long-term outcomes for both primary and elective PCI in a propensity score analysis of 1,007 cases from a PCI center without surgery on site matched to the same number of patients from a center with surgery on site. Of note, these Mayo Clinic facilities did not participate in the NCDR, and thus their patients were not included in our analysis.

Finally, in a recent report based on SCAAR (Swedish Coronary Angiography and Angioplasty Registry), Carlsson et al. (18) compared 8,838 PCI procedures from 14 PCI facilities that did not have cardiac surgery on site to 25,525 procedures from 10 PCI centers that did have surgery on site. Their analysis was adjusted for baseline variables, and demonstrated comparable 30-day and 1-year mortality and morbidity outcomes for both primary PCI and nonacute PCI. Although different variables were used in our risk-

Table 4 Observed Unadjusted Procedural Outcomes

Outcome	All PCI Patients			Primary PCI Patients			Nonprimary PCI Patients		
	Off-Site (n = 8,736)	On-Site (n = 299,425)	p Value	Off-Site (n = 1,934)	On-Site (n = 31,099)	p Value	Off-Site (n = 6,802)	On-Site (n = 268,312)*	p Value
PCI procedure success	8,194 (94)	278,844 (93)	0.010	1,756 (92)	27,909 (91)	0.139	6,438 (95)	250,923 (94)	<0.001
Total complications	567 (6.5)	18,796 (6.3)	0.399	222 (11.6)	4,104 (13.4)	0.029	345 (5.1)	14,692 (5.5)	0.150
General complications	320 (3.7)	11,629 (3.9)	0.304	144 (7.5)	2,792 (9.1)	0.021	176 (2.6)	8,837 (3.3)	0.001
Bleeding complications	261 (3.0)	7,036 (2.4)	<0.001	104 (5.4)	1,620 (5.3)	0.749	157 (2.3)	5,416 (2.0)	0.093
Vascular complications	66 (0.8)	3,198 (1.1)	0.005	14 (0.7)	344 (1.1)	0.115	52 (0.8)	2,854 (1.1)	0.017
Overall mortality	151 (1.7)	3,632 (1.2)	<0.001	97 (5.1)	1,607 (5.2)	0.869	54 (0.8)	2,025 (0.8)	0.700
Emergency CABG	26 (0.3)	1,110 (0.4)	0.271	14 (0.7)	357 (1.2)	0.091	12 (0.2)	753 (0.3)	0.107
Mortality									
Emergency CABG	3/22† (13.6)	142/1,110† (12.8)	0.907	2/12† (16.7)	59/357† (16.5)	0.990	1/10† (10.0)	83/753† (11.0)	0.918
No emergency CABG	148/8,669† (1.7)	3,488/298,293† (1.2)	<0.001	95/1,894† (5.0)	1,547/30,741† (5.0)	0.975	53/6,775† (0.8)	1,941/267,538† (0.7)	0.587
Reperfusion times (h), nontransfer patients				(n = 1,678)	(n = 19,708)				
Mean ± SD				2.1 ± 5.1	2.6 ± 8.4	<0.001			
Median				1.4	1.5				

Procedure success was defined as residual stenosis <50% with Thrombolysis In Myocardial Infarction flow grade 3 and minimal decrease in stenosis ≤20% in all lesions attempted. Total complications was defined as any of the following complications: general complications: periprocedural MI, cardiogenic shock, congestive heart failure, cerebrovascular accident, tamponade, thrombocytopenia, contrast reaction, renal failure; bleeding complications: bleeding at the access site, retroperitoneal, gastrointestinal, genitourinary, or other; vascular complications: access site occlusion, peripheral embolization, arterial dissection, arterial pseudoaneurysm, or arterio-venous fistula. Primary PCI was defined as PCI performed as first-line therapy for reperfusion in the presence of STEMI; does not include rescue or facilitated PCI or PCI for non-STEMI. Reperfusion time indicates time of arrival to facility to time of first intracoronary treatment device deployment. *14 patients not included due to missing value for variable "Acute PCI." †Clarified data.

Abbreviations as in Tables 1 and 2.

adjusted model, the in-hospital mortality/morbidity results are similar to these 2 studies.

The nonprimary PCI patient cohort in our study is not a reflection of purely elective PCI, as this group includes some patients who presented with acute coronary syndromes, NSTEMI, or after STEMI. However, the consideration of this group as "nonurgent" and a reasonable surrogate for elective PCI is consistent with the analyses done in the literature cited in the preceding text. In our study, the differentiation of patients in off-site versus on-site PCI centers into primary PCI and nonprimary PCI permitted a more comprehensive assessment and risk-adjustment analysis of the major clinical end points.

Within our study cohort, the aggregate incidence of emergency surgery was comparably low at off- and on-site PCI facilities (0.3% to 0.4%, respectively) and consistent with contemporary studies (2,3). When emergency surgery was necessary, the mortality rate was similarly high between off- (13.6%) and on-site (12.8%) facilities, and comparable to that reported in prior literature (2,3).

There have been concerns that off-site PCI facilities may tend to keep some borderline stable patients with suboptimal procedural results rather than initiate the logistics of emergency transfer to an outside surgical center. These patients may have adverse outcomes, as seems to be suggested by the aggregate unadjusted mortality rate in our study. However, in the risk-adjusted analyses, there was comparable in-hospital mortality for those off-site patients who were not transferred for emergency surgery.

Conversely, the 1.5-fold higher risk-adjusted incidence of emergency surgery at on-site PCI centers could reflect a lower threshold to opt for emergency surgery if there is any doubt about a suboptimal result, as surgery is available without the added logistics of transfer. An alternative explanation could be that on-site centers perform higher risk elective cases, as is suggested by the clinical and lesion characteristics profiles in this study. In addition, it is possible that patients may have had initial angiography at off-site facilities, found to have complex coronary anatomy and/or high-risk MI subsets with a higher predisposition to emergency surgery, then deferred and transferred to an on-site center for PCI. These complicated potential scenarios and the detailed reasons for case selection were beyond the scope of the NCDR database elements. Regardless, the increased risk-adjusted incidence of emergency surgery at on-site PCI programs did not translate into an increase in mortality.

Data from the Capabilities Survey revealed a mean transit time of 25 ± 17 min from off-site facilities. The British Cardiovascular Interventional Society has recommended a 90 min to emergency surgery standard (29).

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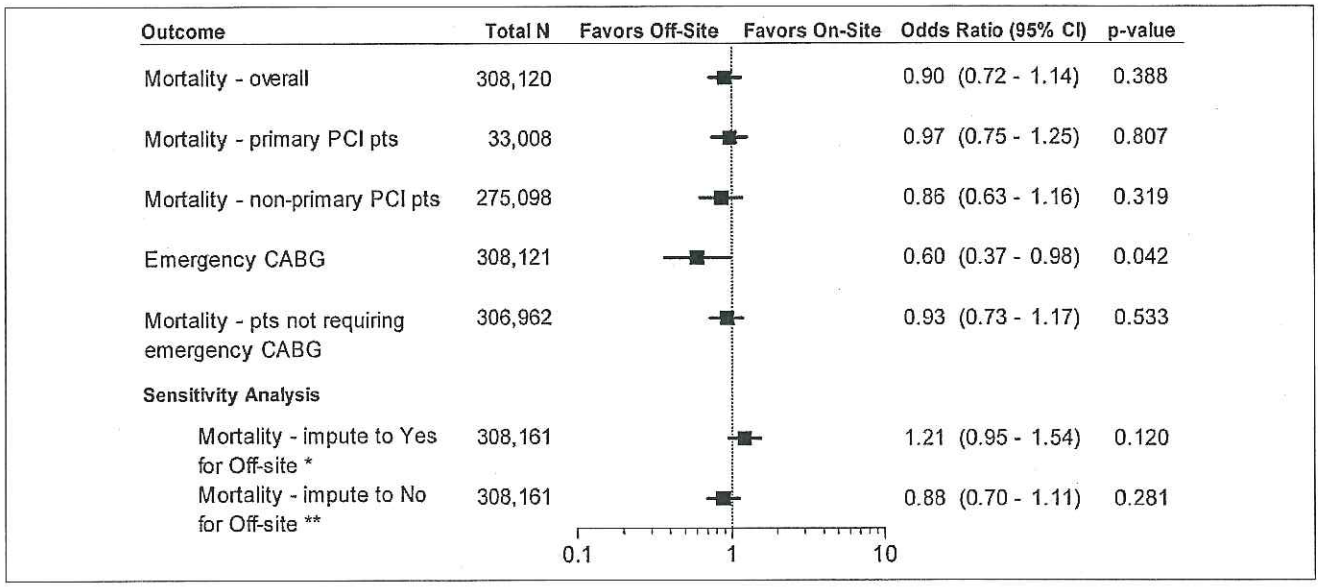
Figure 2 Risk-Adjusted Analysis of Outcomes

Odds ratio plot of risk-adjusted outcomes, including sensitivity analysis for missing mortality data. Odds ratio: outcomes for patients at off-site (vs. on-site) facilities, adjusting for within site correlations and potential confounding variables. *Worst case scenario: all patients with missing mortality data were considered to have died. **Best case scenario: all patients with missing mortality data were considered as alive. CABG = coronary artery bypass graft surgery; CI = confidence interval; PCI = percutaneous coronary intervention; pts = patients.



This includes not only the transit time, but also the total time from the initial decision to transport (including call time, transfer of patient from catheterization laboratory to vehicle, vehicle to operating suite), to the actual time of initiating cardiopulmonary bypass at the receiving surgical center. The transit time in the NCDR survey was an estimate of basic travel time and did not include the above additional time elements. However, based on the transit time, most off-site PCI programs in our study may be able to meet this global standard of 90 min by having a clear decision process and heightened logistical coordination with ambulance services and the receiving surgical center.

The demographics of the off-site centers in our study suggests these facilities conform to the stated goals of lowering geographic barriers and facilitating access to PCI, particularly for those patients presenting with STEMI (5,6). The Capabilities Survey also indicates these programs are well staffed and organized with good logistical plans. The fact that 81% of the off-site center operators rotated to an on-site PCI center suggests that most of the off-site facilities were hub-and-spoke centers staffed by large group practices. Overall, the information suggests that the off-site PCI programs in this study have demonstrated a strong commitment to the classic Donabedian triad of structure, process, and outcomes measurements (30).

Study limitations. First, this study is subject to the usual concerns regarding observational registry data. There may be an inherent bias in off-site PCI programs that are either mandated by regulatory agencies or choose on their own to participate in the NCDR. Participants in any registry may be prone to "game" the system, particularly if score carding and public disclosure is an issue.

Second, this study includes outcomes up to the time of hospital discharge. Data regarding long-term outcomes are not currently captured in the NCDR CathPCI Registry. In addition, outcomes are assessed and analyzed on an institutional level, not on an individual operator level.

Third, specific in-depth details regarding clinical presentation, case selection, procedural complications, morbidity, and mortality were sometimes beyond the purview of the basic datasets. However, a special data clarification effort was utilized to resolve the 172 of 8,736 off-site patients (2%) for whom mortality or transfer data were questioned, resulting in clarification of 154 of these patients (90%), leaving 18 of 8,736 (0.2%) not clarified. A sensitivity analysis confirmed that the unclarified data would not have affected the risk-adjusted mortality analysis results.

Fourth, although this NCDR study indicates that nonprimary PCI can be done safely at off-site facilities, the efficacy of truly elective PCI at off-site facilities can perhaps be best addressed by a large randomized prospective trial such as the C-PORT (Cardiovascular Patient Outcome Research Team) Elective Angioplasty Study, which is under way. However, such studies are difficult to conduct, and results may not be forthcoming for some time. In the interim, a comprehensive large database such as the NCDR CathPCI Registry offers a realistic and

relative contemporary quality assurance standard to monitor these issues. Based on the experiences gained with this current study, the NCDR plans to sponsor a proactive comprehensive working group of off-site PCI centers to further communicate and track outcomes. This effort will coincide with the upcoming transition to the next CathPCI database version 4.0.

Finally, a participation bias cannot be excluded. The total number of PCI centers in the U.S. that do not have surgery on site is not definitively known (22) but may number ≈250. Of these, it is estimated that one-third submit data to another peer-reviewed registry, a spoke and hub partner database, or a multicenter trial. Thus, the 60 off-site PCI facilities in this NCDR study may represent a minority of such programs in the nation and are probably in the upper tier of quality. With this perspective, the results reported here may not be applicable to all PCI centers without surgical backup on site, particularly those that do not participate in any formal data registry or clinical trial.

Conclusions

Compared with on-site PCI centers, off-site PCI programs in the NCDR were predominantly located in nonurban areas, had lower annual PCI volume, treated a higher percentage of patients who presented with subsets of MI, and had better reperfusion times in primary PCI. Off-site PCI centers had similar observed procedure success, morbidity, emergency cardiac surgery rates, and mortality in cases that required emergency surgery. The risk-adjusted mortality rates in off-site PCI facilities were comparable to those of PCI centers that had cardiac surgery on site, regardless of whether PCI was performed as primary therapy for STEMI or in a nonprimary setting.

These findings should not be extrapolated to encourage the widespread proliferation of more PCI programs without surgery on site to fulfill a political or an economic agenda. Rather, our study does confirm the safety of an off-site strategy at PCI centers where rigorous clinical, operator, and institutional criteria are in place and where data are submitted and reviewed in a comprehensive multicenter registry such as the NCDR.

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Reprint requests and correspondence: Dr. Michael A. Kutcher, Professor of Internal Medicine (Cardiology), Wake Forest University School of Medicine, Medical Center Boulevard, Winston-Salem, North Carolina 27157-1045. E-mail: mkutcher@wfubmc.edu.

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Key Words: percutaneous coronary intervention ■ cardiac surgery ■ outcomes analysis.

APPENDIX

For supplemental NCDR information, please see the online version of this article.

ATTACHMENT IV

The Burden of Cardiovascular Diseases in Connecticut –
2010 Surveillance Report
March 2011

The Burden of Cardiovascular Diseases in Connecticut

2010 Surveillance Report

March 2011

State of Connecticut
Department of Public Health
410 Capitol Avenue
P.O. Box 340308
Hartford, CT 06134-0308

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Prepared by
Stephanie M. Poulin, MPH, MT(ASCP) and Margaret M. Hynes, PhD, MPH
Connecticut Department of Public Health
Health Information Systems and Reporting Section
Surveillance and Reporting Unit

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EXECUTIVE SUMMARY

- Cardiovascular diseases (CVD) are a great public health concern. CVD account for about one-third of all Connecticut resident deaths. Coronary heart disease (CHD), cerebrovascular disease (stroke) and heart failure (HF) are the main types, accounting for 48%, 15%, and 8% respectively of all CVD deaths.

- The CVD, CHD, and stroke age-adjusted mortality rates of Connecticut residents decreased significantly between 1999 and 2008.

- Approximately 55% of all Connecticut resident CVD deaths are among females. However, males have significantly higher age-adjusted CVD mortality rates (2006-2008 data).

- Black Connecticut residents have the highest age-adjusted CVD mortality rate as well as higher age-adjusted CVD, CHD, and stroke premature mortality rates compared with White and Hispanic residents (2006-2008 data).

- Hispanic Connecticut residents have significantly lower age-adjusted CVD and CHD mortality rates than White residents (2006-2008 data).

- About 18% of all hospital discharges in Connecticut are due to CVD. Approximately 26% of CVD hospitalizations are due to CHD, 12% to stroke, and 18% to HF (2008 data).

- Connecticut male residents have higher age-adjusted rates of hospitalizations for CVD, CHD, stroke, and HF than female residents. Black Connecticut residents have higher rates of hospitalizations for CVD, stroke, and HF than White and Hispanic residents (2008 data).

- About $2.2 billion was billed for CVD hospitalizations in Connecticut in 2008. Approximately 34% of CVD charges are for CHD, 12% for stroke, and 12% for HF. CVD also incur enormous indirect costs.

- Risk factors for CVD may be modifiable or non-modifiable. Key modifiable risk factors are high blood pressure, high blood cholesterol, smoking, diabetes, obesity, and physical inactivity. Non-modifiable risk factors include increasing age and family history of heart disease and stroke.

- High blood pressure (HBP) is a major risk factor for heart attack and stroke. About 27% of Connecticut adults have HBP. Connecticut males are more likely than females to have HBP. About 25% of White, 36% of Black, and 22% of Hispanic adults in Connecticut have HBP. Also, Connecticut adults with lower annual household incomes are more likely to have HBP compared to adults with higher annual household incomes (2007-2009 data).

- High blood cholesterol (HBC) is a major risk factor for CHD. About 38% of Connecticut adults have HBC. Connecticut males are more likely than females to have HBC. The prevalence of HBC increases with age. Black and Hispanic Connecticut adults are less likely than White adults to have had their blood cholesterol tested. Connecticut adults with lower annual household incomes are less likely than adults with higher annual household incomes to have had their blood cholesterol tested (2007-2009 data).

- Cigarette smoking increases the risk of heart attack, stroke, and death from CHD. About 16% of Connecticut adults are current smokers. Current adult smokers are more likely to be younger, have lower annual household incomes, and be less educated. Among adults, smoking rates do not vary significantly by gender or race and ethnicity (2007-2009 data). According the 2009 Connecticut School Health Survey, 15.3% of high school students are current smokers. White high school students are more likely than Black and Hispanic students to be current smokers.

- Diabetes has been recognized as a major risk factor for CVD. An estimated 6.9% of Connecticut adults have diagnosed diabetes. Connecticut males are more likely to have diabetes than females. Also, high rates of diabetes are associated with older age, lower socioeconomic position, and racial and ethnic minority status. About 5.6% of White, 14.9% of Black, and 10.5% of Hispanic adults in Connecticut have diabetes (2007-2009 data).

- Obesity is an independent risk factor for CVD. An estimated 10.4% of high school students in Connecticut are obese. High school males are more likely to be obese than females and Hispanic students are more likely to be obese than White and Black students (2009 data). Approximately 21% of Connecticut adults are obese. Older adults are more likely to be obese than younger adults; males are more likely to be obese than females; and those with lower annual household incomes are more likely to be obese than those with higher annual household incomes. Also, Black and Hispanic adults are more likely to be obese than White adults (2007-2009 data).

- Physical inactivity is associated with an increased risk of a number of chronic health conditions including CHD, high blood pressure, and obesity. Approximately 47% of Connecticut adults participate in less than the recommended amount of physical activity. Older adults, females, and adults with lower annual household incomes have higher rates of physical inactivity. About 44.5% of White, 59.7% of Black, and 54.2% of Hispanic Connecticut adults are physically inactive (2007-2009 data).

- The co-prevalence of risk factors places an individual at elevated risk for CHD and stroke. About 42% of Connecticut adults have two or more modifiable risk factors for CVD (2007-2009 data).

- Early recognition of the signs and symptoms of heart attack and stroke increase the likelihood of immediate emergency transport to the hospital and timely medical care. Only 13.6% of Connecticut adults can identify all the proper heart attack signs and only 22.6% can identify all the proper stroke signs. Women tend to be more knowledgeable than men about the signs and symptoms of heart attack and stroke (2007-2009 data).

- Access to health care is crucial to the prevention, treatment, and management of CVD. About 9% of adults in Connecticut do not have health insurance. Approximately 6% of White, 21% of Black, and 30% of Hispanic adults in Connecticut do not have health insurance (2007-2009).

- Targeted public health interventions are warranted for all Connecticut residents with multiple risk factors. Special emphasis should be placed on evidence-based interventions that address risk factor reduction among Black, Hispanic, and lower-income Connecticut adults.

THE BURDEN OF CARDIOVASCULAR DISEASES IN CONNECTICUT

INTRODUCTION

Cardiovascular disease refers to a wide variety of heart and blood vessel diseases. The most common forms of cardiovascular disease are coronary heart disease (CHD) and cerebrovascular disease. Essential hypertension, heart failure (HF), and atherosclerosis are other common cardiovascular diseases (CVD).[1] CVD are of great public health concern because more than one-third of all deaths in Connecticut are due to CVD and because prevention efforts have shown great potential in reducing the morbidity, mortality, and disability of CVD.[2, 3]

MORTALITY

CVD accounted for 9,351 Connecticut resident deaths in 2008, or about 33% of all deaths for the period. In contrast, cancer deaths accounted for 24%; chronic lower respiratory disease, 5%; unintentional injuries, 5%; and diabetes, 2% of all Connecticut resident deaths (Table 1).[3]

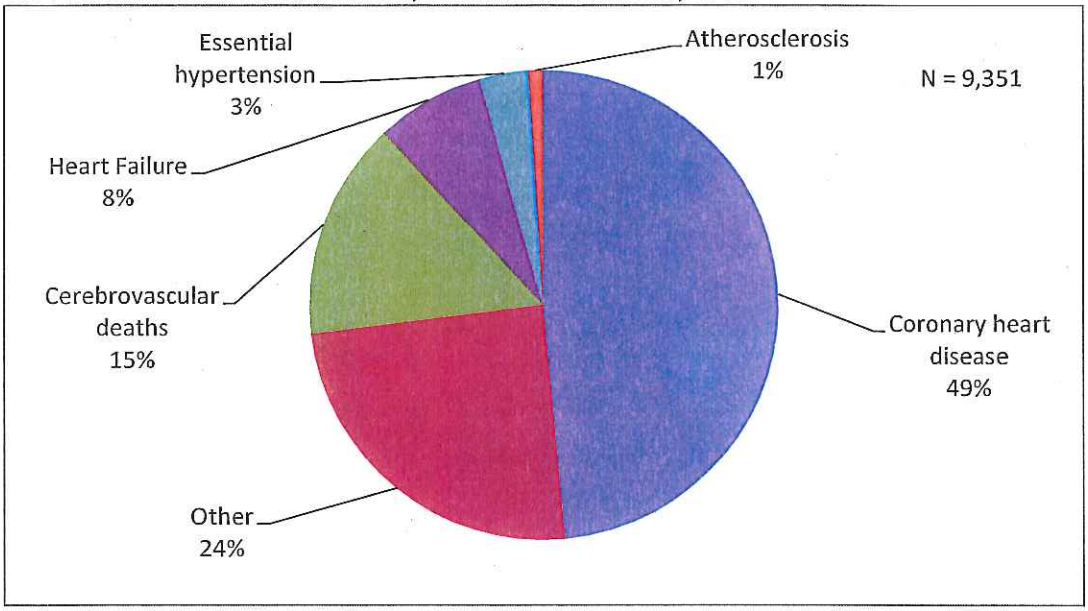
Table 1. Connecticut Resident Deaths, 2008

Cause of Death	Number of Deaths	Percent of Deaths
All Causes	28,749	100%
Cardiovascular Disease	9,351	33%
Cancer	6,765	24%
Chronic Lower Respiratory Disease	1,494	5%
Unintentional Injury	1,362	5%
Alzheimer's Disease	831	3%
Pneumonia and Influenza	688	2%
Diabetes	618	2%

Source: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

The major CVD are CHD and cerebrovascular disease or "stroke". Stroke is the most severe clinical manifestation of cerebrovascular disease, and the terms are used interchangeably in this report.[4] CHD accounts for 49% of all CVD deaths and includes hypertensive heart disease and ischemic heart disease (2008 data). Stroke is responsible for about 15% of CVD deaths in Connecticut, and includes two major types - ischemic stroke and hemorrhagic stroke. HF accounts for 8% of all CVD deaths, while essential hypertension and atherosclerosis account for 4% of all CVD deaths in Connecticut (Figure 1).[3]

Figure 1. Cardiovascular Disease Deaths, Connecticut Residents, 2008

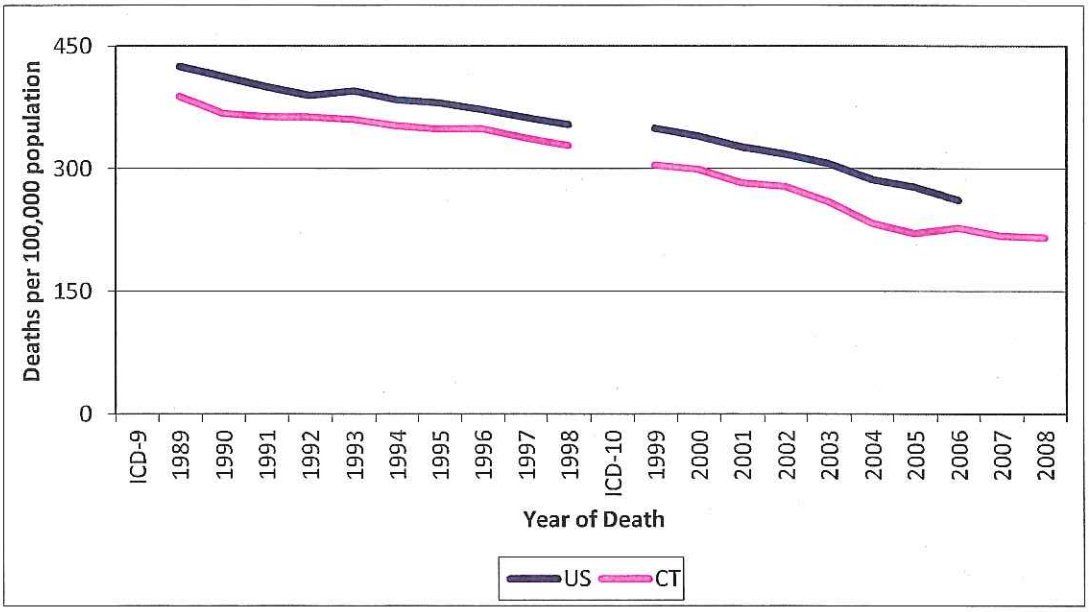


Sources: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

Trends in Age-adjusted Mortality

Since the 1990s, CVD and CHD mortality rates* have decreased significantly for all Connecticut residents.[5, 6] This continuing decrease in Connecticut CVD and CHD mortality rates mirrors a similar decline in CVD and CHD mortality rates nationwide.[7] CVD and CHD mortality rates for Connecticut residents have been consistently lower than those for the United States population (Figure 2 and Figure 3).[3, 7] Since 2001, the Connecticut resident CHD mortality rate has been below the *Healthy People 2010* target of 166 per 100,000 population (Figure 3). There is no *Healthy People 2010* target for CVD.[8]

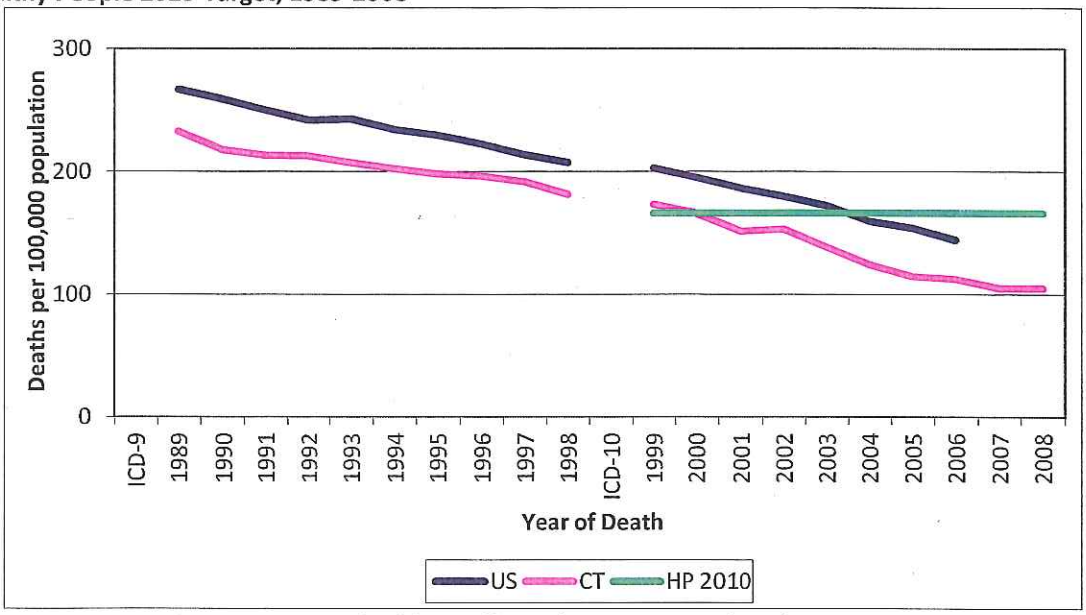
Figure 2. Age-adjusted Mortality Rates for Cardiovascular Disease, Connecticut & United States, 1989-2008



Sources: Connecticut Department of Public Health, Vital Statistics Mortality Files, 2010. Centers for Disease Control and Prevention, 2010. Note: Rates are adjusted to the 2000 US standard population. Classification includes deaths with ICD-9 codes: 390-459.9 (1989 to 1998); ICD-10 codes: I00-I78.9 (1999 to 2008).

* The mortality rates presented in this report are age-adjusted mortality rates (AAMR). The AAMRs were computed by the direct method using the 2000 U.S. standard million population. The AAMRs were calculated using the death records of Connecticut residents.

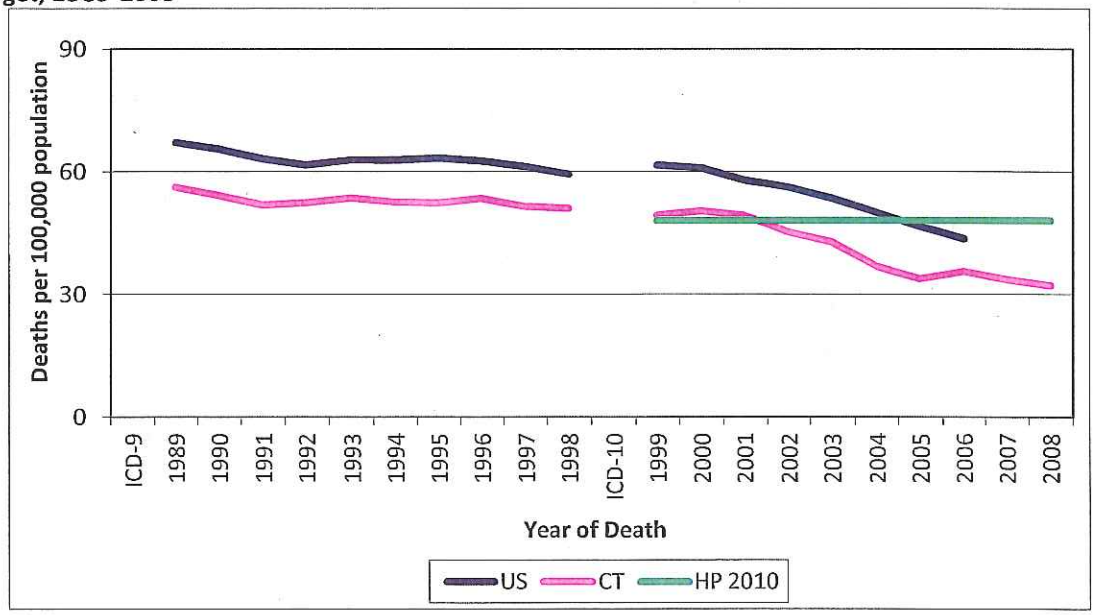
Figure 3. Age-adjusted Mortality rates for Coronary Heart Disease, Connecticut, United States, & Healthy People 2010 Target, 1989-2008



Source: Connecticut Department of Public Health, Vital Statistics Mortality Files, 2010. Centers for Disease Control and Prevention, 2010. Note: Rates are adjusted to the 2000 US standard population. Classification includes deaths with ICD-9 codes: 402,410-414, 429.2 (1989 to 1998); ICD-10 codes: I11, I20-25 (1999 to 2008).

Stroke mortality rates of Connecticut residents did not change significantly in the 1990s.[5] However, decreasing trends have been observed since 1999.[6] Connecticut resident mortality rates from stroke have been consistently lower than those of the U.S.[7] Since 2002, the Connecticut resident stroke mortality rate has been below the *Healthy People 2010* target of 48 per 100,000 population (Figure 4).[3, 8]

Figure 4. Age-adjusted Mortality Rates for Stroke, Connecticut, United States, & Healthy People 2010 Target, 1989-2008

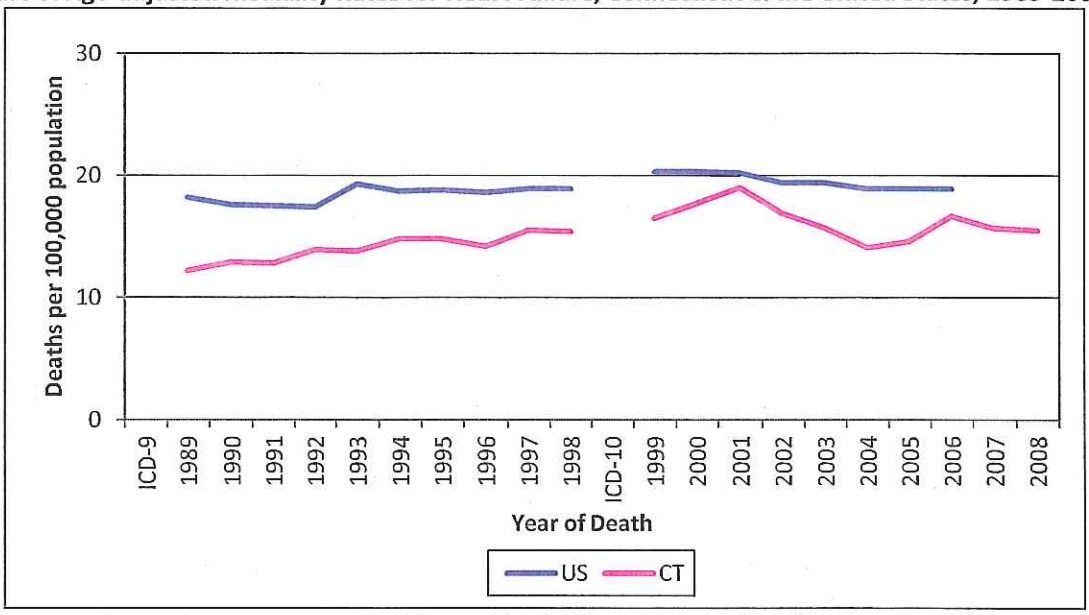


Sources: Connecticut Department of Public Health, Vital Statistics Mortality Files, 2010. Centers for Disease Control and Prevention, 2010. Note: Rates are adjusted to the 2000 US standard population. Classification includes deaths with ICD-9 codes: 430-438 (1989 to 1998); ICD-10 codes: I60-69 (1999 to 2008).

During the 1990s, the Connecticut resident HF mortality rates increased significantly.[5] The increase in the HF mortality rates throughout the 1990s has been attributed to more people surviving heart attacks experienced earlier in life and to the aging population.[1] Approximately 60% of all HF deaths in Connecticut occur in persons aged 85 or older. In contrast, 45% of all CHD deaths and 49% of all cerebrovascular disease deaths occur in persons 85 and older.[7] The 2006-2008 Connecticut resident HF mortality rate was significantly lower than the 1999-2001 rate [data not shown]; however, linear trend analyses of HF mortality rates did not show a statistically significant change ($p \leq 0.05$) for the period 1999-2008.[3,6]

Connecticut HF mortality rates have been consistently lower than those of the U.S.[3,7] There is no *Healthy People 2010* target for HF (Figure 5).[8]

Figure 5. Age-adjusted Mortality Rates for Heart Failure, Connecticut & the United States, 1989-2008



Sources: Connecticut Department of Public Health, Vital Statistics Mortality Files, 2010. Centers for Disease Control and Prevention, 2010. Note: Rates are adjusted to the 2000 US standard population. Classification includes deaths with ICD-9 code: 428.0 (1989 to 1998); ICD-10 code: 150.0 (1999 to 2008).

Mortality by Gender

Approximately 55% of all Connecticut resident CVD deaths are among females (2006-2008 data). While more females than males die from CVD in Connecticut, males have higher CVD mortality rates (Table 2). Connecticut males have a 45% higher mortality rate due to CVD compared with females, a 71% higher mortality rate due to CHD, and a 30% higher mortality rate due to HF ($p<0.001$ for all comparisons). The stroke mortality rates of Connecticut males and females do not differ significantly.[3]

Table 2. Cardiovascular Diseases Deaths and Age-adjusted Mortality Rates (AAMR) per 100,000 Population, Connecticut Residents, 2006-2008

Cause of Death	All		Male		Female	
	Deaths	AAMR	Deaths	AAMR	Deaths	AAMR
All Cardiovascular Diseases	28,369	219.7	12,889	266.8	15,480	184.4
Coronary Heart Disease	13,840	107.4	6,874	141.3	6,966	82.7
Stroke	4,385	33.8	1,646	34.5	2,739	32.6
Heart failure	2,139	16.0	863	18.6	1,276	14.4

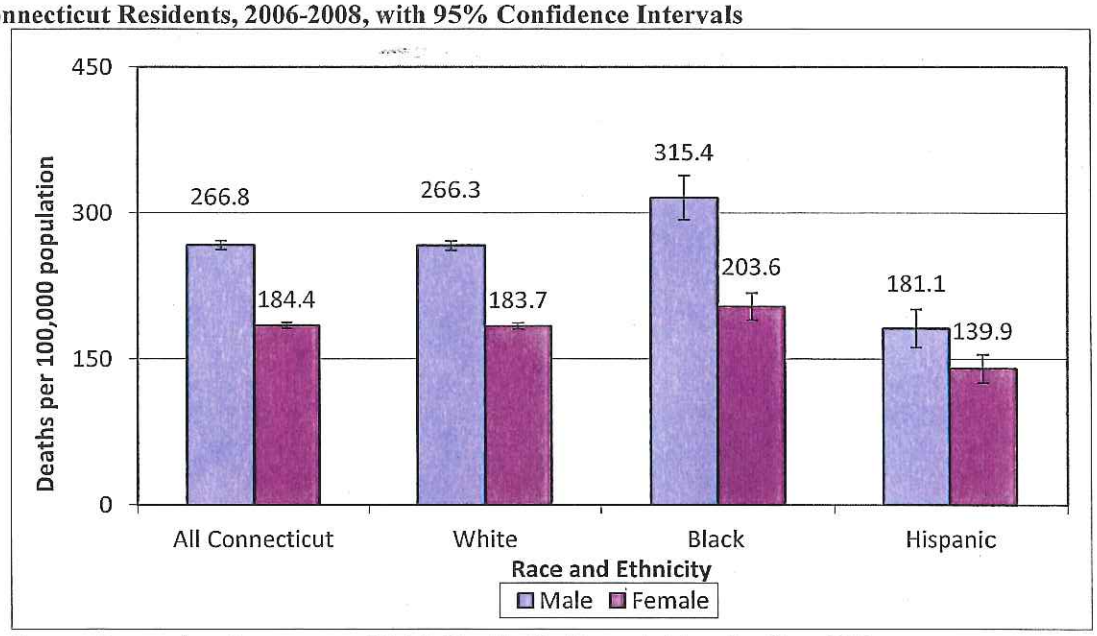
Source: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

Mortality by Gender, Race and Ethnicity

Cardiovascular Disease

The Connecticut resident CVD mortality rates differ by gender, race and ethnicity[†] with Black Connecticut residents having the highest CVD mortality rates (2006-2008 data). The CVD mortality rates of Black males and females are significantly higher than those of White males ($p<0.001$) and females ($p<0.05$), respectively. Black males and females also have significantly higher CVD mortality rates compared with Hispanic males and females ($p<0.001$ for both comparisons).[3] Conversely, Hispanic males and females have significantly lower mortality rates due to CVD than White males and females ($p<0.001$ for both comparisons) [Figure 6].[3] CVD mortality rates declined significantly for all subpopulation groups between 1999-2001 and 2006-2008 ($p<0.001$ for White and Black males and females; $p<0.005$ for Hispanic males; $p<0.01$ for Hispanic females) [data not shown].[3]

Figure 6. Age-adjusted Mortality Rates for Cardiovascular Disease by Gender, Race and Ethnicity, Connecticut Residents, 2006-2008, with 95% Confidence Intervals



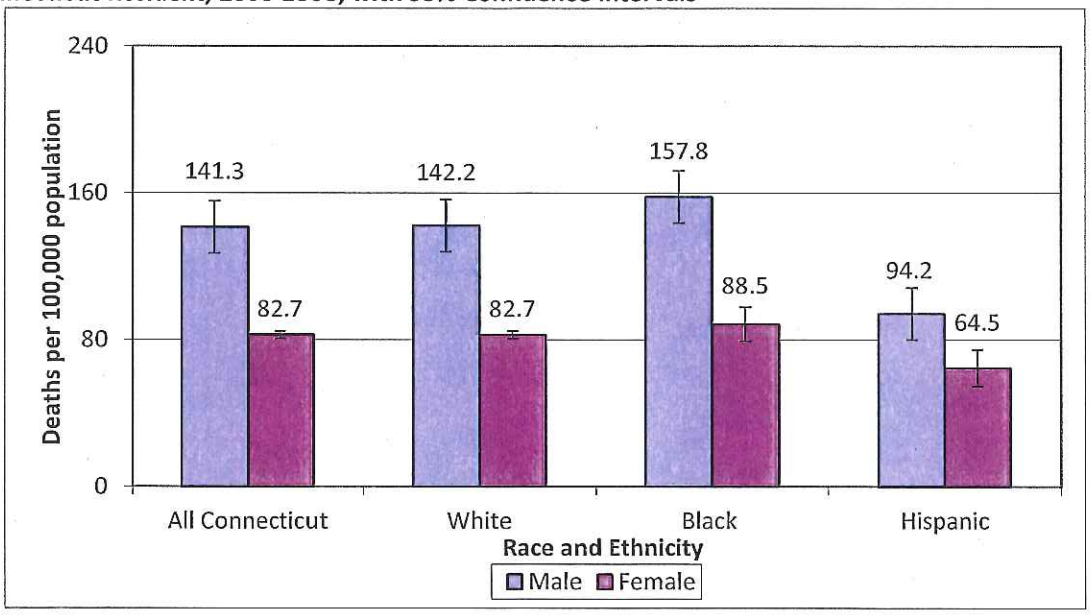
Source: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

[†] Throughout this report racial groupings (e.g., "Black", "White") exclude persons of Hispanic ethnicity. A Hispanic ethnicity category is included in figures and tables reflecting data separate from race categories. Therefore, the modifier "non-Hispanic" is assumed.

Coronary Heart Disease

The CHD mortality rates differ somewhat by gender, race and ethnicity (2006-2008 data). Hispanic males and females have significantly lower CHD mortality rates than White males and females as well as Black males and females ($p < 0.001$ for males; $p<0.005$ for females) [Figure 7].[3] The CHD mortality rates of White males and females do not differ significantly from the rates of Black males and females (Figure 7).[3] CHD mortality rates declined significantly for all subpopulation groups in Connecticut between 1999-2001 and 2006-2008 ($p<0.01$ for Hispanic females; $p<0.001$ for other comparisons) [data not shown].[3]

Figure 7. Age-adjusted Mortality Rates for Coronary Heart Disease by Gender, Race and Ethnicity, Connecticut Resident, 2006-2008, with 95% Confidence Intervals

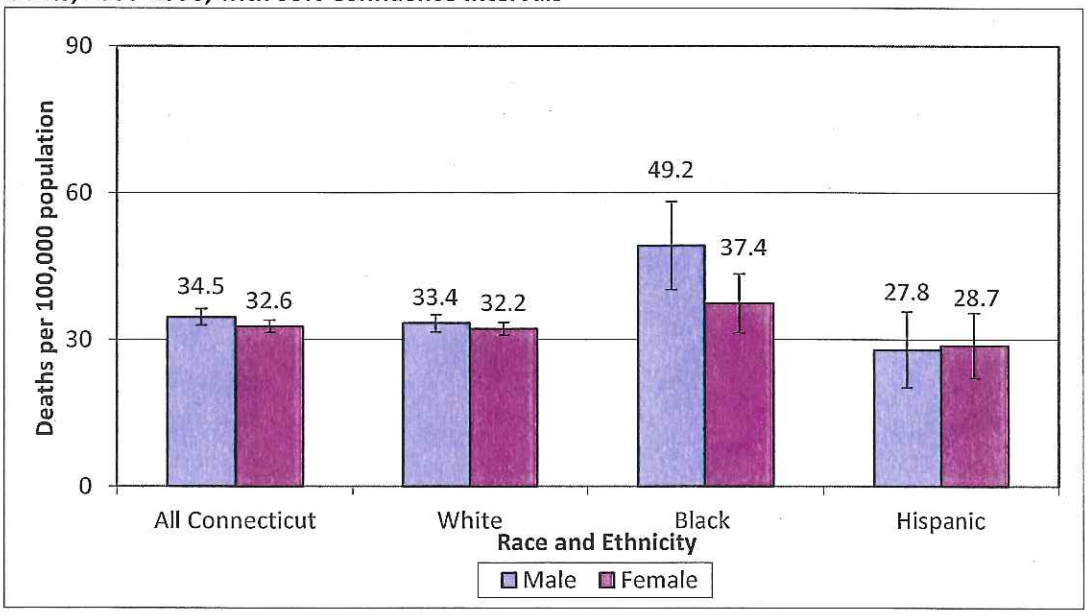


Source: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

Stroke

Stroke mortality rates differ somewhat by gender, race and ethnicity (2006-2008). Black males have a significantly higher stroke mortality rate than White ($p<0.005$) and Hispanic males ($p<0.05$) [Figure 8].[3] However, the stroke mortality rates for Hispanic and White males do not differ significantly.[3] Likewise, the stroke mortality rates for White, Black, and Hispanic females do not differ significantly (Figure 8).[3] Stroke mortality rates declined significantly for White males ($p<0.001$), White females ($p<0.001$) and Black females ($p<0.005$) between 1999-2001 and 2006-2008 [data not shown].[3]

Figure 8. Age-adjusted Mortality Rates for Stroke by Gender, Race and Ethnicity, Connecticut Residents, 2006-2008, with 95% Confidence Intervals

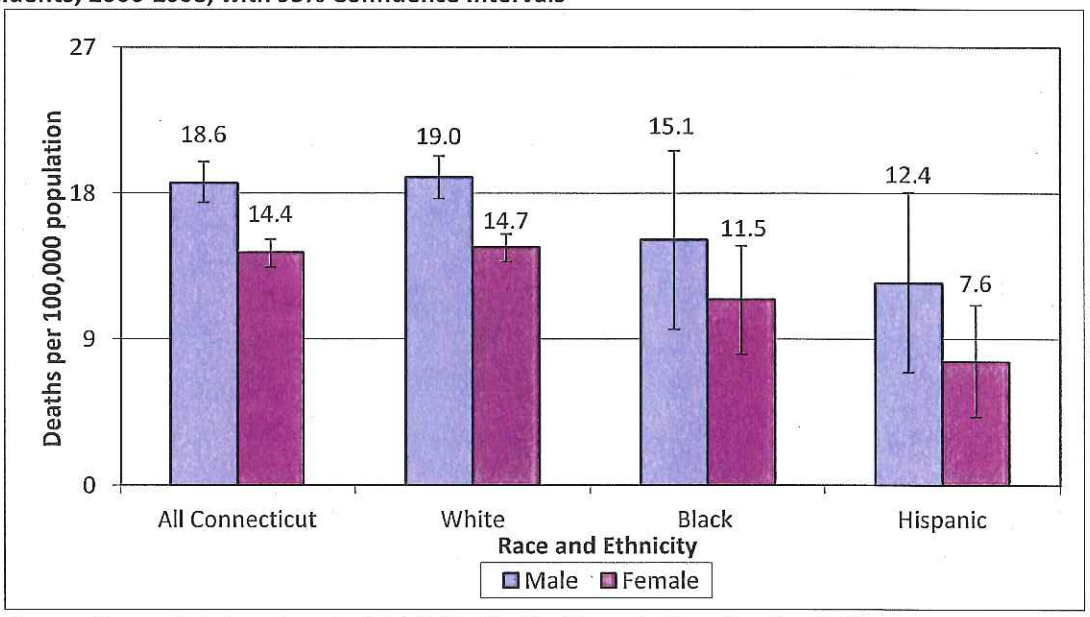


Source: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

Heart failure

HF mortality rates vary little by gender, race and ethnicity (2006-2008 data). While the HF mortality rate of White females is significantly higher than the rate of Hispanic females ($p<0.005$), the HF mortality rate of White and Black females does not differ significantly [Figure 9].[3] The difference in the mortality rates of Black and Hispanic females does not reach statistical significance.[3] Also, the HF mortality rates of White, Black, and Hispanic males do not differ significantly [Figure 9].[3] White females and the overall Black Connecticut population experienced a statistically significant decline in the HF mortality rate between 1999-2001 and 2006-2008 ($p<0.05$ for both comparisons) [data not shown].[3]

Figure 9. Age-adjusted Mortality Rates for Heart Failure by Gender, Race and Ethnicity, Connecticut Residents, 2006-2008, with 95% Confidence Intervals



Source: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

Premature Mortality by Gender, Race and Ethnicity

Premature mortality[‡], defined as the "years of potential life lost before age 75," focuses on deaths that occur at younger ages. For example, a person who dies at age 45 is considered to have lost 30 years of life, and a person who dies at 70 is considered to have lost 5 years of life.[9] Premature mortality is important because it emphasizes the years of productive life that are lost to society.

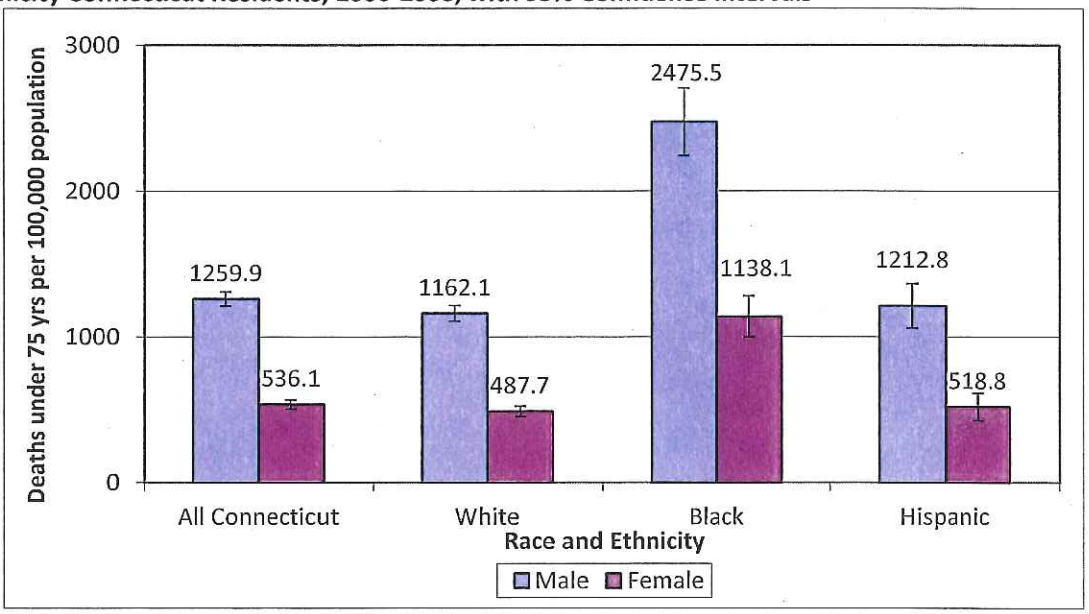
Cardiovascular Disease

CVD premature mortality rates differ by race and ethnicity as well as gender (2006-2008 data). Black males and females have significantly higher CVD premature mortality rates compared with White and Hispanic males and females ($p < 0.001$ for all comparisons) [Figure 10].[3] However, the CVD premature mortality rates of White males and females do not differ significantly from the rates of Hispanic males and females.[3] Also, males have significantly higher CVD premature mortality rates than females ($p<0.001$) (Figure 10).[3]

The CVD premature mortality rate declined significantly for the overall Connecticut population between 1999-2001 and 2006-2008 ($p<0.001$) [data not shown]. Similarly, CVD premature mortality rates declined significantly for White males ($p<0.001$), White females ($p<0.001$), Black females ($p<0.001$), Hispanic males ($p<0.05$), and Hispanic females ($p<0.05$) [data not shown]. CVD premature mortality rates for Black males did not change significantly from 1999-2001 to 2006-2008 [data not shown].[3]

[‡] The premature mortality rates presented in this report are age-adjusted "Years of Potential Life Lost (YPLL) under 75 years". Age-adjusted rates were computed by the direct method using the 2000 U.S. standard million population and Connecticut resident death records.

Figure 10. Age-adjusted Premature Mortality Rates for Cardiovascular Disease by Gender, Race and Ethnicity Connecticut Residents, 2006-2008, with 95% Confidence Intervals



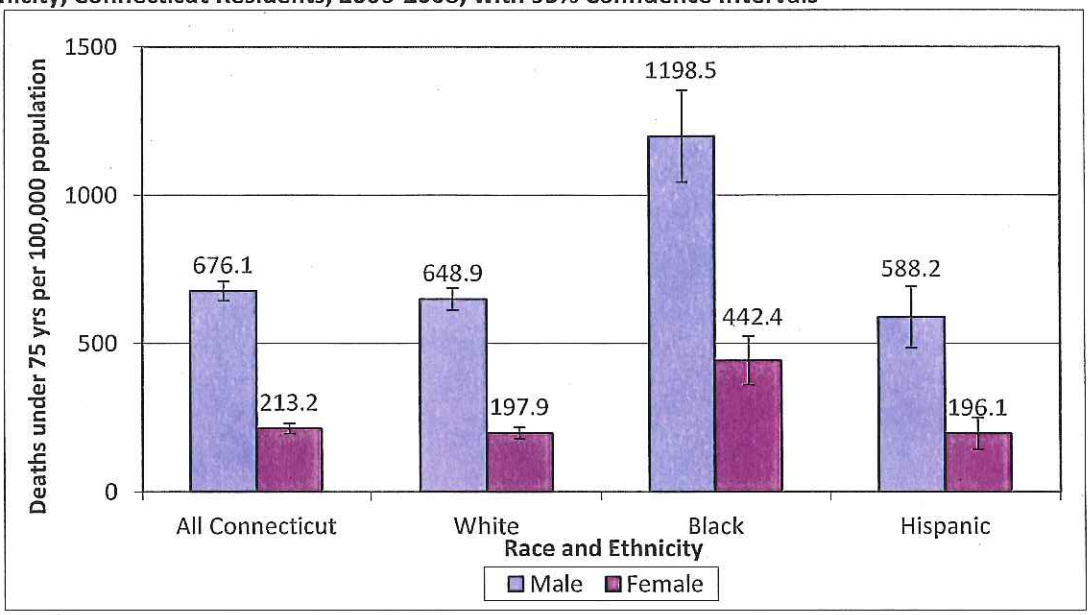
Source: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

Coronary Heart Disease

CHD premature mortality rates differ by race, ethnicity, and gender (2006-2008 data). The CHD premature mortality rates of Black males and females are significantly higher than those of White and Hispanic males and females ($p<0.001$ for all comparisons) [Figure 11].[3] However, the CHD premature mortality rates of White and Hispanic residents do not differ significantly.[3] Also, males have a significantly higher CHD premature mortality rate than females ($p<0.001$) [Figure 11].[3]

The CHD premature mortality rate declined significantly for the overall Connecticut population between 1999-2001 and 2006-2008 ($p<0.001$) [data not shown]. Similarly, CHD premature mortality rates declined significantly for all subpopulation groups (White males, $p<0.001$; White females $p<0.001$; Black males, $p<0.05$; Black females, $p<0.001$; Hispanic males, $p<0.005$; and Hispanic females, $p<0.05$) [data not shown].[3]

Figure 11. Age-adjusted Premature Mortality Rates for Coronary Heart Disease by Gender, Race and Ethnicity, Connecticut Residents, 2006-2008, with 95% Confidence Intervals



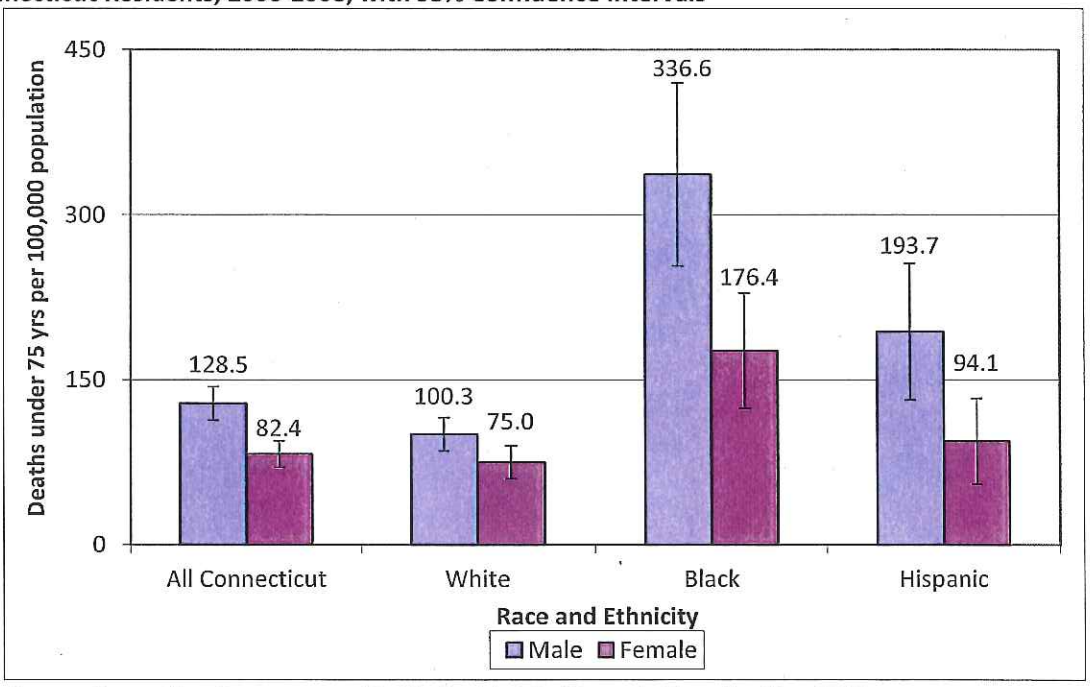
Source: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

Stroke

Stroke premature mortality rates vary by gender, race and ethnicity (2006-2008 data). Overall, males have a significantly higher stroke premature mortality rate than females ($p<0.005$) [Figure 12].[3] The stroke premature mortality rates of Black and Hispanic males are significantly higher than that of White males ($p<0.001$ for Black and White male comparison; $p<0.05$ for Hispanic and White male comparison) [Figure 12].[3] However, the stroke premature mortality rates of Hispanic and Black males do not differ significantly.[3] While Black females have a significantly higher stroke premature mortality rate than White females ($p<0.005$), the stroke premature mortality rates of Hispanic and White females are not statistically different [Figure 12].[3] Also, the stroke premature mortality rates of Black and Hispanic females do not differ significantly.[3]

The stroke premature mortality rate declined significantly for the overall Connecticut population ($p<0.005$), White males ($p<0.05$), and White females ($p<0.05$) between 1999-2001 and 2006-2008 ($p<0.005$) [data not shown]. The decline in the stroke premature mortality rates for Black and Hispanic males and females do not reach statistical significance (data not shown).[3]

Figure 12. Age-adjusted Premature Mortality Rates for Stroke by Gender, Race and Ethnicity, Connecticut Residents, 2006-2008, with 95% Confidence Intervals

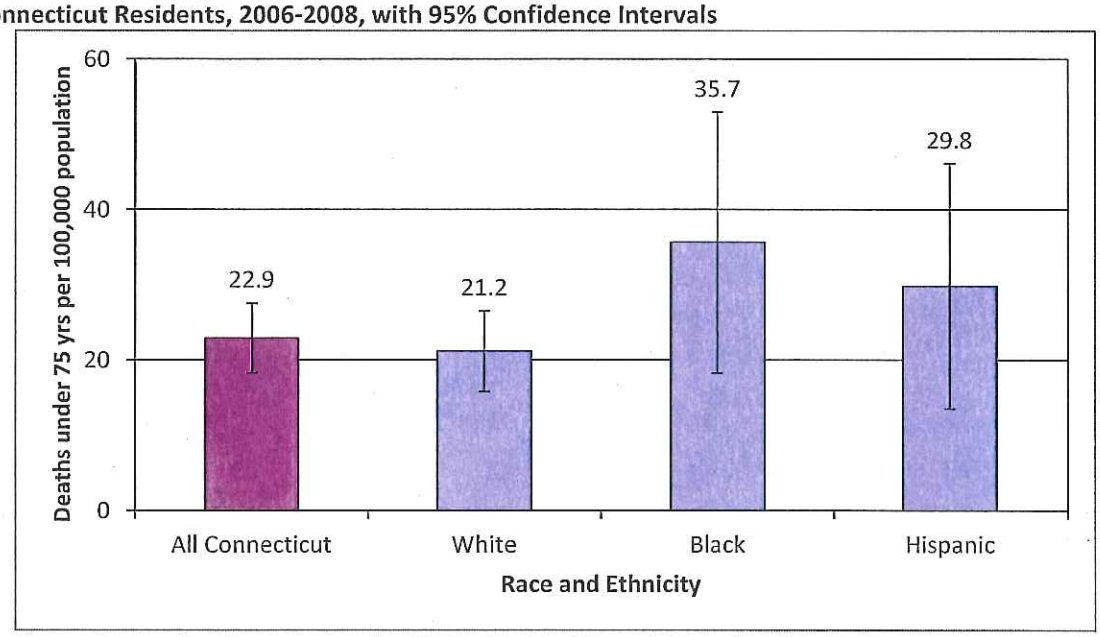


Source: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

Heart failure

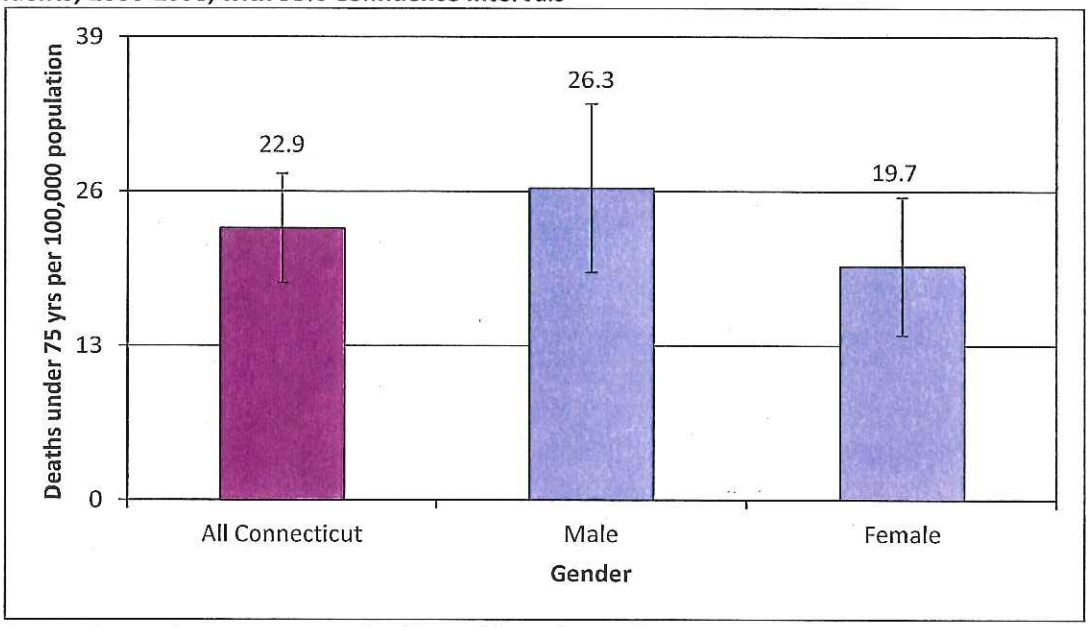
The Connecticut resident HF premature mortality rate does not differ significantly by gender or race and ethnicity (Figure 13 and Figure 14) [2006-2008 data].[3] HF premature mortality rates did not decline significantly between 1999-2001 and 2006-2008 [data not shown].[3]

Figure 13. Age-adjusted Premature Mortality Rates for Heart Failure by Gender, Race and Ethnicity, Connecticut Residents, 2006-2008, with 95% Confidence Intervals



Source: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

Figure 14. Age-adjusted Premature Mortality Rates for Heart Failure by Gender, Connecticut Residents, 2006-2008, with 95% Confidence Intervals



Source: Connecticut Department of Public Health, Vital Records Mortality Files, 2010.

MORBIDITY

There were 59,664 Connecticut resident discharges from Connecticut hospitals for all CVD in 2008. This represents 18% of all hospital discharges (excluding pregnancy and childbirth related discharges) and 23% of all hospital billing charges in the state.[10] Approximately 26% of all CVD discharges are due to CHD, 12% are for stroke, and 18% are for HF. The median length of stay for CHD, stroke, and HF is two, three, and four days, respectively. The median length of stay for all hospital discharges in Connecticut is three days.[10]

Hospitalizations by Gender

Hospitalization rates[§] vary by gender (2008 data). Males have significantly higher rates of hospitalizations for all CVD, CHD, stroke, and HF compared with females ($p < 0.001$). More females than males, however, are hospitalized for stroke and HF [Table 3].[10]

Table 3. Hospitalizations and Age-adjusted Hospitalization Rates (AAHR) for Cardiovascular Diseases per 100,000 Population, Connecticut Residents by Gender, 2008

Diagnostic Group	All		Male		Female	
	Discharges	AAHR	Discharges	AAHR	Discharges	AAHR
All Cardiovascular Diseases	59,664	1,483.1	31,748	1,862.9	27,916	1,184.1
Coronary Heart Disease	15,779	392.0	9,877	559.2	5,902	254.2
Stroke	7,413	183.6	3,626	216.1	3,787	158.1
Heart failure	10,725	259.9	5,331	326.8	5,394	213.8

Source: Connecticut Department of Public Health, Connecticut Hospital Discharge Abstract and Billing Data Base, 2010.

[§]Hospitalization rates were calculated using 2008 Connecticut resident hospitalization discharge data and were age-adjusted based on the 2000 U.S. standard million population.

Hospitalization Rates by Race and Ethnicity

Hospitalization rates differ by race and ethnicity (2008 data). Black residents have significantly higher rates of hospitalizations for CVD, stroke, and HF than both White and Hispanic residents ($p<0.001$ for all comparisons). Black residents' rate of hospitalizations for CHD, however, is not significantly different than that of White and Hispanic residents.[10] Hispanic residents have significantly higher hospitalization rates for CVD ($p<0.001$) and CHD ($p<0.01$) than White residents. In contrast, Hispanic residents have a significantly lower rate of hospitalization for HF compared with White residents ($p<0.05$). Furthermore, the rates of hospitalization for stroke of Hispanic and White residents are not significantly different (Table 4).[10]

Table 4. Hospitalizations and Age-adjusted Hospitalization Rates (AAHR) for Cardiovascular Diseases per 100,000 Population, Connecticut Residents by Race and Ethnicity, 2008

Diagnostic Group	All		White, non-Hispanic		Black, non-Hispanic		Hispanic	
	Discharges	AAHR	Discharges	AAHR	Discharges	AAHR	Discharges	AAHR
All Cardiovascular Diseases	59,664	1,483.1	48,395	1,380.4	5,555	2,114.2	3,667	1,713.6
Coronary Heart Disease	15,779	392.0	13,106	378.2	992	375.9	954	427.2
Stroke	7,413	183.6	6,033	170.5	700	270.5	403	195.7
Heart failure	10,725	259.9	8,568	231.0	1,185	463.9	731	390.1

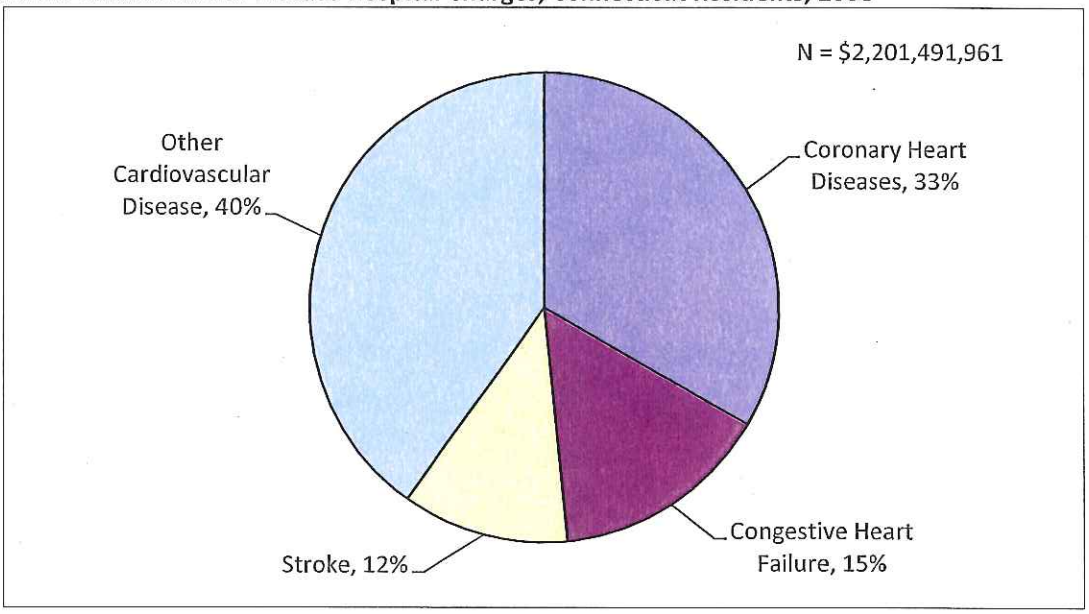
Source: Connecticut Department of Public Health, Connecticut Hospital Discharge Abstract and Billing Data Base, 2010.

Economic Costs

The estimated national annual cost for the medical management of CVD was $503.2 billion in 2010, or about $1600 per person.[2] This estimate includes direct medical costs and indirect costs. The indirect cost of CVD is associated with lost productivity from illness and premature death. Also, CVD are major causes of disability, limiting an individual's ability to live independently and negatively impacting the quality of life for individuals and families. For these reasons, CVD can incur enormous indirect costs. Assuming that disease rates and per person costs are the same in Connecticut as they are nationwide, the estimated economic burden of CVD in the state is about $5.8 billion. A large portion of these costs is attributable to inpatient hospitalizations.

Total Connecticut CVD hospital charges in 2008 were about $2.2 billion, with a median charge of $23,172 (Figure 15). About 33% of total CVD hospitalization charges were for CHD, 12% were for stroke, and 15% were for HF.[10] Median hospital charges were $34,792 for CHD, $19,772 for stroke, and $17,408 for HF. In contrast, the median charge for all hospital discharges in Connecticut was $16,727.[10]

Figure 15. Cardiovascular Disease Hospital Charges, Connecticut Residents, 2008



Source: Connecticut Department of Public Health, Connecticut Hospital Discharge Abstract and Billing Data Base, 2010.

RISK FACTORS

Risk factors for CVD may be non-modifiable (e.g., increasing age or family history) or modifiable (high blood pressure, high cholesterol, smoking, diabetes, obesity, physical inactivity) [Table 5]. Increasing age is a key risk factor for heart disease, stroke, and HF.[1] About 86% of all CVD deaths in Connecticut occur among those aged 65 years and older. About 85% of all CHD deaths, 90% of all stroke deaths, and 96% of all HF deaths in Connecticut occur among persons aged 65 years and older.[7] For men and women, major increases in the CVD mortality rate begin in the 35-to-44-year-old age group.[4] A family history of heart disease and stroke increases one's risk of developing these diseases. A combination of inherited characteristics and behavioral patterns (e.g. similar dietary, smoking, and activity habits) are thought to partially explain increased risk within families.[11]

Lower socioeconomic position (SEP) is an important risk marker for CVD. SEP is commonly measured by personal income, household income, or educational attainment level. Persons of lower SEP have higher CVD morbidity and mortality than do middle- or upper-income persons. Behavioral risk factors such as smoking, hypertension, and obesity are more prevalent in persons of lower SEP and may explain some of the observed disparity; however, other factors, like neighborhood socioeconomic environment, appear to have effects on individuals' risk for CVD.[1] Low-income neighborhood environments may contribute to increased CVD risk and poorer health outcomes because of such factors like poorer air quality, fewer food choices, and lower quality and/or lack of public services. Persons with lower incomes tend to have less access to and/or less effectively use preventive health services that are important to the early detection and treatment of hypertension.[12] While low-socioeconomic position may be considered "modifiable" in the sense that people can move in and out of poverty during a lifetime or over generations, it is not usually within a given individual's control to change his or her social position or neighborhood environment.

Table 5. Risk Factors for Cardiovascular Disease

Modifiable Risk Factors	Non-Modifiable Risk Factors
• High blood pressure • High cholesterol • Smoking • Diabetes • Obesity • Physical inactivity	• Increasing age • Family history

Modifiable Risk Factors

Current Connecticut Behavioral Risk Factor Surveillance System (BRFSS)** data show that about one out of three Connecticut adults report having one modifiable risk factor for CVD.[14] Following are summaries of the six main risk factors (high blood pressure, high blood cholesterol, tobacco use, diabetes, obesity, and physical inactivity) for CVD.

High Blood Pressure

High blood pressure (HBP) is a major risk factor for heart attack and the most important modifiable risk factor for stroke. People with elevated blood pressure (≥140 mmHg systolic / 90 mmHg diastolic) are 2 to 4 times more likely to develop CHD as are people with normal blood pressure (<120 mmHg systolic / 80 mmHg diastolic).[1] Studies have found that individuals with a normal blood pressure have approximately half the lifetime risk of stroke compared to those with high blood pressure.[13]

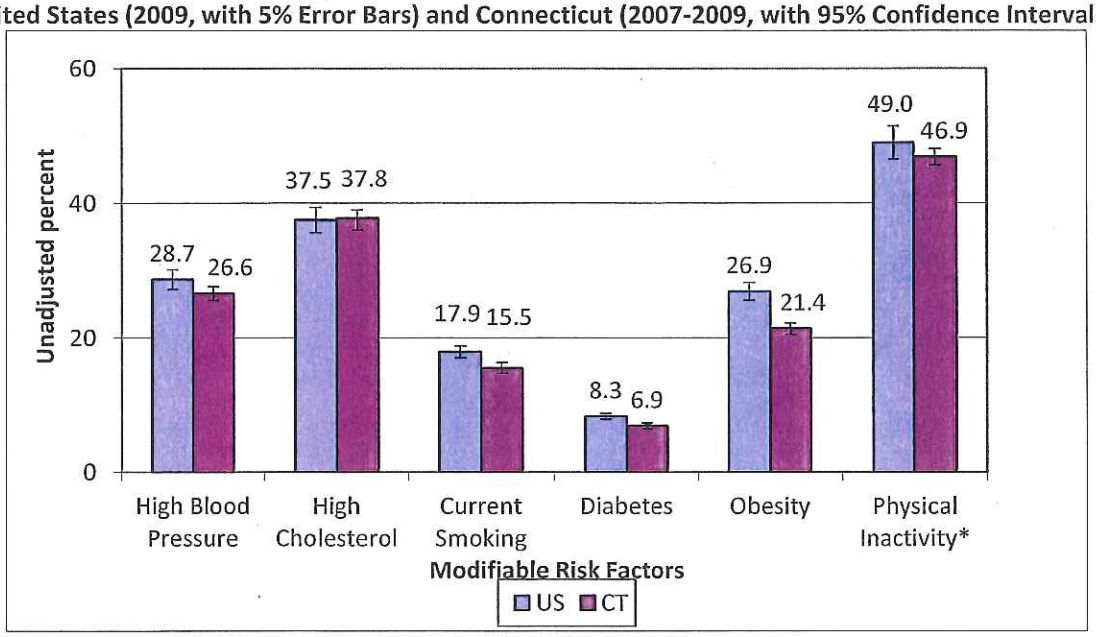
Approximately 27% of Connecticut adults report having HBP (2007-2009 data) compared with about 29% of adults nationwide (2009 data) (Figure 16).[14, 15] The risks for hypertension-related CVD increase markedly with age, as does the prevalence of hypertension, and drug treatment for HBP.[13] For example, 15.4% of Connecticut adults aged 35-44 years report having HBP compared with 57.8% of Connecticut adults aged 65 years and older ($p<0.001$) [data not shown].[14]

The rates of HBP also differ by gender. Approximately 27.4% of Connecticut males have HBP compared with 22.5% of females ($p<0.001$) [data not shown].[14]

The prevalence of HBP varies by race and ethnicity. Black Connecticut adults are more likely to have HBP than White and Hispanic Connecticut adults ($p<0.001$ for both comparisons). The rates of HBP among White and Hispanics adults do not differ significantly. About 25% of White, 36% of Black, and 22% of Hispanic adults report that they were told they had hypertension (Figure 17).[14]

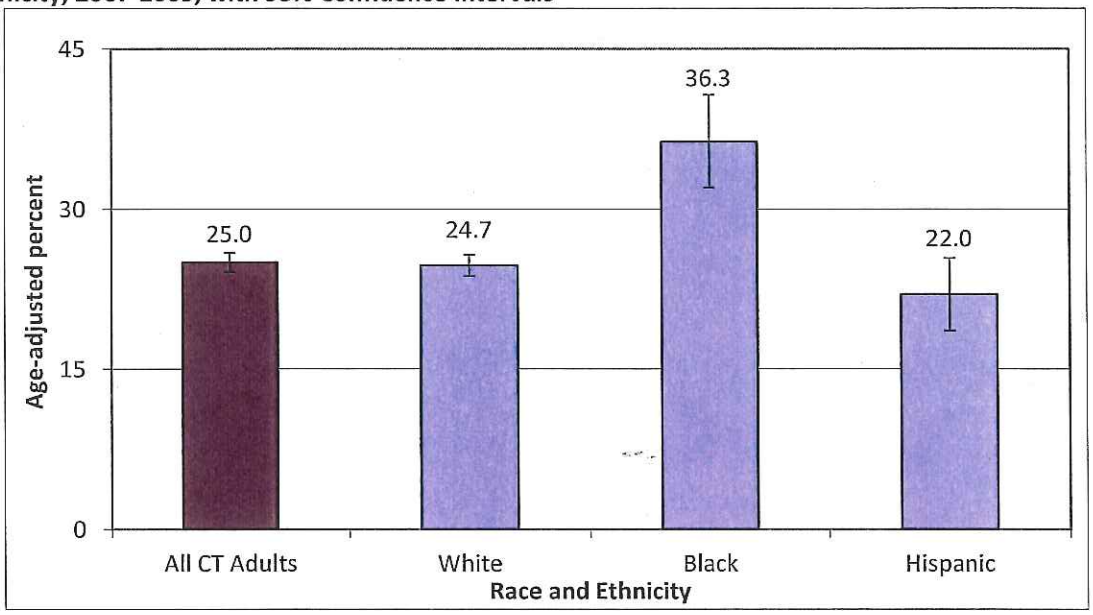
** Unless otherwise stated, the BRFSS data presented in this report are based on 2007-2009 survey responses from non-institutionalized Connecticut adults.

Figure 16. Prevalence of Modifiable Risk Factors for Cardiovascular Diseases among Adults in the United States (2009, with 5% Error Bars) and Connecticut (2007-2009, with 95% Confidence Intervals)



Sources: Centers for Disease Control and Prevention, Behavioral Risk Factor Surveillance System (BRFSS), 2010. Connecticut Department of Public Health, BRFSS, 2010.
*Participated in less than the recommended amount of physical activity.

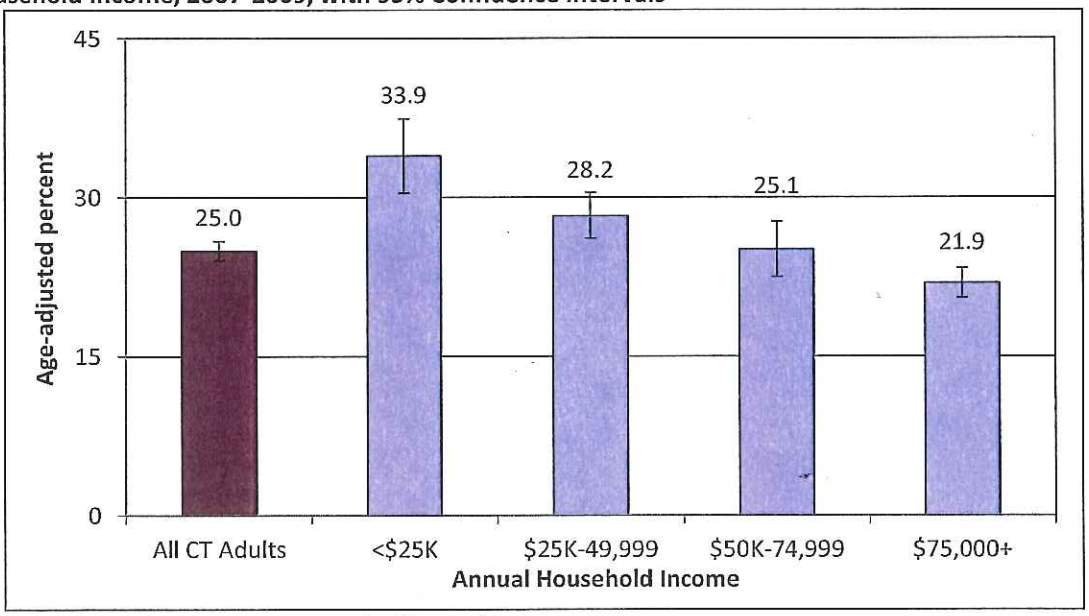
Figure 17. Age-adjusted Prevalence of High Blood Pressure among Connecticut Adults by Race and Ethnicity, 2007-2009, with 95% Confidence Intervals



Source: Connecticut Department of Public Health, BRFSS, 2010.

Connecticut adults with lower annual household incomes tend to have a higher prevalence of HBP compared to Connecticut adults with higher annual household incomes. For example, 33.9% of adults with an annual household income less than $25,000 have diagnosed HBP compared to 21.9% of adults with annual household income of at least $75,000 (p<0.001) [Figure 18].[14]

Figure 18. Age-adjusted Prevalence of High Blood Pressure among Connecticut Adults by Annual Household Income, 2007-2009, with 95% Confidence Intervals



Source: Connecticut Department of Public Health, BRFSS, 2010.

High Blood Cholesterol

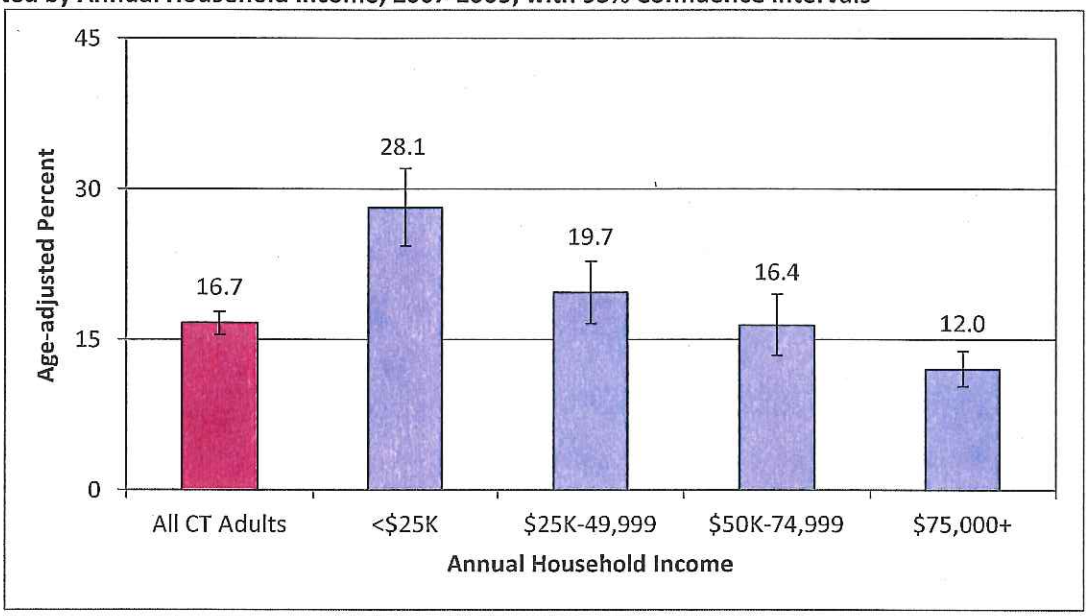
High blood cholesterol (HBC) is considered a major risk factor for CHD.[16, 17] Dyslipidemias, or an abnormal amount of lipids (e.g. high blood cholesterol) in the blood, were not traditionally regarded as a risk factor for stroke; however, a recent meta-analysis of statin therapy found that treatment of dyslipidemia decreases the risk of nonhemorrhagic stroke.[1] Control and reduction of HBC is important. A 10% decrease in total blood cholesterol levels may reduce the incidence of CHD by as much as 30%.[18]

About 38% of adults in Connecticut (2007-2009 data) and nationwide (2009 data) were told they had HBC (Figure 16).[14, 15] The prevalence of HBC increases with age. For example, 38.1% of Connecticut's adults aged 45-54 years report having HBC compared with 53.4% of Connecticut's adults aged 65 years and older ($p<0.001$) [data not shown].[14]

The prevalence of HBC also varies by gender. Approximately, 39.2% of Connecticut males have HBC compared with 29.7% of females ($p<0.001$) [data not shown]. [14]

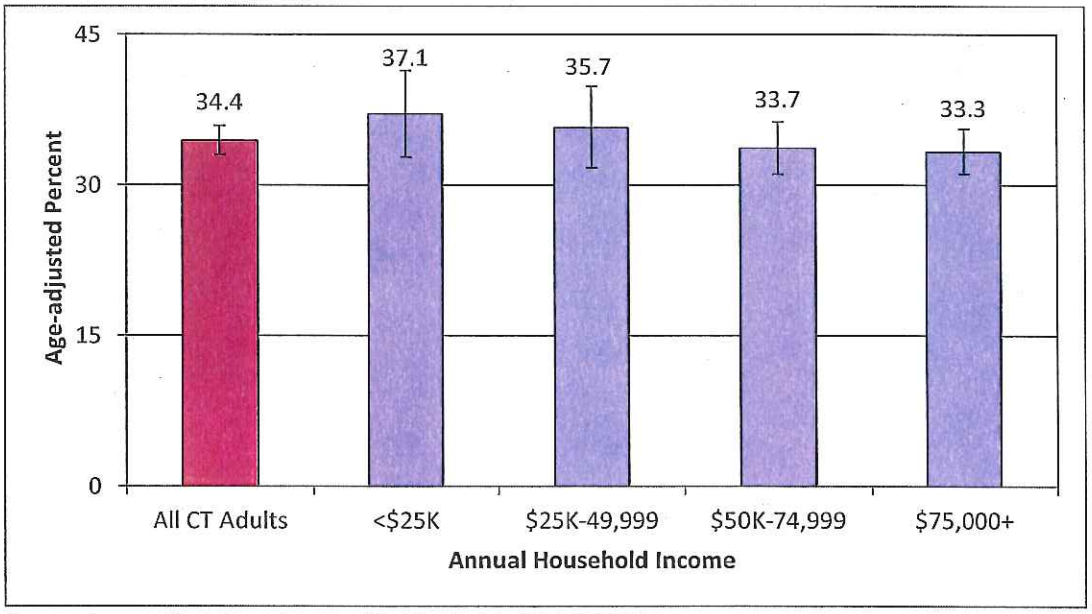
Connecticut adults compare favorably to adults nationwide in terms of cholesterol screening. About 82% of Connecticut adults report having had their blood cholesterol screened within the last five years (2007-2009 data) compared with 77% of adults in the U.S. (2009 data).[14, 15] Connecticut adults with lower incomes are more likely to report that they have never had their blood cholesterol tested compared to adults with higher incomes. For example, adults with annual household incomes less than $25,000 are significantly more likely to report that they have never had their blood cholesterol tested compared to individuals with annual household incomes of $75,000 or more ($p<0.001$) [Figure 19]. In contrast, the prevalence of HBC does not differ significantly by annual household income [Figure 20].[14]

Figure 19. Age-adjusted Percentage of Connecticut Adults Who Have Never Had Their Cholesterol Tested by Annual Household Income, 2007-2009, with 95% Confidence Intervals



Source: Connecticut Department of Public Health, BRFSS, 2010.

Figure 20. Age-adjusted Percentage of Connecticut Adults Who had Their Cholesterol Tested in the Past 5 Years and Were Told It was High by Annual Household Income, 2007-2009, with 95% Confidence Intervals

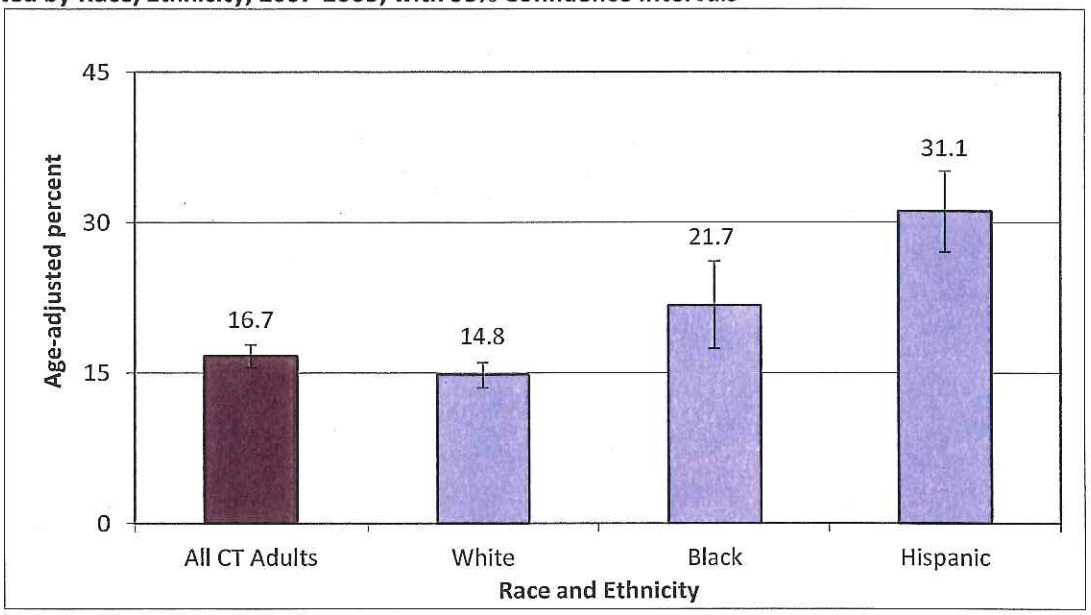


Source: Connecticut Department of Public Health, BRFSS, 2010.

Black and Hispanic adults are significantly more likely than White adults to report never having had their blood cholesterol tested ($p<0.05$ for Black and White comparison; $p<0.001$ for Hispanic and White comparison). Hispanic adults are also more likely than Black adults to report never having had their blood cholesterol tested ($p<0.05$). An estimated 14.8% of White, 21.7% of Black, and 31.1% of Hispanic adults report never having had their blood cholesterol tested [Figure 21]. In contrast, the prevalence of HBC does not differ significantly by race and ethnicity [data not shown].[14]

The rates of never having had blood cholesterol tested do not differ significantly by gender. Approximately, 16.9% of males and 16.4% of females in Connecticut have never had their blood cholesterol tested [data not shown].[14]

Figure 21. Age-adjusted Percentage of Connecticut Adults Who Have Never Had Their Cholesterol Tested by Race/Ethnicity, 2007-2009, with 95% Confidence Intervals



Source: Connecticut Department of Public Health, BRFSS, 2010.

Smoking

Cigarette smoking is a major modifiable risk factor for CVD. Smoking causes reduced blood vessel elasticity by increasing arterial wall stiffness. Smoking increases the risk of heart attack two-fold. Smokers have higher CHD mortality rates than non-smokers and the risk of death increases with greater number of cigarettes smoked. Current smokers have more than twice the risk of stroke compared with those who have never smoked. People who stop smoking decrease their stroke risk and their risk of CHD mortality.[1]

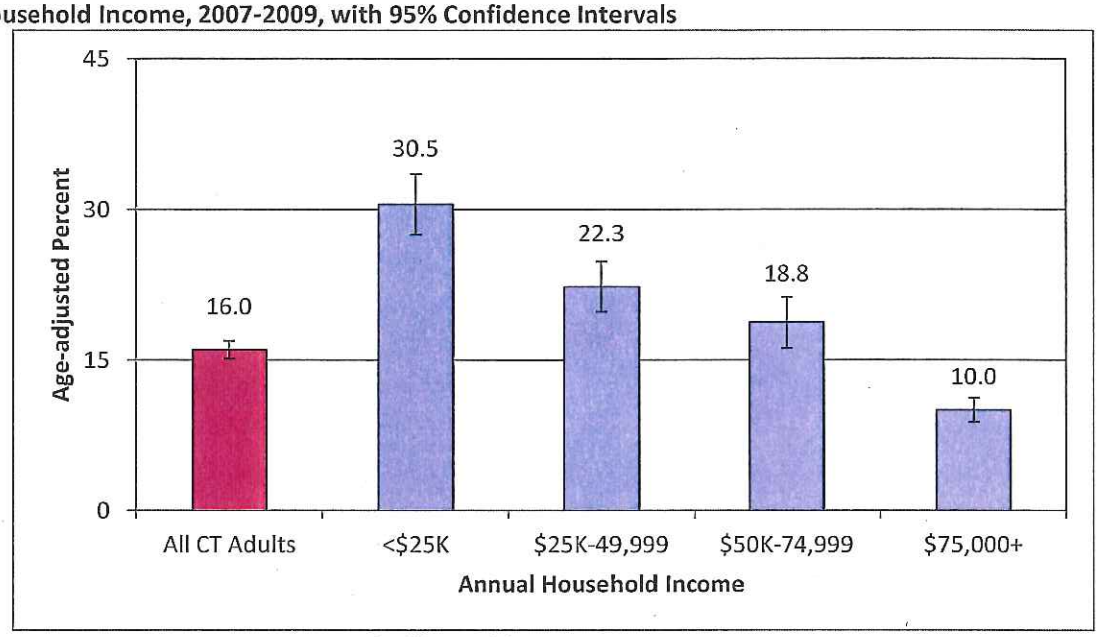
About 16% of Connecticut adults report being current smokers (2007-2009 data) compared with about 18% of adults nationwide (2009 data) [Figure 16].[14,15] According to the 2009 Connecticut School Health Survey (CSHS), 17.8% of high school students report being current smokers.[19]

Among adults, current smokers are more likely to be younger. For example, an estimated 22% of Connecticut adults aged 18 to 24 years old are current smokers compared with 14% of those aged 55 to 64 ($p<0.01$), and 6% of those aged 65 and older ($p<0.001$) [data not shown].[14] Smokers are also more likely to be individuals who have lower incomes and are less educated. For instance, about 31% of Connecticut's adults with annual household incomes under $25,000 are current smokers, compared to 10% of adults with annual household incomes of $75,000 or more ($p<0.001$) [Figure 22].[14] Similarly, about 31% of adults with less than a high school education report being current smokers compared to about 9% of adults who graduated from college ($p<0.001$) [data not shown].[14]

The rates of smoking do not differ significantly by gender. An estimated 16.8% of adult males and 15.2% of adult females are current smokers while an estimated 19.0% of high school males and 16.5% of high school females are current smokers (data not shown).[14,19]

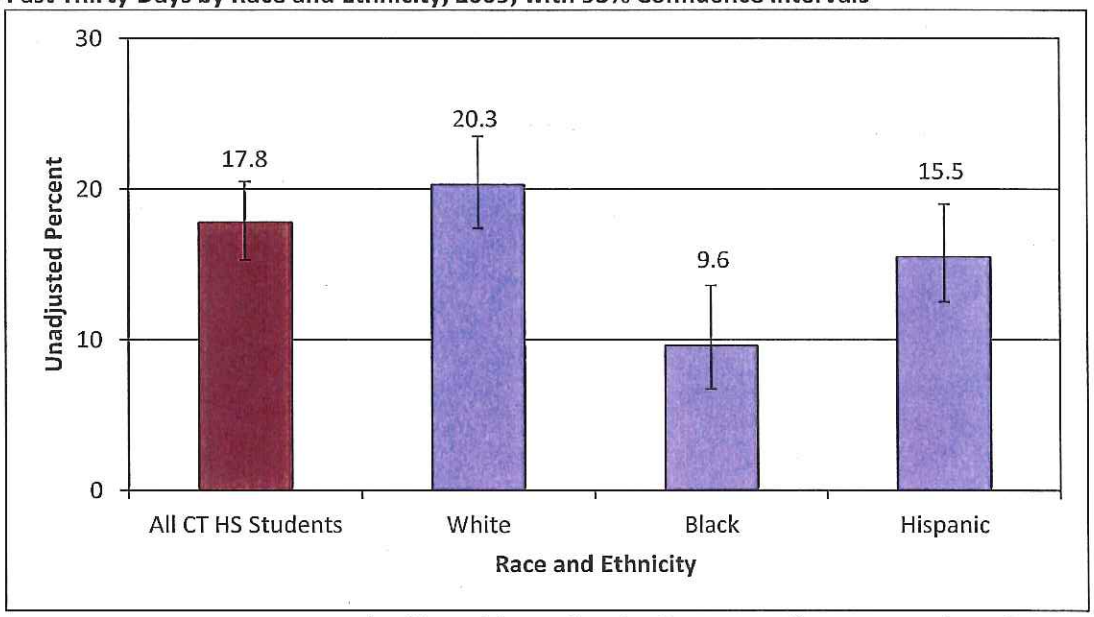
Among Connecticut adults, smoking rates do not differ significantly by race and ethnicity. An estimated 15.8% of White, 19.1% of Black, and 15.6% Hispanic adults report being current smokers [data not shown].[14] However, the rates of smoking among high school students do vary by race and ethnicity. White Connecticut high school students are more likely to be current smokers than Black ($p<0.001$) and Hispanic ($p<0.05$) students. Also, Hispanic students are more likely than Black students to be current smokers ($p<0.05$) [Figure 23].[19]

Figure 22. Age-adjusted Percentage of Connecticut Adults Who Are Current Smokers by Annual Household Income, 2007-2009, with 95% Confidence Intervals



Source: Connecticut Department of Public Health, BRFSS, 2010.

Figure 23. Percentage of Connecticut High School Students Who Smoked Cigarettes on One or More of the Past Thirty Days by Race and Ethnicity, 2009, with 95% Confidence Intervals



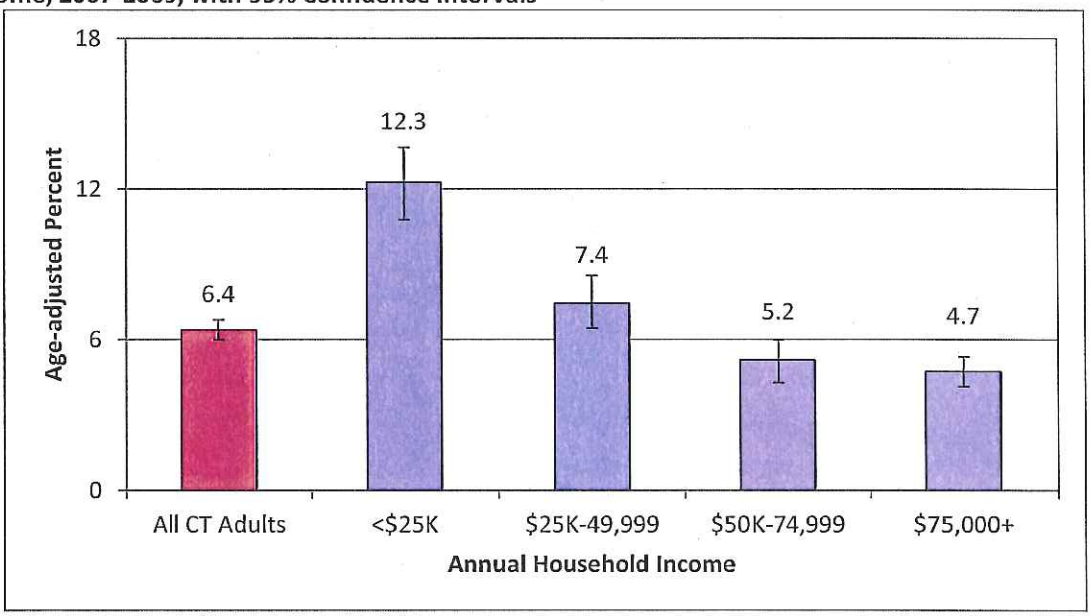
Source: Connecticut Department of Public Health, Youth Risk Behavior Surveillance System (YRBSS), 2010.

Diabetes

Diabetes has been recognized as a major risk factor for CVD. CVD is the primary cause of death for persons with diabetes, accounting for about 65% of the mortality. Individuals with diabetes are 2 to 4 times more likely to develop CHD and 2 to 5 times more likely to have a stroke than the rest of the population. People with diabetes often have HBP, HBC, and are overweight, further increasing their risk for CVD.[1]

An estimated 6.9% of Connecticut adults have diagnosed diabetes (2007-2009 data) compared with about 8% of adults nationwide (2009 data) [Figure 16].[14, 15] The prevalence of diabetes varies by gender, age, race and ethnicity, and SEP.[14, 20] Males are more likely to have diabetes than females. An estimated 7.3% of Connecticut males have diabetes compared with 5.7% of females ($p<0.005$) [data not shown].[14] Also, the prevalence of diabetes increases with age. Approximately 3% of adults aged 35-44 years report having diabetes compared to approximately 16.5% of adults aged 65 years and older ($p<0.001$) [data not shown].[14] Black and Hispanic adults have a significantly higher prevalence of diabetes compared with White adults ($p<0.001$ for both comparisons). The prevalence of diabetes among Black and Hispanic adults does not differ significantly. An estimated 5.6% of White, 14.9% of Black, and 10.5% of Hispanic adults report having diabetes [data not shown].[14] Adults with lower annual household incomes have a higher prevalence of diabetes compared to adults with higher annual household incomes. For example, approximately 12% of adults with annual household incomes under $25,000 report having diabetes, compared with about 5% of adults with household incomes over $75,000 ($p<0.001$) [Figure 24].[14]

Figure 24. Age-adjusted Prevalence of Diabetes among Connecticut Adults by Annual Household Income, 2007-2009, with 95% Confidence Intervals



Source: Connecticut Department of Public Health, BRFSS, 2010.

Diabetes self-management education is essential because improperly controlled diabetes can result in CVD, kidney disease, blindness and loss of limb. It is, therefore, a particular concern that about 52% of Connecticut adults with diabetes report that they have never taken a course to manage the disease.[14]

Obesity

Body mass index (BMI), or weight adjusted for height, is a widely used screening method for obesity. For children and adolescents, BMI is compared to age- and gender-specific percentiles on the Centers for Disease Control and Prevention (CDC) growth charts. Children and adolescents with a BMI greater than or equal to the 85 percentile but less than the 95 percentile are considered overweight. Children and adolescents with a BMI greater than or equal to the 95 percentile are considered obese.[21] Medical guidelines for adults identify normal/desirable weight as a BMI under 25, overweight as a BMI of 25 to 29.9, and obese as a BMI of 30 or more. The prevalence of obesity has more than doubled over the past three decades in the United States.[21] The development of obesity involves social, behavioral, cultural, physiological, metabolic, and genetic factors. High calorie diets, along with less physical activity, have contributed to the obesity epidemic in our society.[21, 22]

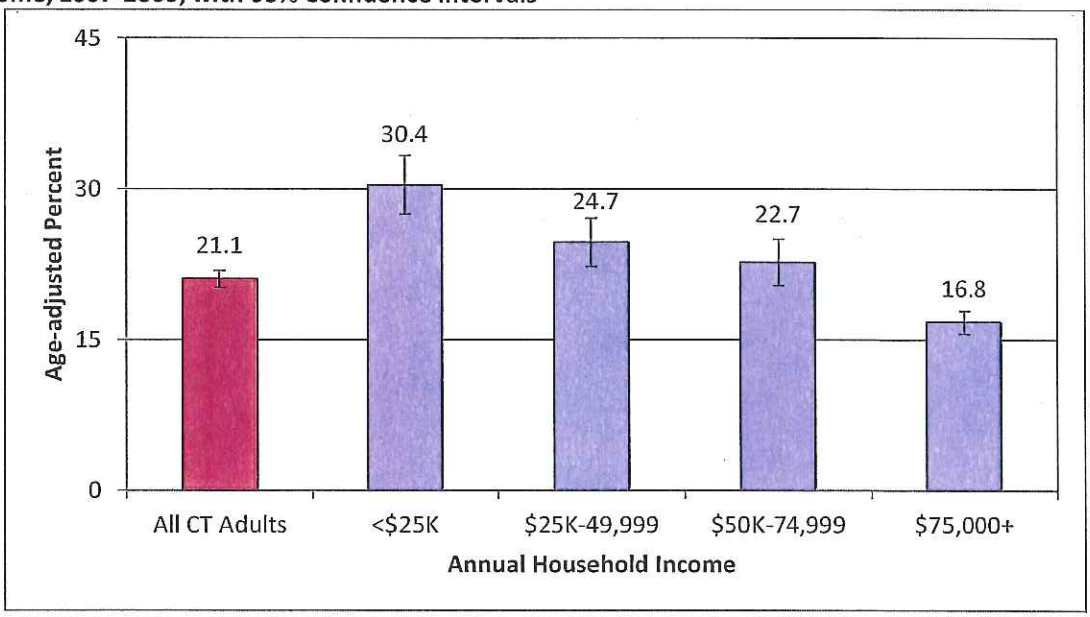
Obesity increases the risk of morbidity from hypertension, dyslipidemia, CHD, and stroke. All-cause mortality increases with increasing body weight.[22] Obesity is also an independent risk factor for CVD. The risk of ischemic stroke increases with increasing BMI. Studies have also suggested that body fat distribution may affect CHD risk. Upper body or abdominal fat seems to increase CHD risk regardless of BMI. Weight reduction can affect several of the modifiable risk factors for stroke thereby reducing the incidence of stroke.[1]

According to responses to the 2009 CSHS, an estimated 14.5% of Connecticut high school students were overweight and 10.4% were obese.[19] Obesity rates among high school students in Connecticut vary by gender and race and ethnicity. Male Connecticut high school students are significantly more likely to be obese than female high school students ($p<0.05$). An estimated 13.8% of male and 6.7% of female high school students in Connecticut are obese [data not shown].[19] Also, Hispanic Connecticut high school students have higher rates of obesity than both White ($p<0.001$) and Black ($p<0.05$) high school students. The difference in the rate of obesity among White and Black high school students does not reach statistical significance. An estimated 8.7% of White, 12.5% of Black, and 17% of Hispanic Connecticut high school students are obese [data not shown].[19]

An estimated 21% of Connecticut adults are obese (2007-2009 data) compared with about 27% of adults nationwide (2009 data) [Figure 16].[14, 15] Approximately 38% of Connecticut adults are overweight and 41% are neither overweight nor obese [data not shown].[14] Rates of obesity differ by SEP. For example, approximately 30% of adults with annual household incomes less than $25,000 are obese compared with 17% of those with annual household incomes over $75,000 ($p<0.001$) [Figure 25].[14] Rates of obesity also differ by race and ethnicity. Black and Hispanic adults are more likely to be obese than White adults ($p<0.001$ for both comparisons) [data not shown]. Black adults are also more likely to be obese than Hispanic adults ($p<0.05$). About 20% of White, 36% of Black, and 27% of Hispanic adults are obese [data not shown].[14] Furthermore, males are more likely to be obese than females. An estimated 27.9% of males are obese compared with 19.2% of females ($p<0.005$) [data not shown].[14] Additionally, older adults are more likely to be obese than younger adults. Approximately 11% of adults age 18-24 years are obese compared with 25% of adults aged 55-64 years ($p<0.001$) [data not shown].[14]

Obese adults are significantly more likely to report that they are in poorer health compared with non-obese adults. About 19% of adults who are obese report that they are in fair or poor health compared with about 9% of Connecticut adults who are not obese ($p<0.001$) [data not shown].[14]

Figure 25. Age-adjusted Prevalence of Obesity among Connecticut Adults by Annual Household Income, 2007-2009, with 95% Confidence Intervals



Source: Connecticut Department of Public Health, BRFSS, 2010.

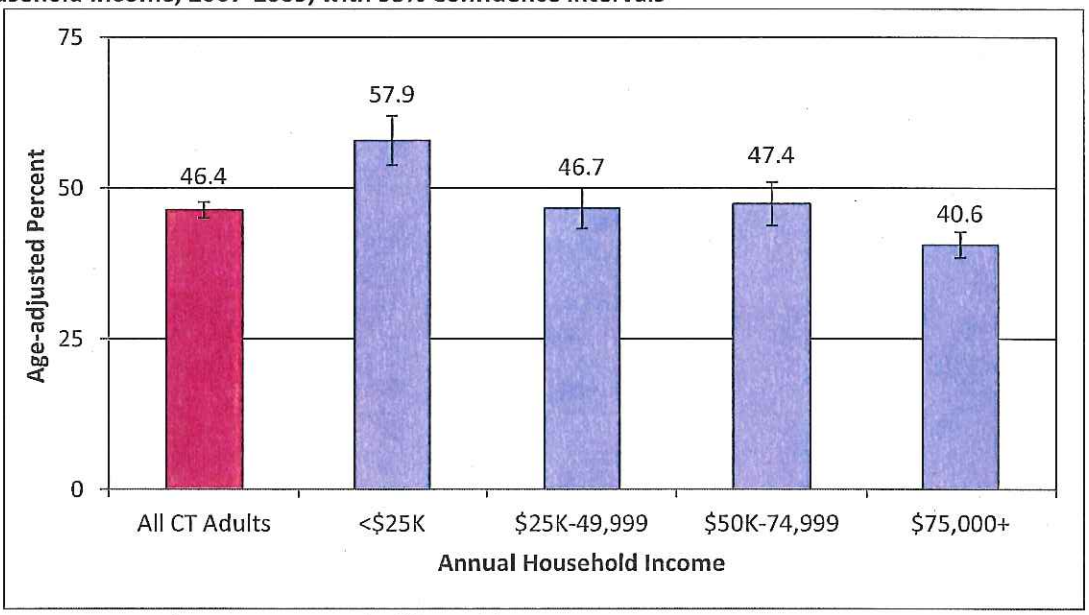
Physical Inactivity

Physical inactivity is associated with an increased risk of a number of chronic health conditions including CHD, diabetes, some cancers, HBP, obesity, and osteoporosis. Studies have shown that physical activity has protective effects on strokes.[1, 23]

The American College of Sports Medicine (ACSM), the American Heart Association (AHA), and the CDC recommend that healthy adults aged 18-65 years participate in moderate-intensity aerobic physical activity for a minimum of 30 minutes on five days per week or vigorous-intensity aerobic physical activity for a minimum of 20 minutes on three days per week.[24, 25] The guidelines are the same for adults aged 65 years and older; however, if older adults are unable to meet these guidelines because of chronic conditions, it is recommended that they participate in as much physical activity as possible.[25]

"Physical inactivity" is defined here as not meeting the recommendations of the ACSM, AHA, and CDC as described above. Approximately 47% of Connecticut adults report participating in less than the recommended amount of physical activity (2007-2009 data) compared with 49% nationwide (2009 data) (Figure 16).[14, 15] Rates of physical inactivity are higher among older adults, women, racial or ethnic minorities, and people with low incomes.[23] Physical inactivity increases with age. About 56% of adults 65 years old and older are physically inactive compared with about 48% of adults aged 45 to 64 years , and 43% of adults aged 18 to 44 years ($p<0.001$ for both comparisons) [data not shown]. Similarly, the physical inactivity rate among adults aged 45 to 64 years is significantly higher than that of adults aged 18 to 44 years ($p<0.005$) [data not shown].[14] Likewise, females are more likely to be physically inactive than males. An estimated 48.5% of adult females are physically inactive compared with 44% of adult males ($p<0.05$) [data not shown].[14] Additionally, Black and Hispanic adults are significantly more likely to report higher rates of physical inactivity than White adults ($p<0.001$ for Black and White comparison; $p<0.005$ for Hispanic and White comparison). The rates of physical inactivity among Black and Hispanic adults do not differ significantly. Approximately 44.5% of White, 59.7% of Black, and 54.2% of Hispanic adults report that they are physically inactive (data not shown).[14] Furthermore, adults with lower incomes are more likely to be physically inactive compared to adults with higher incomes. For example, about 58% of adults with annual household incomes of less than $25,000 are physically inactive compared to 41% of adults with annual household incomes of $75,000 or more ($p<0.001$) [Figure 26].[14]

Figure 26. Age-adjusted Prevalence of Physical Inactivity among Connecticut Adults by Annual Household Income, 2007-2009, with 95% Confidence Intervals



Source: Connecticut Department of Public Health, BRFSS, 2010.

Co-Prevalence of Cardiovascular Risk Factors

The co-prevalence of risk factors places an individual at elevated risk of CHD and stroke.[26] Approximately 42% of Connecticut adults report having two or more and 19% report having three or more modifiable risk factors for CVD.[14] The co-prevalence of risk factors contributes to the complexity of disease management.

RECOGNIZING THE SIGNS AND SYMPTOMS OF HEART ATTACK AND STROKE

The *Healthy People 2010* national objectives for both heart disease and stroke include increasing the proportion of persons who are aware of the early warning signs and symptoms of heart attack and stroke and the necessity of calling 911 when persons are suffering from either of these conditions (Table 6).[8] Early recognition of heart attack and stroke and calling 911 increase the likelihood of immediate emergency transport to the hospital and timely medical care that can reduce disability and death.

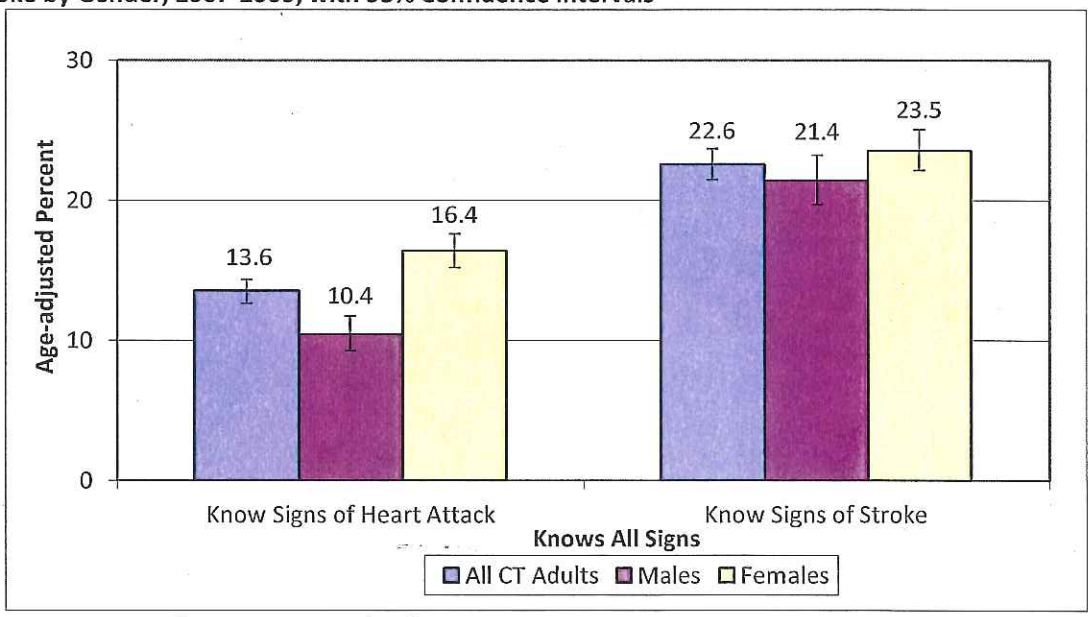
Table 6. Warning Signs for Heart Attack and Stroke

Heart Attack	Stroke
• Jaw, neck, back pain • Lightheaded, faint • Shortness of breath • Arm or shoulder discomfort • Chest pain or discomfort	• Severe headache with no known cause • Trouble seeing in one or both eyes • Confusion, trouble speaking • Trouble walking, dizziness, or loss of balance • Sudden numbness/weakness of face, arm, or leg

Source: American Heart Association, 2010.

The percentage of Connecticut adults who know all the warning signs and symptoms for heart attack and stroke tends to be very low. Only 13.6% of adults can identify all the proper heart attack signs and only 22.6% can identify all the proper stroke signs (2007-2009 data).[14] Women tend to be more knowledgeable than men about the signs and symptoms of heart attack and stroke. An estimated 16.4% of females know all heart attack signs compared with about 10.4% of males ($p<0.001$).[14] Also, approximately 23.5% of females know all signs of stroke compared with about 21.4% of males; however, this difference is not statistically significant [Figure 27].[14] Most adults, 91.4%, know that they should call 911 if they thought that someone was having a heart attack or stroke [data not shown].[14]

Figure 27. Age-adjusted Percentage of Connecticut Adults Who Know All the Signs of Heart Attack and Stroke by Gender, 2007-2009, with 95% Confidence Intervals

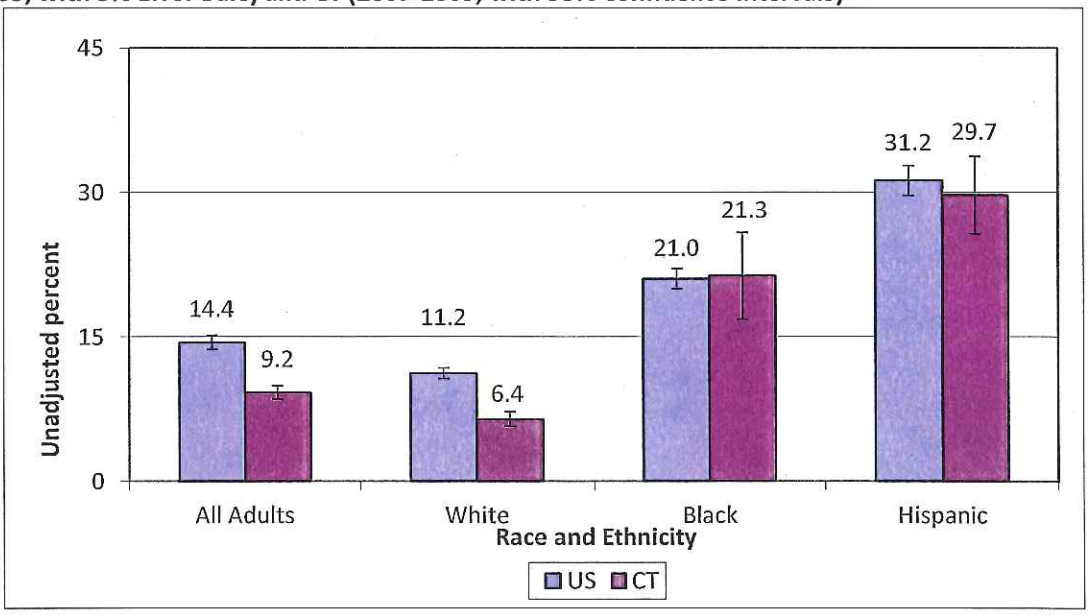


Source: Centers for Disease Control and Prevention, BRFSS, 2010.

ACCESS TO HEALTH CARE

Access to health care is crucial to the prevention, treatment, and management of heart disease and stroke. People without health insurance are less likely than those with health insurance to have a usual source of care, to receive preventive health care services, and to receive appropriate medical management of chronic conditions such as HBP, HBC, and diabetes.[27] About 9% of adults aged 18 and over do not have health insurance (2007-2009 data) compared with approximately 14% of adults nationwide (2009 data).[14, 15] Black and Hispanic Connecticut adults are significantly less likely to have health insurance than White Connecticut adults ($p<0.001$ for both comparisons). Approximately 6% of White, 21% of Black, and 30% of Hispanic adults do not have health insurance.[14] Comparable national figures show that about 11% of White, 21% of Black, and 31% of Hispanic adults report having no health insurance (Figure 28).[15]

Figure 28. Percentage of Adults Who Do Not Have Health Care Coverage by Race and Ethnicity, US (2009, with 5% Error Bars) and CT (2007-2009, with 95% Confidence Intervals)



Source: Centers for Disease Control and Prevention, BRFSS, 2010. Connecticut Department of Public Health, BRFSS, 2010.

TARGETING HIGH-RISK POPULATIONS

The high co-prevalence of modifiable risk factors for CVD indicates the need for public health interventions that focus on the prevention, early detection, and control of modifiable risk factors. The CDC recommends focusing efforts on increasing low dose aspirin therapy according to recognized guidelines; preventing and controlling HBC; reducing sodium intake; preventing and controlling HBC; and increasing the number of smokers counseled to quit and referred to quit lines as well as increasing the availability of no or low-cost cessations products.[28] The CDC also recommends addressing the priority areas through policies, systems, and environmental changes with the potential for broad reach and impact on the general population and high-risk populations.[28]

High-risk populations in Connecticut include Black, Hispanic, and lower-income residents. Black Connecticut residents have higher CVD and stroke mortality rates as well as higher CVD, CHD, and stroke premature mortality rates compared with White Connecticut residents. Black and Hispanic Connecticut residents have significantly higher rates of some important modifiable risk factors for CVD, such as HBC, diabetes, obesity, and physical inactivity compared with White Connecticut residents. Lower-income residents are also more likely to have higher rates of HBC, never having had cholesterol tested, diabetes, current smoking, obesity, and physical inactivity compared with higher-income residents.

Targeted, evidence-based public health interventions are warranted for all Connecticut residents with multiple risk factors. Special emphasis should be placed on interventions that address risk factor reduction among Black, Hispanic, and lower-income Connecticut residents. Evidence-based guidelines for disease prevention in the areas of diabetes, nutrition, physical activity, tobacco, and obesity are provided in the CDC's *Guide to Community Preventive Services*.[29] The 2011 Connecticut Chronic Disease planning process has focused its statewide health promotion and disease prevention efforts on policy, systems, and environmental changes at the state and local levels. Such policy, systems, and environmental changes have the potential to influence health-related behaviors in the general and high-risk populations.

APPENDICES AND REFERENCES

Appendix 1. Data Sources

Connecticut Vital Records Mortality Files

The Connecticut Vital Records Mortality Files are part of the state's vital statistics data base that contains records pertaining to deaths that occur within the state as well as deaths of Connecticut residents occurring in other states, or in Canada. Mortality statistics are compiled in accordance with the World Health Organization (WHO) regulations, which specify that deaths be classified by the current Manual of the International Statistical Classification of Diseases, Injuries, and Causes of Death. Deaths for the 1989-1998 period included in this report are classified by the Ninth Revision of the International Classification of Diseases [ICD-9].[30] Deaths for the 1999-2008 period are classified by the Tenth Revision of the International Classification of Diseases [ICD-10].[31]

The race-ethnicity designation is typically based on report by next of kin, a funeral director, coroner, or other official, often based on observations. As such, the race-ethnicity designation based on observation may be reported incorrectly. Another potential source of error is the fact that death rates are calculated using two different sources of data – the death certificate for the numerator and the U.S. Census Bureau population estimates for the denominator. Errors in under- or over-counting populations by race and/or ethnicity will affect the death rates reported for these groups. Mortality data are reported using racial categories that exclude persons of Hispanic origin (White, non-Hispanic and Black, non-Hispanic) and by Hispanic ethnicity (Hispanics of any race). Death Registry data follow the National Center for Health Statistics guidelines for coding race and Hispanic ethnicity.[5]

Connecticut Hospital Discharge Abstract and Billing Data Base

The Connecticut Hospital Discharge Abstract and Billing Data Base is the source of inpatient hospitalization data. It is maintained by the Connecticut Office of Health Care Access, and it contains patient-level demographic, clinical, and billing data for all non-federal acute care hospitals in the state. In addition to age, gender, and town of residence, the demographic data elements include race and ethnicity. Race and ethnicity may be based upon observation of the patient or self-reporting by the patient. Race is designated as White, non-Hispanic and Black, non-Hispanic; Hispanic ethnicity includes persons of any race.

It should be noted that counts reflect hospitalizations not persons. For example, a patient admitted to a hospital on two separate occasions in 2008 would be counted twice in these data. Another limitation of the data is the fact that it is an administrative data set. It contains diagnoses and procedures based on the International Classification of Diseases, Clinical Modification (ICD-9-CM) codes. The literature contains many reports on the reliability and validity of hospital discharge data with clinical conditions emphasizing discrepancies between ICD-9-CM codes and clinical data.[32]

Behavioral Risk Factor Surveillance System

The Behavioral Risk Factor Surveillance System (BRFSS) survey is a state-based system of health surveys that generate information about health risk behaviors, clinical preventive practices, and health care access and use. The BRFSS, sponsored by the Centers for Disease Control and Prevention, is the world's largest telephone survey, and is conducted in all 50 states. It is an on-going random sample telephone survey of non-institutionalized adults, 18 years and older. Information from the survey is used to improve the health of people nationwide and in Connecticut. Racial and ethnic classifications are based on self-report and include White, non-Hispanic, Black, non-Hispanic, and Hispanic (including persons of any race). Other national and state-specific risk factor data and information regarding BRFSS methodology can be accessed on the CDC's BRFSS Web site at: http://www.cdc.gov/brfss/.

Connecticut School Health Survey

The Connecticut School Health Survey (CSHS) is a comprehensive survey that consists of two components: Youth Tobacco Component (YTC) and the Youth Behavior Component (YBC). The CSHS is conducted by the Connecticut Department of Public Health in cooperation with the CDC, the Connecticut State Department of Education, and partners from local school health districts and local health departments. The YTC is a comprehensive survey of tobacco use, access, cessation, knowledge and attitudes, and exposure among Connecticut students in grades 6-12. The YBC collects data that is used to monitor priority health-risk behaviors and the prevalence of obesity and asthma among high school students in Connecticut. The YBC is administered to a representative sample of all regular public high school students in Connecticut. Racial and ethnic classifications are based on self-report and include White, non-Hispanic; Black, non-Hispanic; and Hispanic (including persons of any race). Further information about the CSHS can be found on the Connecticut Department of Public Health's web site: http://www.ct.gov/dph/cshs. Other national and state-specific youth risk factor data and information can be accessed on the CDC's web site: http://www.cdc.gov/HealthyYouth/YRBS/.

Appendix 2A. ICD-10 Coding for Selected Causes of Death, 1999-2008

Cause of Death	ICD-10 Code
All Causes	A00.0 – Y89.9
All Cancers	C00 – C97
Diabetes Mellitus	E10 – E14
Alzheimer's Disease	G30
Cardiovascular Disease	I00-I78
Diseases of the Heart	I00 – I09, I11, I13, I20 – I51
Coronary Heart Disease	I11, I20-I25
Congestive Heart Failure	I50.0
Essential Hypertension & Hypertensive Renal Disease	I10, I12
Cerebrovascular Disease	I60 – I69
Atherosclerosis	I71
Pneumonia and Influenza	J10 – J18
Chronic Lower Respiratory Diseases	J40 – J47
Unintentional Injuries	V01 – X59, Y85 – Y86

Source: World Health Organization. 1992. Manual of the International Statistical Classification of Diseases, Injuries, and Causes of Death, based on the recommendations of the Tenth Revision Conference, 1992 (ICD-10). World Health Organization, Geneva.

Appendix 2B. ICD-9 Coding for Selected Causes of Death, 1989-1998

Cause of Death	ICD-9 Code
All Causes	1-E999
Cardiovascular Disease Deaths	390-459
Diseases of the Heart	390-398,402,404-429
Coronary Heart Disease	402, 410-414, 429.2
Congestive Heart Failure	428.0
Hypertension without Renal Disease	401, 403
Cerebrovascular Disease	430-438
Atherosclerosis	440

Source: World Health Organization. 1977. Manual of the International Statistical Classification of Diseases, Injuries, and Causes of Death, based on the recommendations of the Ninth Revision Conference, 1975 (ICD-9). World Health Organization, Geneva.

Appendix 2C. ICD-9-CM Coding for Selected Causes of Hospitalizations

Cause of Hospitalization	ICD-9-CM Code
Circulatory	390-459
Coronary Heart Disease	402, 410-414, 429.2
Congestive Heart Failure	428
Cerebrovascular Disease	430-438

Source: Practice Management Information Corporation (PMIC). 2004. The International Classification of Diseases, Ninth Revision, Clinical Modification. 6th ed. PMIC, Los Angeles, CA.

Appendix 3A. Glossary of Statistical Terms

Age-adjustment. "Age adjustment, using the direct method, is the application of observed age-specific rates to a standard age distribution to eliminate differences in crude rates in populations of interest that result from differences in the populations' age distributions. This adjustment is usually done when comparing two or more populations at one point in time or one population at two or more points in time. Age adjustment is particularly relevant when populations being compared have different age structures, for example, the U.S. white and Hispanic populations...."[33]

Age-adjusted BRFSS rates. Some of the Behavioral Risk Factor Surveillance System (BRFSS) rate estimates presented in this report were age-adjusted, using the direct method, in order to eliminate differences in crude rates in populations of interest that result from differences in the populations' age distributions, such as those of Hispanics and Whites. The following age distributions and age-adjustment weights, based on the 2000 projected U.S. population, were used[34]:

Age Distributions and Age-adjustment Weights, 2000 Projected U.S. Population

Age	Population in thousands	Adjustment weight
18 years and over	203,851	1.000000
18 – 24 years	26,258	0.128810
25 – 44 years	81,892	0.401725
45 – 64 years	60,991	0.299194
65 years and over	34,710	0.170271

Age-adjusted Mortality Rates (AAMR) and Age-adjusted Hospitalization Rates (AAHR) are used to compare relative mortality and hospitalization risk, respectively, across groups and over time. They are not actual measures of risk but rather an index of risk. They are weighted statistical averages of the age-specific rates, in which the weights represent the fixed population proportions by age.[35] The AAMR and AAHR were computed by the direct method. The 1940 and 2000 U.S. standard million population distributions are shown below:

Age group	1940	2000
0-4	80,057	69,136
5-9	81,151	72,533
10-14	89,209	73,032
15-19	93,665	72,169
20-24	88,002	66,477
25-29	84,280	64,529
30-34	77,787	71,044
35-39	72,501	80,762
40-44	66,744	81,851
45-49	62,696	72,118
50-54	55,116	62,716
55-59	44,559	48,454
60-64	36,129	38,793
65-69	28,519	34,264
70-74	19,519	31,773
75-79	11,423	26,999
80-84	5,878	17,842
85+	2,765	15,508
Total	1,000,000	1,000,000

Cause-of-death classification. Mortality statistics for this report were compiled in accordance with the World Health Organization (WHO) regulations, which specify that member nations classify causes of death by the current Manual of the International Statistical Classification of Diseases, Injuries, and Causes of Death. Deaths for the 1989-1998 period were classified by the Manual of the International Statistical Classification of Diseases, Injuries, and Causes of Death, Ninth Revision of the International Classification of Diseases (ICD-9).[30] Deaths for the 1999-2008 period were classified according to the Tenth Revision of the International Classification of Diseases (ICD-10).[31]

Healthy People 2010 is part of a national strategy addressing the prevention of major chronic illnesses, injuries, and infectious diseases. It is the product of an effort, involving expert working groups, a consortium of national organizations, all state health departments, and the Institute of Medicine of the National Academy of Sciences to set health objectives for the nation. After extensive national and regional hearings were conducted with a period of public review and comment, the health objectives were published in 1990 as *Healthy People 2000—National Health Promotion and Disease Prevention Objectives.* It established national objectives and served as the basis for the development of state and community plans. *Healthy People 2010* provides a comprehensive view of the nation's health in 2000, and establishes national goals and targets to be achieved by 2010, and monitors progress over time.[36]

Hispanic origin refers to people whose origins are from Spain, the Spanish-speaking countries of Central America, South America, and the Caribbean, or persons of Hispanic origin identifying themselves as Spanish, Spanish-American, Hispanic, Hispano, or Latino. Since 1988, the Connecticut death certificate has had a separate line item for Hispanic ethnicity. Individuals identified as "Hispanic" can be of any race, and are also counted in the race breakdown as either "white," "black," "Asian or Pacific Islander," "American Indian," or other.[5]

International Classification of Diseases 9th and 10th Revisions(ICD-9, ICD-10) have been the internationally accepted coding system for determining cause of death since the early 1900s. It is periodically revised. The Ninth Revision (ICD-9) was in use from 1975 through 1998. Beginning with 1999 deaths, the Tenth Revision (ICD-10) is being used.

Preliminary estimates of the comparability of ICD-9 to ICD-10 have been published and indicate that the discontinuity in trends from 1998 to 1999 for some leading causes of death (septicemia, influenza and pneumonia, Alzheimer's disease, nephritis, nephrotic syndrome, and nephrosis) is substantial.[37]

International Classification of Diseases, Clinical Modification (ICD-9-CM) is a coding system recommended for use in all clinical settings to describe medical procedures and diagnoses. It is required for reporting diagnoses and diseases to all U.S. Public Health Service and Department of Health and Human Services programs, including Medicare and Medicaid. The foundation of the ICD-9-CM is the *International Classification of Diseases, 9th Revision* published by the World Health Organization.[30]

Population bases for computing rates are taken from the U.S. Census Bureau's *Estimates of the population of states by age, sex, race, and Hispanic origin*. These data are estimates of the population of Connecticut by 5-year age groups (age 0 to 4, 5 to 9,...85 and over), sex (male, female), modified race (white; black; Native American including Alaska Natives; Asian and Pacific Islander) and Hispanic origin (Hispanic, non-Hispanic) for each year, July 1, 1999 through July 1, 2009.[5]

Premature mortality. See Years of Potential Life Lost.

Race refers to a population of individuals identified from a common history, nationality, or geographical place. Race is widely considered a valid scientific category, but not a valid biological or genetic category.[38, 39] Available scientific evidence indicates that racial and ethnic classifications do not capture biological distinctiveness, and that there is more genetic variation within racial groups than there is between racial groups.[40, 41] Contemporary race divisions result from historical events and circumstances and reflect current social realities. Thus, racial categories may be viewed more accurately as proxies for social and economic conditions that put individuals at higher risk for certain disease conditions.[32]

Data in this report include two racial groups in Connecticut: white, non-Hispanic and black, non-Hispanic. Individuals identified as "Hispanic" can be of any race.

Socioeconomic position refers to a person's social and economic place in a society, and is operationalized or measured by characteristics such as per capita or household income, educational attainment, or occupation. Historically, lower socioeconomic position has been strongly correlated with less favorable health outcomes such as premature mortality and higher death rates from all causes; conversely, persons of higher socioeconomic position do better on most measures of health status.[12]

Years of potential life lost (YPLL) represents the number of years of potential life lost by each death before a predetermined end point (e.g., 65 or 75 years of age). Whereas the crude and adjusted death rates are heavily influenced by the large number of deaths among the elderly, the YPLL measure provides a picture of premature mortality by weighting deaths that occur at younger ages more heavily than those occurring at older ages, thereby emphasizing different causes of death. Age-adjusted YPLLs are calculated using the methodology of Romeder and McWhinnie.[42] This method consists of a summation of the number of deaths occurring at each age (betweem 1 and 75) multiplied by the remaining years of life had the deceased lived up to age 75.

Appendix 3B. Glossary of Medical Terms

Atherosclerosis: A disease that affects the arteries, particularly those supplying the heart, the brain, the aorta, and the lower extremities. Atherosclerosis underlies the occurrence of heart attacks, many strokes, peripheral arterial disease, and ruptures of the aorta.[43]

Cardiovascular Diseases (CVD): Diseases of the circulatory system, which include acute myocardial infarction, ischemic heart disease, valvular heart disease, peripheral vascular disease, arrhythmias, high blood pressure and stroke.[44]

Coronary Heart Disease (CHD): A form of heart disease resulting from impaired circulation in one or more coronary arteries. Common clinical manifestations of CHD include chest pain (angina pectoris) or "heart attack".[44]

Cerebrovascular Disease: A disease of one or more blood vessels in the brain, which often results in the sudden development of a focal neurologic deficit, or stroke. Stroke, or a "brain attack" is the most severe clinical manifestation of cerebrovascular disease.[1, 45]

Congestive Heart Failure: The inability of the heart to maintain adequate pumping function, which can be caused by a number of factors, such as untreated hypertension, heart attacks, or infections. Heart failure increases the risk for other cardiovascular disease events and often results in physical disability. Congestive Heart Failure is commonly referred to as "heart failure".[43-45]

Diabetes (or diabetes mellitus): A metabolic disorder that results from the body's insufficient production or utilization of insulin. The most common types of diabetes includes "Type 1 diabetes," formerly known as "juvenile diabetes," and "Type 2 diabetes," formerly known as "adult-onset diabetes." Long-term effects of diabetes include cardiovascular complications.[43]

Dyslipidemia: A disorder of lipoprotein metabolism, such as an overproduction or deficiency of lipoprotein. Dyslipidemia is often manifested by elevated levels of total cholesterol, the "bad" or low-density lipoprotein (LDL) cholesterol, and the triglyceride concentrations, as well as decreased levels of the "good" or high-density lipoprotein (HDL) cholesterol concentration in the blood.[46]

Essential Hypertension: high blood pressure without a secondary cause such as renal failure. Approximately 95% of all cases of hypertension are classified as essential hypertension.[47]

Heart Failure: See Congestive Heart Failure.

Hemorrhagic Stroke: Hemorrhagic stroke occurs when a weakened blood vessels ruptures causing bleeding within the brain. The resulting accumulation of blood compresses nearby brain tissue. Hemorrhagic stroke is often associated with high blood pressure. About 13% of all strokes are hemorrhagic.[48]

High Blood Cholesterol: Cholesterol is a substance found in all cells of the body; it is carried in lipoproteins, made of fat (lipid) on the inside and proteins on the outside. Low-density lipoprotein (LDL) cholesterol is sometimes called "bad cholesterol" because it leads to a buildup of cholesterol in arteries. The chance of heart disease increases with increasing LDL levels in the blood. The buildup of cholesterol in the arteries is called plaque, which over time causes the narrowing of the arteries, or "atherosclerosis." Some plaques can burst, releasing fat and cholesterol into the bloodstream, which may cause the blood to clot and block the flow of blood. This blockage can cause angina or a heart attack. Lowering one's cholesterol level decreases the chance of having a plaque burst and a subsequent heart attack. Lowering cholesterol may also slow down, reduce, or even stop plaque from building up.[49]

High Blood Pressure: A condition in which the pressure in the arterial circulation system is greater than clinically recommended, that is a systolic pressure greater than or equal to 140 mm Hg or a diastolic pressure greater than or equal to 90 mm Hg. High blood pressure is associated with increased risk for heart disease, stroke, and chronic kidney disease.[43]

Hypertensive Heart Disease: An abnormality in the structure and function of the heart caused by long-standing high blood pressure. A common, clinical manifestation of hypertensive heart disease is heart failure.[43]

Ischemic Heart Disease: A condition in which heart muscle is damaged or works inefficiently because of an absence or deficiency of its blood supply. Ischemic heart disease is most often caused by atherosclerosis, and includes angina pectoris, acute myocardial infarction, chronic ischemic heart disease, and sudden death.[44]

Ischemic Stroke: The most common type of stroke that results from an obstruction within a blood vessel supplying blood to the brain. Atherosclerosis is the cause of the obstruction. About 87% of strokes are ischemic strokes.[50]

Obesity: Defined in terms of body mass index (BMI), and calculated as body weight in kilograms (1 kg = 2.2 lbs.) divided by height in meters (1 m = 39.37 in) squared. Adults with a BMI of greater than or equal to 30.0 kg/m2 are considered "obese," and those with a BMI of 25–29.9 kg/m2 are considered "overweight".[43]

Classification of Overweight and Obesity in Adults According to BMI.[44] Obesity is classified as BMI $\geq$ 30 kg/m^2.		
Classification	**BMI (kg/m^2)**	**Risk of Health Problems**
Underweight	< 18.5	Low (but risk of other clinical problems increased)
Normal range	18.5-24.9	Average
Overweight	25.0-29.9	Mildly increased
Obese	**> 30.0**	
Class I	30.0-34.9	Moderate
Class II	35.0-39.9	Severe
Class III	> 40.0	Very severe
Note that these values are age-independent and correspond to the same degree of fatness across different populations.		

Serum (Blood) Lipids: Cholesterol and triglycerides are types of lipids circulating in the blood. Over time, elevated cholesterol and triglycerides in the blood can become plaque in artery walls leading to atherosclerosis. Elevated cholesterol and triglyceride levels are often found in individuals with other major risk factors for heart disease (obesity, diabetes, and/or high blood pressure).[51]

Stroke: The most common clinical manifestation of cerebrovascular disease. Stroke describes an interruption of the blood supply in the brain that results in damaged brain tissue. It can be caused by clots or by bleeding in the brain from a ruptured blood vessel or a significant injury.[1, 52]

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ATTACHMENT V

Letters of Support

Cardiovascular Services
of Greenwich

HEART INSTITUTE
GREENWICH
HOSPITAL
YALE NEW HAVEN HEALTH

Harvey Seidenstein, MD, FACC
Medical Director, Clinical Cardiology

Alexander Del Vecchio, MD
Clinical Cardiac Electrophysiology

Christopher J. Howes, MD, FACC
Clinical and Interventional Cardiology

John F. Setaro, MD, FACC
Preventive and Interventional Cardiology, Hypertension

November 8, 2011

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134

Dear Deputy Commissioner Davis:

I am writing this letter to express my support for the proposed elective angioplasty program at Greenwich Hospital as a satellite of the Yale-New Haven Heart and Vascular Center. Since the inception of the primary angioplasty program at Greenwich Hospital, I have been the Medical Director overseeing its daily operation. This program has demonstrated success and has saved lives in the community. The excellent outcomes and safety we have demonstrated with the primary angioplasty program puts us in a unique position to expand our access of high quality care to patients of this community and offer them elective angioplasty at Greenwich Hospital.

We are seeking to build on the unique structure that is already in place at Greenwich Hospital. It is cost effective and efficient to use what is already available for *emergency* angioplasty patients to also provide care to *elective* angioplasty patients. An elective angioplasty program will improve access to care locally. Patient and family satisfaction will improve as Greenwich Hospital patients will no longer have to transfer out of the region despite the availability of equipment and facilities, qualified staff and high volume operators. Currently, the transfer of patients out of the region produces an emotional, financial and occasionally physical hardship on patients and their families.

The elective angioplasty program at Greenwich Hospital would adhere to the standards set forth by the Yale-New Haven Heart and Vascular Center. We will continue the current comprehensive quality and outcome monitoring that we have created for our primary angioplasty program. Approval of an elective angioplasty program at Greenwich Hospital will improve the overall quality of the Greenwich Hospital cardiology program as it will provide the staff and operators with greater number of patients with a broader spectrum of disease to maintain competency and high quality standards.

Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Christopher J. Howes, MD
Medical Director of PAMI Program and Interventional
Cardiology at Greenwich Hospital
Assistant Professor of Medicine,
Yale School of Medicine

Yale University School of Medicine
CARDIOVASCULAR MEDICINE
333 Cedar Street · 3 FMP · PO Box 208017
New Haven CT 06520-8017
T: 203 785-4129 · F: 203 737-2437

Branford Office
11 Harrison Avenue
Branford CT 06405
T: 203 483-8300 · F: 203 483-8314

Henry S. Cabin, MD
Professor of Medicine and Pathology
Clinical Chief of Cardiology
Yale University
Medical Director
Yale-New Haven Hospital Heart Center

November 8, 2011

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134

Dear Deputy Commissioner Davis:

I am writing this letter to express my support for the proposed elective angioplasty program at Greenwich Hospital as a satellite of the Yale-New Haven Heart and Vascular Center. As Clinical Chief of Cardiology for Yale School of Medicine and Medical Director of the Yale-New Haven Heart and Vascular Center, I have played a key role in the implementation of the primary angioplasty program at Greenwich Hospital. This program has demonstrated success and has saved lives in the community. We are seeking to build on the unique structure that is already in place at Greenwich Hospital. This program will improve continuity of care as Greenwich Hospital patients now must be transferred for elective angioplasty despite the availability of equipment and facilities, qualified staff and high volume operators.

The program will be supervised and directed by the Yale Interventional Group and all procedures will be performed by highly qualified physicians. The elective angioplasty program at Greenwich Hospital would adhere to the high standards set forth by the Yale-New Haven Heart and Vascular Center. Quality and outcomes monitoring would be provided by the Yale-New Haven Heart and Vascular Center. The facility, physicians, staff and equipment required to perform elective angioplasty services are already in place at Greenwich Hospital. It is cost effective and efficient to use what is already available for *emergency* angioplasty patients to also provide care to *elective* angioplasty patients.

Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Henry S. Cabin, MD
Clinical Chief of Cardiology,
Yale School of Medicine
Medical Director
Yale-New Haven Heart and Vascular Center

WESTMED
MEDICAL GROUP

Barney Newman, M.D.
Medical Director

November 17, 2011

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134

Dear Deputy Commissioner Davis:

I am writing this letter in support of Greenwich Hospital's application to provide elective angioplasty to the communities it serves. I am the Chief Medical Officer for WESTMED Medical Group, a large multi-specialty group of over 200 physicians with locations throughout Westchester County, New York. Many of our cardiologists are on the medical staff at Greenwich Hospital. It is our experience that our patients in the Greenwich Hospital service area use the Hospital's services for their health care needs including cardiac services. If Greenwich Hospital offered elective angioplasty, we feel confident that these patients would prefer the convenient location of Greenwich Hospital along with the high quality and competent physicians and staff, up-to-date facilities and appropriate safety measures in place at the Hospital.

An elective angioplasty service at Greenwich Hospital will provide cardiac patients with local access to high quality interventional cardiology services. Patients from the Greenwich Hospital service area that need elective angioplasty are currently required to go to another hospital to receive these services since Greenwich Hospital is not approved to provide elective angioplasty services. However, the same facility, physicians, staff and equipment required to perform *elective* angioplasty services are already in place for Greenwich Hospital's approved *emergency* angioplasty program. This is a more cost effective use of resources. In addition, the ability to provide elective angioplasty will improve the continuity of care available to patients at Greenwich Hospital.

Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Barney D. Newman MD

Dr. Barney D. Newman
Chief Medical Officer
WESTMED Medical Group

JOSEPH J. TARTAGLIA, M.D., D-IM (C.D.), (GM) F.A.C.C., P.C.
311 NORTH STREET
WHITE PLAINS, N. Y. 10605
TELEPHONE 946-3388

November 7, 2011

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134

Dear Deputy Commissioner Davis:

I am writing this letter in support of Greenwich Hospital's application to provide elective angioplasty to the communities it serves. I am on the medical staff at Greenwich Hospital. Many of my patients use the Hospital's services for their health care needs including cardiac services. If Greenwich Hospital offered elective angioplasty, I feel confident that my patients in the Greenwich Hospital service area would prefer the convenient location of Greenwich Hospital along with the high quality and competent physicians and staff, up-to-date facilities and appropriate safety measures in place at the Hospital.

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Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Joseph Tartaglia, MD

RYE BROOK CARDIOLOGY
& VASCULAR MEDICINE, P.C.

16 Rye Ridge Plaza
Rye Brook, NY 10573
Telephone: (914) 251-1070
Fax: (914) 935-9047

November 7, 2011

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134

Dear Deputy Commissioner Davis:

I am writing this letter in support of Greenwich Hospital's application to provide elective angioplasty to the communities it serves. I am on the medical staff at Greenwich Hospital. Many of my patients use the Hospital's services for their health care needs including cardiac services. If Greenwich Hospital offered elective angioplasty, I feel confident that my patients in the Greenwich Hospital service area would prefer the convenient location of Greenwich Hospital along with the high quality and competent physicians and staff, up-to-date facilities and appropriate safety measures in place at the Hospital.

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Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Myung-Ho Lee, MD

Cardiovascular Services
of Greenwich

Harvey Seidenstein, MD, FACC
Medical Director, Clinical Cardiology

Alexander Del Vecchio, MD
Clinical Cardiac Electrophysiology

Christopher J. Howes, MD, FACC
Clinical and Interventional Cardiology

John F. Setaro, MD, FACC
Preventive and Interventional Cardiology, Hypertension

HEART INSTITUTE
GREENWICH
HOSPITAL
YALE NEW HAVEN HEALTH

November 7, 2011

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134

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Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Harvey Seidenstein, MD

PRACTICE LIMITED TO CARDIOLOGY BY APPOINTMENT

KEVIN E. CONBOY, M.D.

38 LAKE AVENUE
GREENWICH, CONNECTICUT 06830

TELEPHONE (203) 622-9102
FAX (203) 622-0508

November 7, 2011

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134

Dear Deputy Commissioner Davis:

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Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Kevin Conboy MD

Kevin Conboy, MD

Joel M. Blumberg, MD, FACP, FACC
Internal Medicine & Cardiology

Affiliated Physician
MDVIP
PERSONALIZED HEALTHCARE

November 7, 2011

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
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Hartford, CT 06134

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Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Joel Blumberg, MD

55 Holly Hill Lane, Suite 210, Greenwich, CT 06830 • Phone 203.661.4242 • Fax 203.625.9626

Greenwich **Cardiology** Associates, LLC

67 Holly Hill Lane, Suite 102, Greenwich, CT 06830 | Ph: 203.869.5515 | F: 203.869.5765 | www.gcardiology.com

November 7, 2011

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
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Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Glenn Gandelman, MD

Greenwich **Cardiology** Associates, LLC

67 Holly Hill Lane, Suite 102, Greenwich, CT 06830 | Ph: 203.869.5515 | F: 203.869.5765 | www.gcardiology.com

November 7, 2011

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Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
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Hartford, CT 06134

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Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Bartel Crisafi, Sr., MD

Francis J. Neeson , M.D. FACC

Cardiology

75 Holly Hill Lane
Greenwich , CT 06830
Phone (203) 869-6960
Fax (203) 869-5103

November 7, 2011

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
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P.O. Box 340308
Hartford, CT 06134

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Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Francis Neeson, MD

ROBERT M. STARK, M.D., P.C.
FELLOW, AMERICAN COLLEGE OF PHYSICIANS
FELLOW, AMERICAN COLLEGE OF CARDIOLOGY
40 WEST ELM STREET
GREENWICH, CONNECTICUT 06830

(203) 622-1102
FAX (203) 622-1508
www.robertstarkmd.com

November 7, 2011

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
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Hartford, CT 06134

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Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Robert Stark, MD

Robert Stark, MD

ATTACHMENT VI

Practice Guidelines
2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions

Executive Summary
The Current Status and Future Direction of Percutaneous Coronary Intervention Without On-Site Surgical Backup: An Expert Consensus Document for the Society for Cardiovascular Angiography and Interventions

Practice Guidelines

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PRACTICE GUIDELINE

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions

WRITING COMMITTEE MEMBERS*

Glenn N. Levine, MD, FACC, FAHA, Chair[†], **Eric R. Bates,** MD, FACC, FAHA, Vice Chair[*†], **James C. Blankenship,** MD, FACC, FSCAI, Vice Chair[*‡], **Steven R. Bailey,** MD, FACC, FSCAI[*‡], **John A. Bittl,** MD, FACC[†§], **Bojan Cercek,** MD, FACC, FAHA[†], **Charles E. Chambers,** MD, FACC, FSCAI[‡], **Stephen G. Ellis,** MD, FACC[*†], **Robert A. Guyton,** MD, FACC[*‖], **Steven M. Hollenberg,** MD, FACC[*†], **Umesh N. Khot,** MD, FACC[*†], **Richard A. Lange,** MD, FACC, FAHA[§], **Laura Mauri,** MD, MSC, FACC, FSCAI[*†], **Roxana Mehran,** MD, FACC, FAHA, FSCAI[*‡], **Issam D. Moussa,** MD, FACC, FAHA, FSCAI[‡], **Debabrata Mukherjee,** MD, FACC, FSCAI[†], **Brahmajee K. Nallamothu,** MD, FACC[¶], **Henry H. Ting,** MD, FACC, FAHA[†]

ACCF/AHA TASK FORCE MEMBERS

Alice K. Jacobs, MD, FACC, FAHA, Chair, **Jeffrey L. Anderson,** MD, FACC, FAHA, Chair-Elect, **Nancy Albert,** PHD, CCNS, CCRN, FAHA, **Mark A. Creager,** MD, FACC, FAHA, **Steven M. Ettinger,** MD, FACC, **Robert A. Guyton,** MD, FACC, **Jonathan L. Halperin,** MD, FACC, FAHA, **Judith S. Hochman,** MD, FACC, FAHA, **Frederick G. Kushner,** MD, FACC, FAHA, **E. Magnus Ohman,** MD, FACC, **William Stevenson,** MD, FACC, FAHA, **and Clyde W. Yancy,** MD, FACC, FAHA

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*Writing committee members are required to recuse themselves from voting on sections to which their specific relationships with industry and other entities may apply; see Appendix 1 for recusal information. [†]ACCF/AHA Representative. [‡]SCAI Representative. [§]Joint Revascularization Section Author. [‖]ACCF/AHA Task Force on Practice Guidelines Liaison. [¶]ACCF/AHA Task Force on Performance Measures Liaison.

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PREAMBLE

The medical profession should play a central role in evaluating the evidence related to drugs, devices, and procedures for the detection, management, and prevention of disease. When properly applied, expert analysis of available data on the benefits and risks of these therapies and procedures can improve the quality of care, optimize patient outcomes, and favorably affect costs by focusing resources on the most effective strategies. An organized and directed approach to a thorough review of evidence has resulted in the production of clinical practice guidelines that assist physicians in selecting the best management strategy for an individual patient. Moreover, clinical practice guidelines can provide a foundation for other applications, such as performance measures, appropriate use criteria, and both quality improvement and clinical decision support tools.

The American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) have jointly produced guidelines in the area of cardiovascular disease since 1980. The ACCF/AHA Task Force on Practice Guidelines (Task Force), charged with developing, updating, and revising practice guidelines for cardiovascular diseases and procedures, directs and oversees this effort. Writing committees are charged with regularly reviewing and evaluating all available evidence to develop balanced, patient-centric recommendations for clinical practice.

Experts in the subject under consideration are selected by the ACCF and AHA to examine subject-specific data and write guidelines in partnership with representatives from other medical organizations and specialty groups. Writing committees are asked to perform a formal literature review; weigh the strength of evidence for or against particular tests, treatments, or procedures; and include estimates of expected outcomes where such data exist. Patient-specific modifiers, comorbidities, and issues of patient preference that may influence the choice of tests or therapies are considered. When available, information from studies on cost is considered, but data on efficacy and outcomes constitute the primary basis for the recommendations contained herein.

In analyzing the data and developing recommendations and supporting text, the writing committee uses evidence-based methodologies developed by the Task Force (1). The Class of Recommendation (COR) is an estimate of the size of the treatment effect considering risks versus benefits in addition to evidence and/or agreement that a given treatment or procedure is or is not useful/effective or in some situations may cause harm. The Level of Evidence (LOE) is an estimate of the certainty or precision of the treatment effect. The writing committee reviews and ranks evidence supporting each recommendation with the weight of evidence ranked as LOE A, B, or C according to specific definitions that are included in Table 1. Studies are identified as observational, retrospective, prospective, or randomized where appropriate. For certain conditions for which inadequate data are available, recommendations are based on expert consensus and clinical experience and are ranked as LOE C. When recommendations at LOE C are supported by historical clinical data, appropriate references (including clinical reviews) are cited if available. For issues for which sparse data are available, a survey of current practice among the clinicians on the writing committee is the basis for LOE C recommendations and no references are cited. The schema for COR and LOE is summarized in Table 1, which also provides suggested phrases for writing recommendations within each COR. A new addition to this methodology is separation of the Class III recommendations to delineate if the recommendation is determined to be of "no benefit" or is associated with "harm" to the patient. In addition, in view of the increasing number of comparative effectiveness studies, comparator verbs and suggested phrases for writing recommendations for the comparative effectiveness of one treatment or strategy versus another have been added for COR I and IIa, LOE A or B only. T1

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TABLE 1. Applying Classification of Recommendations and Level of Evidence

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	CLASS I *Benefit >>> Risk* Procedure/Treatment **SHOULD** be performed/ administered	CLASS IIa *Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	CLASS IIb *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	CLASS III *No Benefit* or CLASS III *Harm* COR III: No benefit — Procedure/Test: Not Helpful; Treatment: No Proven Benefit COR III: Harm — Procedure/Test: Excess Cost w/o Benefit or Harmful; Treatment: Harmful to Patients
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care
Suggested phrases for writing recommendations	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR III: No Benefit — is not recommended; is not indicated; should not be performed/ administered/ other; is not useful/ beneficial/ effective COR III: Harm — potentially harmful; causes harm; associated with excess morbidity/mortality; should not be performed/ administered/ other
Comparative effectiveness phrases†	treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B		

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use. †For comparative effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

In view of the advances in medical therapy across the spectrum of cardiovascular diseases, the Task Force has designated the term *guideline-directed medical therapy (GDMT)* to represent optimal medical therapy as defined by ACCF/AHA guideline recommended therapies (primarily Class I). This new term, GDMT, will be used herein and throughout all future guidelines.

Because the ACCF/AHA practice guidelines address patient populations (and healthcare providers) residing in North America, drugs that are not currently available in North America are discussed in the text without a specific COR. For studies performed in large numbers of subjects outside North America, each writing committee reviews the potential influence of different practice patterns and patient populations on the treatment effect and relevance to the ACCF/AHA target population to determine whether the findings should inform a specific recommendation.

The ACCF/AHA practice guidelines are intended to assist healthcare providers in clinical decision making by describing a range of generally acceptable

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approaches to the diagnosis, management, and prevention of specific diseases or conditions. The guidelines attempt to define practices that meet the needs of most patients in most circumstances. The ultimate judgment regarding care of a particular patient must be made by the healthcare provider and patient in light of all the circumstances presented by that patient. As a result, situations may arise for which deviations from these guidelines may be appropriate. Clinical decision making should involve consideration of the quality and availability of expertise in the area where care is provided. When these guidelines are used as the basis for regulatory or payer decisions, the goal should be improvement in quality of care. The Task Force recognizes that situations arise in which additional data are needed to inform patient care more effectively; these areas will be identified within each respective guideline when appropriate.

Prescribed courses of treatment in accordance with these recommendations are effective only if followed. Because lack of patient understanding and adherence may adversely affect outcomes, physicians and other healthcare providers should make every effort to engage the patient's active participation in prescribed medical regimens and lifestyles. In addition, patients should be informed of the risks, benefits, and alternatives to a particular treatment and be involved in shared decision making whenever feasible, particularly for COR IIa and IIb, where the benefit-to-risk ratio may be lower.

The Task Force makes every effort to avoid actual, potential, or perceived conflicts of interest that may arise as a result of industry relationships or personal interests among the members of the writing committee. All writing committee members and peer reviewers of the guideline are asked to disclose all such current relationships, as well as those existing 12 months previously. In December 2009, the ACCF and AHA implemented a new policy for relationships with industry and other entities (RWI) that requires the writing committee chair plus a minimum of 50% of the writing committee to have no *relevant* RWI (Appendix 1 for the ACCF/AHA definition of relevance). These statements are reviewed by the Task Force and all members during each conference call and/or meeting of the writing committee and are updated as changes occur. All guideline recommendations require a confidential vote by the writing committee and must be approved by a consensus of the voting members. Members are not permitted to write, and must recuse themselves from voting on, any recommendation or section to which their RWI apply. Members who recused themselves from voting are indicated in the list of writing committee members, and section recusals are noted in Appendix 1. Authors' and peer reviewers' RWI pertinent to this guideline are disclosed in Appendixes 1 and 2, respectively. Additionally, to ensure complete transparency, writing committee members' comprehensive disclosure information—including RWI not pertinent to this document—is available as an online supplement. Comprehensive disclosure information for the Task Force is also available online at www.cardiosource.org/ACC/ About-ACC/Leadership/Guidelines-and-Documents-Task-Forces.aspx. The work of the writing committee was supported exclusively by the ACCF, AHA, and the Society for Cardiovascular Angiography and Interventions (SCAI) without commercial support. Writing committee members volunteered their time for this activity.

In an effort to maintain relevance at the point of care for practicing physicians, the Task Force continues to oversee an ongoing process improvement initiative. As a result, in response to pilot projects, several changes to these guidelines will be apparent, including limited narrative text, a focus on summary and evidence tables (with references linked to abstracts in PubMed) and more liberal use of summary recommendation tables (with references that support LOE) to serve as a quick reference.

In April 2011, the Institute of Medicine released 2 reports: *Finding What Works in Health Care: Standards for Systematic Reviews* and *Clinical Practice Guidelines We Can Trust* (2, 3). It is noteworthy that the ACCF/AHA guidelines were cited as being compliant with many of the standards that were proposed. A thorough review of these reports and of our current methodology is under way, with further enhancements anticipated.

The recommendations in this guideline are considered current until they are superseded by a focused update or the full-text guideline is revised. Guidelines are official policy of both the ACCF and AHA.

Alice K. Jacobs, MD, FACC, FAHA, Chair
ACCF/AHA Task Force on Practice Guidelines

1. INTRODUCTION

1.1. Methodology and Evidence Review

The recommendations listed in this document are, whenever possible, evidence based. An extensive evidence review was conducted through November 2010, as well as selected other references through August 2011. Searches were limited to studies, reviews, and other evidence conducted in human subjects and that were published in English. Key search words included but were not limited to the following: *ad hoc angioplasty, angioplasty, balloon angioplasty, clinical trial, coronary stenting, delayed angioplasty, meta-analysis,*

percutaneous transluminal coronary angioplasty, randomized controlled trial (RCT), percutaneous coronary intervention (PCI) and angina, angina reduction, antiplatelet therapy, bare-metal stents (BMS), cardiac rehabilitation, chronic stable angina, complication, coronary bifurcation lesion, coronary calcified lesion, coronary chronic total occlusion (CTO), coronary ostial lesions, coronary stent (BMS and drug-eluting stents [DES]; and BMS versus DES), diabetes, distal embolization, distal protection, elderly, ethics, late stent thrombosis, medical therapy, microembolization, mortality, multiple lesions, multi-vessel, myocardial infarction (MI), non—ST-elevation myocardial infarction (NSTEMI), no-reflow, optical coherence tomography, proton pump inhibitor (PPI), return to work, same-day angioplasty and/or stenting, slow flow, stable ischemic heart disease (SIHD), staged angioplasty, STEMI, survival, and *unstable angina (UA)*. Additional searches cross-referenced these topics with the following subtopics: *anticoagulant therapy, contrast nephropathy, PCI-related vascular complications, unprotected left main PCI, multivessel coronary artery disease (CAD), adjunctive percutaneous interventional devices, percutaneous hemodynamic support devices*, and *secondary prevention*. Additionally, the committee reviewed documents related to the subject matter previously published by the ACCF and AHA. References selected and published in this document are representative and not all-inclusive.

To provide clinicians with a comprehensive set of data, whenever deemed appropriate or when published, the absolute risk difference and number needed to treat or harm will be provided in the guideline, along with confidence intervals (CIs) and data related to the relative treatment effects such as odds ratio (OR), relative risk, hazard ratio (HR), or incidence rate ratio.

The focus of this guideline is the safe, appropriate, and efficacious performance of PCI. The risks of PCI must be balanced against the likelihood of improved survival, symptoms, or functional status. This is especially important in patients with SIHD.

1.2. Organization of the Writing Committee

The committee was composed of physicians with expertise in interventional cardiology, general cardiology, critical care cardiology, cardiothoracic surgery, clinical trials, and health services research. The committee included representatives from the ACCF, AHA, and SCAI.

1.3. Document Review and Approval

This document was reviewed by 2 official reviewers nominated by the ACCF, AHA, and SCAI, as well as 21 individual content reviewers (including members of the ACCF Interventional Scientific Council and ACCF Surgeons' Scientific Council). All information on reviewers' RWI was distributed to the writing committee and is published in this document (Appendix 2). This document was approved for publication by the governing bodies of the ACCF, AHA, and SCAI.

1.4. PCI Guidelines: History and Evolution

In 1982, a 2-page manuscript titled "Guidelines for the Performance of Percutaneous Transluminal Coronary Angioplasty" was published in *Circulation* (4). The document, which addressed the specific expertise and experience physicians should have to perform balloon angioplasty, as well as laboratory requirements and the need for surgical support, was written by an ad hoc group whose members included Andreas Grüntzig. In 1980, the ACC and the AHA established the Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures, which was charged with the development of guidelines related to the role of new therapeutic approaches and of specific noninvasive and invasive procedures in the diagnosis and management of cardiovascular disease. The first ACC/ AHA Task Force report on guidelines for coronary balloon angioplasty was published in 1988 (5). The 18-page document discussed and made recommendations about lesion classification and success rates, indications for and contraindications to balloon angioplasty, institutional review of angioplasty procedures, ad hoc angioplasty after angiography, and on-site surgical backup. Further iterations of the guidelines were published in 1993 (6), 2001 (7), and 2005 (8). In 2007 and 2009, focused updates to the guideline were published to expeditiously address new study results and recent changes in the field of interventional cardiology (9, 10). The 2009 focused update is notable in that there was direct collaboration between the writing committees for the STEMI guidelines and the PCI guidelines, resulting in a single publication of focused updates on STEMI and PCI (10).

The evolution of the PCI guideline reflects the growth of knowledge in the field and parallels the many advances and innovations in the field of interventional cardiology, including primary PCI, BMS and DES, intravascular ultrasound (IVUS) and physiologic assessments of stenosis, and newer antiplatelet and anticoagulant therapies. The 2011 iteration of the guideline continues this process, addressing ethical aspects of PCI, vascular access considerations, CAD revascularization including hybrid revascularization, revascularization before noncardiac surgery, optical coherence tomography, advanced hemodynamic support

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devices, no-reflow therapies, and vascular closure devices. Most of this document is organized according to "patient flow," consisting of preprocedural considerations, procedural considerations, and postprocedural considerations. In a major undertaking, the STEMI, PCI, and coronary artery bypass graft (CABG) surgery guidelines were written concurrently, with additional collaboration with the SIHD guideline writing committee, allowing greater collaboration between the different writing committees on topics such as PCI in STEMI and revascularization strategies in patients with CAD (including unprotected left main PCI, multivessel disease revascularization, and hybrid procedures).

In accordance with direction from the Task Force and feedback from readers, in this iteration of the guideline, the text has been shortened, with an emphasis on summary statements rather than detailed discussion of numerous individual trials. Online supplemental evidence and summary tables have been created to document the studies and data considered for new or changed guideline recommendations.

2. CAD REVASCULARIZATION

Recommendations and text in this section are the result of extensive collaborative discussions between the PCI and CABG writing committees, as well as key members of the SIHD and UA/NSTEMI writing committees. Certain issues, such as older versus more contemporary studies, primary analyses versus subgroup analyses, and prospective versus post hoc analyses, have been carefully weighed in designating COR and LOE; they are addressed in the appropriate corresponding text. The goals of revascularization for patients with CAD are to 1) improve survival and/or 2) relieve symptoms.

Revascularization recommendations in this section are predominantly based on studies of patients with symptomatic SIHD and should be interpreted in this context. As discussed later in this section, recommendations on the type of revascularization are, in general, applicable to patients with UA/NSTEMI. In some cases (e.g., unprotected left main CAD), specific recommendations are made for patients with UA/NSTEMI or STEMI.

Historically, most studies of revascularization have been based on and reported according to angiographic criteria. Most studies have defined a "significant" stenosis as $\geq$ 70% diameter narrowing; therefore, for revascularization decisions and recommendations in this section, a "significant" stenosis has been defined as $\geq$ 70% diameter narrowing ($\geq$50% for left main CAD). Physiological criteria, such as an assessment of fractional flow reserve (FFR), has been used in deciding when revascularization is indicated. Thus, for recommendations about revascularization in this section, coronary stenoses with FFR $\leq$ 0.80 can also be considered to be "significant" (11, 12).

As noted, the revascularization recommendations have been formulated to address issues related to 1) improved survival and/or 2) improved symptoms. When one method of revascularization is preferred over the other for improved survival, this consideration, in general, takes precedence over improved symptoms. When discussing options for revascularization with the patient, he or she should understand when the procedure is being performed in an attempt to improve symptoms, survival, or both.

Although some results from the SYNTAX (Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery) study are best characterized as subgroup analyses and "hypothesis generating," SYNTAX nonetheless represents the latest and most comprehensive comparison of PCI and CABG (13, 14). Therefore, the results of SYNTAX have been considered appropriately when formulating our revascularization recommendations. Although the limitations of using the SYNTAX score for certain revascularization recommendations are recognized, the SYNTAX score is a reasonable surrogate for the extent of CAD and its complexity and serves as important information that should be considered when making revascularization decisions. Recommendations that refer to SYNTAX scores use them as surrogates for the extent and complexity of CAD.

Revascularization recommendations to improve survival and symptoms are provided in the following text and are summarized in Tables 2 and 3. References to studies comparing revascularization with medical therapy are presented when available for each anatomic subgroup. T2 T3

See Online Data Supplements 1 and 2 for additional data regarding the survival and symptomatic benefits with CABG or PCI for different anatomic subsets.

2.1. Heart Team Approach to Revascularization Decisions: Recommendations

CLASS I

1. A Heart Team approach to revascularization is recommended in patients with unprotected left main or complex CAD (14–16). *(Level of Evidence: C)*

CLASS IIa

1. Calculation of the Society of Thoracic Surgeons (STS) and SYNTAX scores is reasonable in patients with unprotected left main and complex CAD (13, 14, 17–22). *(Level of Evidence: B)*

One protocol used in RCTs (14–16, 23) often involves a multidisciplinary approach referred to as the Heart Team. Composed of an interventional cardiologist and a cardiac surgeon, the Heart Team 1) reviews the patient's medical condition and coronary anatomy, 2) determines that PCI and/or CABG are technically feasible and reasonable, and 3) discusses revascularization options with the patient before a treatment strategy is selected. Support for using a Heart Team approach comes from reports that patients with complex CAD referred specifically for PCI or CABG in concurrent trial registries have lower mortality rates than those randomly assigned to PCI or CABG in controlled trials (15, 16).

The SIHD, PCI, and CABG guideline writing committees endorse a Heart Team approach in patients with unprotected left main CAD and/or complex CAD in whom the optimal revascularization strategy is not straightforward. A collaborative assessment of revascularization options, or the decision to treat with GDMT without revascularization, involving an interventional cardiologist, a cardiac surgeon, and (often) the patient's general cardiologist, followed by discussion with the patient about treatment options, is optimal. Particularly in patients with SIHD and unprotected left main and/or complex CAD for whom a revascularization strategy is not straightforward, an approach has been endorsed that involves terminating the procedure after diagnostic coronary angiography is completed: this allows a thorough discussion and affords both the interventional cardiologist and cardiac surgeon the opportunity to discuss revascularization options with the patient. Because the STS score and the SYNTAX score have been shown to predict adverse outcomes in patients undergoing CABG and PCI, respectively, calculation of these scores is often useful in making revascularization decisions (13, 14, 17–22).

2.2. Revascularization to Improve Survival: Recommendations

Left Main CAD Revascularization

CLASS I

1. CABG to improve survival is recommended for patients with significant (≥50% diameter stenosis) left main coronary artery stenosis (24–30). *(Level of Evidence: B)*

CLASS IIa

1. PCI to improve survival is reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcome (e.g., a low SYNTAX score [≤22], ostial or trunk left main CAD); and 2) clinical characteristics that predict a significantly increased risk of adverse surgical outcomes (e.g., STS-predicted risk of operative mortality ≥5%) (13, 17, 19, 23, 31–48). *(Level of Evidence: B)*
2. PCI to improve survival is reasonable in patients with UA/NSTEMI when an unprotected left main coronary artery is the culprit lesion and the patient is not a candidate for CABG (13, 36–39, 44, 45, 47–49). *(Level of Evidence: B)*
3. PCI to improve survival is reasonable in patients with acute STEMI when an unprotected left main coronary artery is the culprit lesion, distal coronary flow is less than TIMI (Thrombolysis In Myocardial Infarction) grade 3, and PCI can be performed more rapidly and safely than CABG (33, 50, 51). *(Level of Evidence: C)*

CLASS IIb

1. PCI to improve survival may be reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low to intermediate risk of PCI procedural complications and an intermediate to high likelihood of good long-term outcome (e.g., low-intermediate SYNTAX score of <33, bifurcation left main CAD); and 2) clinical characteristics that predict an increased risk of adverse surgical outcomes (e.g., moderate-severe chronic obstructive pulmonary disease, disability from previous stroke, or previous cardiac surgery; STS-predicted risk of operative mortality >2%) (13, 17, 19, 23, 31–48, 52). *(Level of Evidence: B)*

CLASS III: HARM

1. PCI to improve survival should not be performed in stable patients with significant (≥50% diameter stenosis) unprotected left main CAD who have unfavorable anatomy for PCI and who are good candidates for CABG (13, 17, 19, 24–32). *(Level of Evidence: B)*

Non-Left Main CAD Revascularization

CLASS I

1. CABG to improve survival is beneficial in patients with significant (≥70% diameter) stenoses in 3 major coronary arteries (with or without involvement of the proximal left anterior descending [LAD] artery) or in the proximal LAD plus 1 other major coronary artery (26, 30, 53–56). *(Level of Evidence: B)*

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TABLE 2. Revascularization to Improve Survival Compared With Medical Therapy

Anatomic Setting	COR	LOE	References
UPLM or complex CAD			
CABG and PCI	I—Heart Team approach recommended	C	(14-16)
CABG and PCI	IIa—Calculation of STS and SYNTAX scores	B	(13,14,17-22)
UPLM*			
CABG	I	B	(24-30)
PCI	IIa—For SIHD when *both* of the following are present: • Anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of good long-term outcome (e.g., a low SYNTAX score of ≤22, ostial or trunk left main CAD) • Clinical characteristics that predict a significantly increased risk of adverse surgical outcomes (e.g., STS-predicted risk of operative mortality ≥5%)	B	(13,17,19,23,31-48)
	IIa—For UA/NSTEMI if not a CABG candidate	B	(13,36-39,44,45,47-49)
	IIa—For STEMI when distal coronary flow is TIMI flow grade <3 and PCI can be performed more rapidly and safely than CABG	C	(33,50,51)
	IIb—For SIHD when *both* of the following are present: • Anatomic conditions associated with a low to intermediate risk of PCI procedural complications and an intermediate to high likelihood of good long-term outcome (e.g., low-intermediate SYNTAX score of <33, bifurcation left main CAD) • Clinical characteristics that predict an increased risk of adverse surgical outcomes (e.g., moderate-severe COPD, disability from prior stroke, or prior cardiac surgery; STS-predicted risk of operative mortality >2%)	B	(13,17,19,23,31-48,52)
	III: Harm—For SIHD in patients (versus performing CABG) with unfavorable anatomy for PCI and who are good candidates for CABG	B	(13,17,19,24-32)
3-vessel disease with or without proximal LAD artery disease*			
CABG	I	B	(26,30 53-56)
	IIa—It is reasonable to choose CABG over PCI in patients with complex 3-vessel CAD (e.g., SYNTAX score >22) who are good candidates for CABG.	B	(32,46,56,71,72)
PCI	IIb—Of uncertain benefit	B	(26,46,53,56,82)
2-vessel disease with proximal LAD artery disease*			
CABG	I	B	(26,30,53-56)
PCI	IIb—Of uncertain benefit	B	(26,53,56,82)
2-vessel disease without proximal LAD artery disease*			
CABG	IIa—With extensive ischemia	B	(60-63)
	IIb—Of uncertain benefit without extensive ischemia	C	(56)
PCI	IIb—Of uncertain benefit	B	(26,53,56,82)
1-vessel proximal LAD artery disease			
CABG	IIa—With LIMA for long-term benefit	B	(30,56,69,70)
PCI	IIb—Of uncertain benefit	B	(26,53,56,82)
1-vessel disease without proximal LAD artery involvement			
CABG	III: Harm	B	(30,53,60,61,94-98)
PCI	III: Harm	B	(30,53,60,61,94-98)
LV dysfunction			
CABG	IIa—EF 35% to 50%	B	(30,64-68)
CABG	IIb—EF <35% without significant left main CAD	B	(30,64-68,83,84)
PCI	Insufficient data		N/A
Survivors of sudden cardiac death with presumed ischemia-mediated VT			
CABG	I	B	(57-59)
PCI	I	C	(57)
No anatomic or physiologic criteria for revascularization			
CABG	III: Harm	B	(30,53,60,61,94-98)
PCI	III: Harm	B	(30,53,60,61,94-98)

*In patients with multivessel disease who also have diabetes, it is reasonable to choose CABG (with LIMA) over PCI (62,74–81)(C/ass *IIa; LOE:* B)

CABG indicates coronary artery bypass graft; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; COR, class of recommendation; EF, ejection fraction; LAD, left anterior descending; LIMA, left internal mammary artery; LOE, level of evidence; LV, left ventricular; N/A, not applicable; PCI, percutaneous coronary intervention; SIHD, stable ischemic heart disease; STEMI, ST-elevation myocardial infarction; STS, Society of Thoracic Surgeons; SYNTAX, Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery; TIMI, Thrombolysis In Myocardial Infarction; UA/NSTEMI, unstable angina/non-ST-elevation myocardial infarction; UPLM, unprotected left main disease; and VT, Ventricular tachycardia.

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TABLE 3. Revascularization to Improve Symptoms With Significant Anatomic (≥50% Left Main or ≥70% Non-Left Main CAD) or Physiological (FFR≤0.80) Coronary Artery Stenoses

Clinical Setting	COR	LOE	References
≥1 significant stenoses amenable to revascularization and unacceptable angina despite GDMT	I–CABG I–PCI	A	(82,99–108)
≥1 significant stenoses and unacceptable angina in whom GDMT cannot be implemented because of medication contraindications, adverse effects, or patient preferences	IIa–CABG IIa–PCI	C	N/A
Previous CABG with ≥1 significant stenoses associated with ischemia and unacceptable angina despite GDMT	IIa–PCI	C	(86,89,92)
	IIb–CABG	C	(93)
Complex 3-vessel CAD (e.g., SYNTAX score >22) with or without involvement of the proximal LAD artery and a good candidate for CABG	IIa–CABG preferred over PCI	B	(32,46,56,71,72)
Viable ischemic myocardium that is perfused by coronary arteries that are not amenable to grafting	IIb–TMR as an adjunct to CABG	B	(109–113)
No anatomic or physiologic criteria for revascularization	III: Harm–CABG III: Harm–PCI	C	N/A

CABG indicates coronary artery bypass graft; CAD, coronary artery disease; COR, class of recommendation; FFR, fractional flow reserve; GDMT, guideline-directed medical therapy; LOE, level of evidence; N/A, not applicable; PCI, percutaneous coronary intervention; SYNTAX, Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery; and TMR, transmyocardial laser revascularization.

2. CABG or PCI to improve survival is beneficial in survivors of sudden cardiac death with presumed ischemia-mediated ventricular tachycardia caused by significant (≥70% diameter) stenosis in a major coronary artery. *(CABG Level of Evidence: B* [57–59]; *PCI Level of Evidence: C* [57])

CLASS IIa

1. CABG to improve survival is reasonable in patients with significant (≥70% diameter) stenoses in 2 major coronary arteries with severe or extensive myocardial ischemia (e.g., high-risk criteria on stress testing, abnormal intracoronary hemodynamic evaluation, or >20% perfusion defect by myocardial perfusion stress imaging) or target vessels supplying a large area of viable myocardium (60–63). *(Level of Evidence: B)*
2. CABG to improve survival is reasonable in patients with mild-moderate left ventricular (LV) systolic dysfunction (ejection fraction [EF] 35% to 50%) and significant (≥70% diameter stenosis) multi-vessel CAD or proximal LAD coronary artery stenosis, when viable myocardium is present in the region of intended revascularization (30, 64–68). *(Level of Evidence: B)*
3. CABG with a left internal mammary artery (LIMA) graft to improve survival is reasonable in patients with significant (≥70% diameter) stenosis in the proximal LAD artery and evidence of extensive ischemia (30, 56, 69, 70). *(Level of Evidence: B)*
4. It is reasonable to choose CABG over PCI to improve survival in patients with complex 3-vessel CAD (e.g., SYNTAX score >22), with or without involvement of the proximal LAD artery who are good candidates for CABG (32, 46, 56, 71, 72). *(Level of Evidence: B)*
5. CABG is probably recommended in preference to PCI to improve survival in patients with multivessel CAD and diabetes mellitus, particularly if a LIMA graft can be anastomosed to the LAD artery (62, 74–81). *(Level of Evidence: B)*

CLASS IIb

1. The usefulness of CABG to improve survival is uncertain in patients with significant (≥70%) diameter stenoses in 2 major coronary arteries not involving the proximal LAD artery and without extensive ischemia (56). *(Level of Evidence: C)*
2. The usefulness of PCI to improve survival is uncertain in patients with 2- or 3-vessel CAD (with or without involvement of the proximal LAD artery) or 1-vessel proximal LAD disease (26, 53, 56, 82). *(Level of Evidence: B)*
3. CABG might be considered with the primary or sole intent of improving survival in patients with SIHD with severe LV systolic dysfunction (EF <35%) whether or not viable myocardium is present (30, 64–68, 83, 84). *(Level of Evidence: B)*
4. The usefulness of CABG or PCI to improve survival is uncertain in patients with previous CABG and extensive anterior wall ischemia on noninvasive testing (85–93). *(Level of Evidence: B)*

CLASS III: HARM

1. CABG or PCI should not be performed with the primary or sole intent to improve survival in patients with SIHD with 1 or more coronary stenoses that

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are not anatomically or functionally significant (e.g., <70% diameter non-left main coronary artery stenosis, FFR >0.80, no or only mild ischemia on noninvasive testing), involve only the left circumflex or right coronary artery, or subtend only a small area of viable myocardium (30, 53, 60, 61, 94–98). *(Level of Evidence: B)*

2.3. Revascularization to Improve Symptoms: Recommendations

CLASS I

1. CABG or PCI to improve symptoms is beneficial in patients with 1 or more significant (≥70% diameter) coronary artery stenoses amenable to revascularization and unacceptable angina despite GDMT (82, 99–108). *(Level of Evidence: A)*

CLASS IIa

1. CABG or PCI to improve symptoms is reasonable in patients with 1 or more significant (≥70% diameter) coronary artery stenoses and unacceptable angina for whom GDMT cannot be implemented because of medication contraindications, adverse effects, or patient preferences. *(Level of Evidence: C)*
2. PCI to improve symptoms is reasonable in patients with previous CABG, 1 or more significant (≥70% diameter) coronary artery stenoses associated with ischemia, and unacceptable angina despite GDMT (86, 89, 92). *(Level of Evidence: C)*
3. It is reasonable to choose CABG over PCI to improve symptoms in patients with complex 3-vessel CAD (e.g., SYNTAX score >22), with or without involvement of the proximal LAD artery who are good candidates for CABG (32, 46, 56, 72, 73). *(Level of Evidence: B)*

CLASS IIb

1. CABG to improve symptoms might be reasonable for patients with previous CABG, 1 or more significant (≥70% diameter) coronary artery stenoses not amenable to PCI, and unacceptable angina despite GDMT (93). *(Level of Evidence: C)*
2. Transmyocardial laser revascularization (TMR) performed as an adjunct to CABG to improve symptoms may be reasonable in patients with viable ischemic myocardium that is perfused by arteries that are not amenable to grafting (109–113). *(Level of Evidence: B)*

CLASS III: HARM

1. CABG or PCI to improve symptoms should not be performed in patients who do not meet anatomic (≥50% diameter left main or ≥70% non-left main stenosis diameter) or physiological (e.g., abnormal FFR) criteria for revascularization. *(Level of Evidence: C)*

2.4. CABG Versus Contemporaneous Medical Therapy

In the 1970s and 1980s, 3 RCTs established the survival benefit of CABG compared with contemporaneous (although minimal by current standards) medical therapy without revascularization in certain subjects with stable angina: the Veterans Affairs Cooperative Study (114), European Coronary Surgery Study (55), and CASS (Coronary Artery Surgery Study) (115). Subsequently, a 1994 meta-analysis of 7 studies that randomized a total of 2,649 patients to medical therapy or CABG (30) showed that CABG offered a survival advantage over medical therapy for patients with left main or 3-vessel CAD. The studies also established that CABG is more effective than medical therapy for relieving anginal symptoms. These studies have been replicated only once during the past decade. In MASS II (Medicine, Angioplasty, or Surgery Study II), patients with multivessel CAD who were treated with CABG were less likely than those treated with medical therapy to have a subsequent MI, need additional revascularization, or experience cardiac death in the 10 years after randomization (104).

Surgical techniques and medical therapy have improved substantially during the intervening years. As a result, if CABG were to be compared with GDMT in RCTs today, the relative benefits for survival and angina relief observed several decades ago might no longer be observed. Conversely, the concurrent administration of GDMT may substantially improve long-term outcomes in patients treated with CABG in comparison with those receiving medical therapy alone. In the BARI 2D (Bypass Angioplasty Revascularization Investigation 2 Diabetes) trial of patients with diabetes mellitus, no significant difference in risk of mortality in the cohort of patients randomized to GDMT plus CABG or GDMT alone was observed, although the study was not powered for this endpoint, excluded patients with significant left main CAD, and included only a small percentage of patients with proximal LAD artery disease or LV ejection fraction (LVEF) <0.50 (116). The PCI and CABG guideline writing committees endorse the performance of the ISCHEMIA (International Study of Comparative Health Effectiveness with Medical and Invasive Approaches) trial, which will provide contemporary data on the optimal management strategy (medical therapy or revascularization with CABG or

PCI) of patients with SIHD, including multivessel CAD, and moderate to severe ischemia.

2.5. PCI Versus Medical Therapy

Although contemporary interventional treatments have lowered the risk of restenosis compared with earlier techniques, meta-analyses have failed to show that the introduction of BMS confers a survival advantage over balloon angioplasty (117–119) or that the use of DES confers a survival advantage over BMS (119, 120).

No study to date has demonstrated that PCI in patients with SIHD improves survival rates (26, 53, 56, 82, 116, 119, 121–124). Neither COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) (82) nor BARI 2D (116), which treated all patients with contemporary optimal medical therapy, demonstrated any survival advantage with PCI, although these trials were not specifically powered for this endpoint. Although 1 large analysis evaluating 17 RCTs of PCI versus medical therapy (including 5 trials of subjects with acute coronary syndromes [ACS]) found a 20% reduction in death with PCI compared with medical therapy (123), 2 other large analyses did not (119, 122). An evaluation of 13 studies reporting the data from 5,442 patients with nonacute CAD showed no advantage of PCI over medical therapy for the individual endpoints of all-cause death, cardiac death or MI, or nonfatal MI (124). Evaluation of 61 trials of PCI conducted over several decades shows that despite improvements in PCI technology and pharmacotherapy, PCI has not been demonstrated to reduce the risk of death or MI in patients without recent ACS (119).

The findings from individual studies and systematic reviews of PCI versus medical therapy can be summarized as follows:

- PCI reduces the incidence of angina (82, 99, 104, 107, 108, 125).
- PCI has not been demonstrated to improve survival in stable patients (119, 121, 122).
- PCI may increase the short-term risk of MI (82, 121, 125, 126).
- PCI does not lower the long-term risk of MI (82, 116, 119, 121, 122, 126).

2.6. CABG Versus PCI

The results of 26 RCTs comparing CABG and PCI have been published: Of these, 9 compared CABG with balloon angioplasty (75, 105, 128–142), 14 compared CABG with BMS implantation (88, 143–160), and 3 compared CABG with DES implantation (14, 161, 162).

2.6.1. CABG Versus Balloon Angioplasty or BMS. A systematic review of the 22 RCTs comparing CABG with balloon angioplasty or BMS implantation concluded the following (163):

1. Survival was similar for CABG and PCI (with balloon angioplasty or BMS) at 1 year and 5 years. Survival was similar for CABG and PCI in subjects with 1-vessel CAD (including those with disease of the proximal portion of the LAD artery) or multivessel CAD.
2. Incidence of MI was similar at 5 years after randomization.
3. Procedural stroke occurred more commonly with CABG than with PCI (1.2% versus 0.6%).
4. Relief of angina was accomplished more effectively with CABG than with PCI 1 year after randomization and 5 years after randomization.
5. During the first year after randomization, repeat coronary revascularization was performed less often after CABG than after PCI (3.8% versus 26.5%). This was also demonstrated after 5 years of follow-up (9.8% versus 46.1%). This difference was more pronounced with balloon angioplasty than with BMS.

A collaborative analysis of data from 10 RCTs comparing CABG with balloon angioplasty (6 trials) or with BMS implantation (4 trials) (164) permitted subgroup analyses of the data from the 7,812 patients. No difference was noted with regard to mortality rate 5.9 years after randomization or the composite endpoint of death or MI. Repeat revascularization and angina were noted more frequently in those treated with balloon angioplasty or BMS implantation (164). The major new observation of this analysis was that CABG was associated with better outcomes in patients with diabetes mellitus and in those >65 years old. Of interest, the relative outcomes of CABG and PCI were not influenced by other patient characteristics, including the number of diseased coronary arteries.

The aforementioned meta-analysis and systematic review (163, 164) comparing CABG and balloon angioplasty or BMS implantation were limited in several ways:

1. Many trials did not report outcomes for other important patient subsets. For example, the available data are insufficient to determine if race, obesity, renal dysfunction, peripheral arterial disease, or previous coronary revascularization affected the comparative outcomes of CABG and PCI.
2. Most of the patients enrolled in these trials were male, and most had 1- or 2-vessel CAD and normal LV systolic function (EF >50%)—subjects known

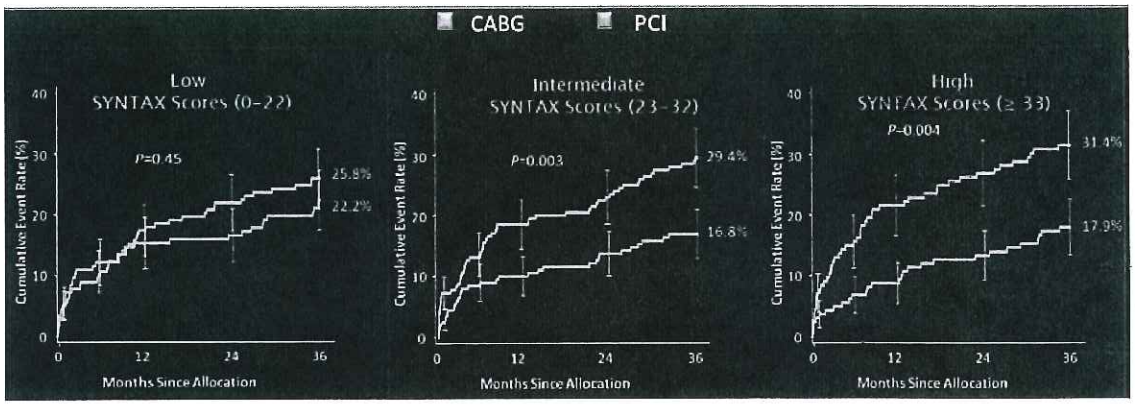

Fig. 1. Cumulative Incidence of MACE in Patients With 3-Vessel CAD Based on SYNTAX Score at 3-Year Follow-Up in the SYNTAX Trial Treated With Either CABG or PCI.

CABG indicates coronary artery bypass graft; CAD, coronary artery disease; MACE, major adverse cardiovascular event; PCI, percutaneous coronary intervention; and SYNTAX, Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery. Adapted with permission from Kappetein (46).

to be unlikely to derive a survival benefit and less likely to experience complications after CABG (30).

3. The patients enrolled in these trials represented only a small fraction (generally <5% to 10%) of those who were screened. For example, most screened patients with 1-vessel CAD and many with 3-vessel CAD were not considered for randomization.

See Online Data Supplements 3 and 4 for additional data comparing CABG with PCI.

2.6.2. CABG Versus DES. Although the results of 9 observational studies comparing CABG and DES implantation have been published (32, 165–172), most of them had short (12 to 24 months) follow-up periods. In a meta-analysis of 24,268 patients with multivessel CAD treated with CABG or DES (173), the incidences of death and MI were similar for the 2 procedures, but the frequency with which repeat revascularization was performed was roughly 4 times higher after DES implantation. Only 1 large RCT comparing CABG and DES implantation has been published. The SYNTAX trial randomly assigned 1,800 patients (of a total of 4,337 who were screened) to receive DES or CABG (14, 46). Major adverse cardiac events (MACE), a composite of death, stroke, MI, or repeat revascularization during the 3 years after randomization, occurred in 20.2% of CABG patients and 28.0% of those undergoing DES implantation ($p<0.001$). The rates of death and stroke were similar; however, MI (3.6% for CABG, 7.1% for DES) and repeat revascularization (10.7% for CABG, 19.7% for DES) were more likely to occur with DES implantation (46).

In SYNTAX, the extent of CAD was assessed using the SYNTAX score, which is based on the location, severity, and extent of coronary stenoses, with a low score indicating less complicated anatomic CAD. In post hoc analyses, a low score was defined as ≤22; intermediate, 23 to 32; and high, ≥33. The occurrence of MACE correlated with the SYNTAX score for DES patients but not for those undergoing CABG. At 12-month follow-up, the primary endpoint was similar for CABG and DES in those with a low SYNTAX score. In contrast, MACE occurred more often after DES implantation than after CABG in those with an intermediate or high SYNTAX score (14). At 3 years of follow-up, the mortality rate was greater in subjects with 3-vessel CAD treated with PCI than in those treated with CABG (6.2% versus 2.9%). The differences in MACE between those treated with PCI or CABG increased with an increasing SYNTAX score (Figure 1) (46). F1

Although the utility of using a SYNTAX score in everyday clinical practice remains uncertain, it seems reasonable to conclude from SYNTAX and other data that outcomes of patients undergoing PCI or CABG in those with relatively uncomplicated and lesser degrees of CAD are comparable, whereas in those with complex and diffuse CAD, CABG appears to be preferable (46).

See Online Data Supplements 5 and 6 for additional data comparing CABG with DES.

2.7. Left Main CAD

2.7.1. CABG or PCI Versus Medical Therapy for Left Main CAD. CABG confers a survival benefit over medical therapy in patients with left main CAD. Subgroup analyses from RCTs performed 3 decades ago included 91 patients with left main CAD in the

Veterans Administration Cooperative Study (28). A meta-analysis of these trials demonstrated a 66% reduction in relative risk in mortality with CABG, with the benefit extending to 10 years (30). The CASS Registry (24) contained data from 1,484 patients with ≥50% diameter stenosis left main CAD initially treated surgically or nonsurgically. Median survival duration was 13.3 years in the surgical group; and 6.6 years in the medical group. The survival benefit of CABG over medical therapy appeared to extend to 53 asymptomatic patients with left main CAD in the CASS Registry (29). Other therapies that subsequently have been shown to be associated with improved long-term outcome, such as the use of aspirin, statins, and internal mammary artery grafting, were not widely used in that era.

RCTs and subgroup analyses that compare PCI with medical therapy in patients with "unprotected" left main CAD do not exist.

2.7.2. Studies Comparing PCI Versus CABG for Left Main CAD. Of all subjects undergoing coronary angiography, approximately 4% are found to have left main CAD (175), >80% of whom have significant (≥70% diameter) stenoses in other epicardial coronary arteries.

Published cohort studies have found that major clinical outcomes are similar with PCI or CABG 1 year after revascularization and that mortality rates are similar at 1, 2, and 5 years of follow-up; however, the risk of needing target-vessel revascularization is significantly higher with stenting than with CABG.

In the SYNTAX trial, 45% of screened patients with unprotected left main CAD had complex disease that prevented randomization; 89% of these underwent CABG (13, 14). In addition, 705 of the 1,800 patients who were randomized had revascularization for unprotected left main CAD. The majority of patients with left main CAD and a low SYNTAX score had isolated left main CAD or left main CAD plus 1-vessel CAD; the majority of those with an intermediate score had left main CAD plus 2-vessel CAD; and most of those with a high SYNTAX score had left main CAD plus 3-vessel CAD. At 1 year, rates of all-cause death and MACE were similar for the 2 groups (13). Repeat revascularization rates were higher in the PCI group than the CABG group (11.8% versus 6.5%), but stroke occurred more often in the CABG group (2.7% versus 0.3%). At 3 years of follow-up, the incidence of death in those undergoing left main CAD revascularization with low or intermediate SYNTAX scores (≤32) was 3.7% after PCI and 9.1% after CABG (p=0.03), whereas in those with a high SYNTAX score (≥33), the incidence of death after 3 years was 13.4% after PCI and 7.6% after CABG (p=0.10) (46). Because the primary endpoint of SYNTAX was not met (i.e., noninferiority comparison of CABG and PCI), these subgroup analyses need to be considered in that context.

In the LE MANS (Study of Unprotected Left Main Stenting Versus Bypass Surgery) trial (23), 105 patients with left main CAD were randomized to receive PCI or CABG. Although a low proportion of patients treated with PCI received DES (35%) and a low proportion of patients treated with CABG received internal mammary grafts (72%), the outcomes at 30 days and 1 year were similar between the groups. In the PRECOMBAT (Premier of Randomized Comparison of Bypass Surgery versus Angioplasty Using Sirolimus-Eluting Stent in Patients with Left Main Coronary Artery Disease) trial of 600 patients with left main disease, the composite endpoint of death, MI, or stroke at 2 years occurred in 4.4% of patients treated with PCI patients and 4.7% of patients treated with CABG, but ischemia-driven target-vessel revascularization was more often required in the patients treated with PCI (9.0% versus 4.2%) (52).

The results from these 3 RCTs suggest (but do not definitively prove) that major clinical outcomes in *selected* patients with left main CAD are similar with CABG and PCI at 1- to 2-year follow-up, but repeat revascularization rates are higher after PCI than after CABG. RCTs with extended follow-up of ≥5 years are required to provide definitive conclusions about the optimal treatment of left main CAD. In a meta-analysis of 8 cohort studies and 2 RCTs (41), death, MI, and stroke occurred with similar frequency in the PCI- and CABG-treated patients at 1, 2, and 3 years of follow-up. Target-vessel revascularization was performed more often in the PCI group at 1 year (OR: 4.36), 2 years (OR: 4.20), and 3 years (OR: 3.30).

See Online Data Supplements 7 to 12 for additional data comparing PCI with CABG for left main CAD.

2.7.3. Revascularization Considerations for Left Main CAD. Although CABG has been considered the "gold standard" for unprotected left main CAD revascularization, more recently PCI has emerged as a possible alternative mode of revascularization in carefully selected patients. Lesion location is an important determinant when considering PCI for unprotected left main CAD. Stenting of the left main ostium or trunk is more straightforward than treating distal bifurcation or trifurcation stenoses, which generally requires a greater degree of operator experience and expertise (176). In addition, PCI of bifurcation disease is associated with higher restenosis rates than when disease is confined to the ostium or trunk (39, 177). Although lesion location influences technical success and long-term outcomes after PCI, location exerts a negligible influence on the success of CABG. In subgroup analyses, patients with left main CAD and a SYNTAX score ≥33 with more

complex or extensive CAD had a higher mortality rate with PCI than with CABG (46). Physicians can estimate operative risk for all CABG candidates using a standard instrument, such as the risk calculator from the STS database. The above considerations are important factors when choosing among revascularization strategies for unprotected left main CAD and have been factored into revascularization recommendations. Use of a Heart Team approach has been recommended in cases in which the choice of revascularization is not straightforward. As discussed in Section 2.9.7, the ability of the patient to tolerate and comply with dual antiplatelet therapy (DAPT) is also an important consideration in revascularization decisions.

The 2005 PCI guideline (8) recommended routine an-giographic follow-up 2 to 6 months after stenting for unprotected left main CAD. However, because angiography has limited ability to predict stent thrombosis and the results of SYNTAX suggest good intermediate-term results for PCI in subjects with left main CAD, this recommendation was removed in the 2009 STEMI/PCI focused update (10).

Experts have recommended immediate PCI for unprotected left main CAD in the setting of STEMI (51). The impetus for such a strategy is greatest when left main CAD is the site of the culprit lesion, antegrade coronary flow is diminished (e.g., TIMI flow grade 0, 1, or 2), the patient is hemodynamically unstable, and it is believed that PCI can be performed more quickly than CABG. When possible, the interventional cardiologist and cardiac surgeon should decide together on the optimal form of revascularization for these subjects, although it is recognized that these patients are usually critically ill and therefore not amenable to a prolonged deliberation or discussion of treatment options.

2.8. Proximal LAD Artery Disease

A cohort study (53) and a meta-analysis (30) from the 1990s suggested that CABG confers a survival advantage over contemporaneous medical therapy for patients with disease in the proximal segment of the LAD artery. Cohort studies and RCTs (30, 133, 146, 148, 161, 178–181) as well as collaborative- and meta-analyses (164, 182–184) showed that PCI and CABG result in similar survival rates in these patients.

See Online Data Supplement 13 for additional data regarding proximal LAD artery revascularization.

2.9. Clinical Factors That May Influence the Choice of Revascularization

2.9.1. Diabetes Mellitus. An analysis performed in 2009 of data on 7,812 patients (1,233 with diabetes) in 10 RCTs demonstrated a worse long-term survival rate in patients with diabetes mellitus after balloon angioplasty or BMS implantation than after CABG (164). The BARI 2D trial (116) randomly assigned 2,368 patients with type 2 diabetes and CAD to undergo intensive medical therapy or prompt revascularization with PCI or CABG, according to whichever was thought to be more appropriate. By study design, those with less extensive CAD more often received PCI, whereas those with more extensive CAD were more likely to be treated with CABG.

The study was not designed to compare PCI with CABG. At 5-year follow-up, no difference in rates of survival or MACE between the medical therapy group and those treated with revascularization was noted. In the PCI stratum, no significant difference in MACE between medical therapy and revascularization was demonstrated (DES in 35%; BMS in 56%); in the CABG stratum, MACE occurred less often in the revascularization group. One-year follow-up data from the SYNTAX study demonstrated a higher rate of repeat revascularization in patients with diabetes mellitus treated with PCI than with CABG, driven by a tendency for higher repeat revascularization rates in those with higher SYNTAX scores undergoing PCI (76). In summary, in subjects requiring revascularization for multivessel CAD, current evidence supports diabetes mellitus as an important factor when deciding on a revascularization strategy, particularly when complex or extensive CAD is present (Figure 2). F2

See Online Data Supplements 14 and 15 for additional data regarding diabetes mellitus.

2.9.2. Chronic Kidney Disease. Cardiovascular morbidity and mortality rates are markedly increased in patients with chronic kidney disease (CKD) when compared with age-matched controls without CKD. The mortality rate for patients on hemodialysis is >20% per year, and approximately 50% of deaths among these patients are due to a cardiovascular cause (187, 188).

To date, randomized comparisons of coronary revascularization (with CABG or PCI) and medical therapy in patients with CKD have not been reported. Some, but not all, observational studies or subgroup analyses have demonstrated an improved survival rate with revascularization compared with medical therapy in patients with CKD and multivessel CAD (189–191), despite the fact that the incidence of periprocedural complications (e.g., death, MI, stroke, infection, renal failure) is increased in patients with CKD compared with those without renal dysfunction. Some studies have shown that CABG is associated with a greater survival benefit than PCI among patients with severe renal dysfunction (190–196).

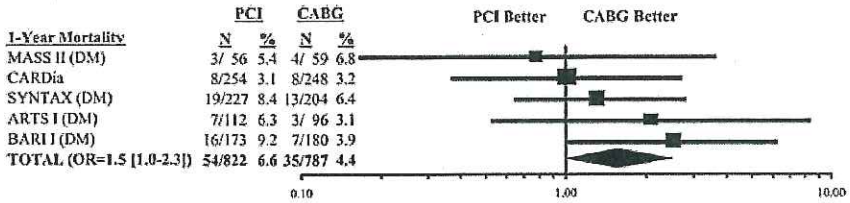

Fig. 2. 1-Year Mortality After Revascularization for Multivessel Disease and Diabetes Mellitus.

An OR of >1 suggests an advantage of CABG over PCI. ARTS I indicates Arterial Revascularization Therapy Study I (185); BARI I, Bypass Angioplasty Revascularization Investigation I (74); CABG, coronary artery bypass graft; CAD, coronary artery disease; CARDia, Coronary Artery Revascularization in Diabetes (186); CI, confidence interval; MASS II, Medicine, Angioplasty, or Surgery Study II (78); OR, odds ratio; PCI, percutaneous coronary intervention; SYNTAX, Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery; and W, weighted (76).

2.9.3. Completeness of Revascularization. Most patients undergoing CABG receive complete or nearly complete revascularization, which seems to influence long-term prognosis positively (197). In contrast, complete revascularization is accomplished less often in subjects receiving PCI (e.g., in <70% of patients), but the extent to which the absence of complete initial revascularization influences outcome is less clear. Rates of late survival and survival free of MI appears to be similar in patients with and without complete revascularization after PCI. Nevertheless, the need for subsequent CABG is usually higher in those whose initial revascularization procedure was incomplete (compared with those with complete revascularization) after PCI (198–200).

2.9.4. LV Systolic Dysfunction. Several older studies and a meta-analysis of the data from these studies reported that patients with LV systolic dysfunction (predominantly mild to moderate in severity) had better survival with CABG than with medical therapy alone (30, 64–68). For patients with more severe LV systolic dysfunction, however, the evidence that CABG results in better survival compared with medical therapy is lacking. In the STICH (Surgical Treatment for Ischemic Heart Failure) trial of subjects with LVEF <35% with or without viability testing, CABG and GDMT resulted in similar rates of survival (death from any cause, the study's primary outcome) after 5 years of follow-up. For a number of secondary outcomes at this time point, including 1) death from any cause or hospitalization for heart failure, 2) death from any cause or hospitalization for cardiovascular causes, 3) death from any cause or hospitalization for any cause, or 4) death from any cause or revascularization with PCI or CABG, CABG was superior to GDMT. Although the primary outcome (death from any cause) was similar in the 2 treatment groups after an average of 5 years of follow-up, the data suggest the possibility that outcomes would differ if the follow-up were longer in duration; as a result, the study is being continued to provide follow-up for up to 10 years (83, 84).

Only very limited data comparing PCI with medical therapy in patients with LV systolic dysfunction are available (68). In several ways, these data are suboptimal, in that many studies compared CABG with balloon angioplasty, many were retrospective, and many were based on cohort or registry data. Some of the studies demonstrated a similar survival rate in patients having CABG and PCI (71, 164, 201–203), whereas others showed that those undergoing CABG had better outcomes (32). The data that exist at present on revascularization in patients with CAD and LV systolic dysfunction are more robust for CABG than for PCI, although data from contemporary RCTs in this patient population are lacking. Therefore, the choice of revascularization in patients with CAD and LV systolic dysfunction is best based on clinical variables (e.g., coronary anatomy, presence of diabetes mellitus, presence of CKD), magnitude of LV systolic dysfunction, patient preferences, clinical judgment, and consultation between the interventional cardiologist and the cardiac surgeon.

2.9.5. Previous CABG. In patients with recurrent angina after CABG, repeat revascularization is most likely to improve survival in subjects at highest risk, such as those with obstruction of the proximal LAD artery and extensive anterior ischemia (85–93). Patients with ischemia in other locations and those with a patent LIMA to the LAD artery are unlikely to experience a survival benefit from repeat revascularization (92).

Cohort studies comparing PCI and CABG among post-CABG patients report similar rates of mid- and long-term survival after the 2 procedures (85, 88–91, 93, 204). In the patient with previous CABG who is referred for revascularization for medically refractory ischemia, factors that may support the choice of repeat CABG include vessels unsuitable for PCI, number of diseased bypass grafts, availability of the internal mammary artery for grafting chronically occluded coronary arteries, and good distal targets for bypass graft placement. Factors favoring PCI over CABG include limited areas of ischemia causing symptoms, suitable

PCI targets, a patent graft to the LAD artery, poor CABG targets, and comorbid conditions.

2.9.6. Unstable Angina/Non-ST-Elevation Myocardial Infarction. The main difference between management of the patient with SIHD and the patient with UA/NSTEMI is that the impetus for revascularization is stronger in the setting of UA/NSTEMI, because myocardial ischemia occurring as part of an ACS is potentially life threatening, and associated anginal symptoms are more likely to be reduced with a revascularization procedure than with GDMT (205–207). Thus, the indications for revascularization are strengthened by the acuity of presentation, the extent of ischemia, and the ability to achieve full revascularization. The choice of revascularization method is generally dictated by the same considerations used to decide on PCI or CABG for patients with SIHD.

2.9.7. DAPT Compliance and Stent Thrombosis: Recommendation

CLASS III: HARM

1. PCI with coronary stenting (BMS or DES) should not be performed if the patient is not likely to be able to tolerate and comply with DAPT for the appropriate duration of treatment based on the type of stent implanted (208–211). *(Level of Evidence: B)*

The risk of stent thrombosis is increased dramatically in patients who prematurely discontinue DAPT, and stent thrombosis is associated with a mortality rate of 20% to 45% (208). Because the risk of stent thrombosis with BMS is greatest in the first 14 to 30 days, this is the generally recommended minimum duration of DAPT therapy for these individuals. Consensus in clinical practice is to treat DES patients for at least 12 months with DAPT to avoid late (after 30 days) stent thrombosis (208, 212). Therefore, the ability of the patient to tolerate and comply with at least 30 days of DAPT with BMS treatment and at least 12 months of DAPT with DES treatment is an important consideration in deciding whether to use PCI to treat patients with CAD.

2.10. TMR as an Adjunct to CABG

TMR has been used on occasion in patients with severe angina refractory to GDMT in whom complete revascularization cannot be achieved with PCI and/or CABG. Although the mechanism by which TMR might be efficacious in these patients is unknown (213, 214), several RCTs of TMR as sole therapy demonstrated a reduction in anginal symptoms compared with intensive medical therapy alone (109–111, 215–217). A single randomized multicenter comparison of TMR (with a holmium: YAG laser) plus CABG and CABG alone in patients in whom some myocardial segments were perfused by arteries considered not amenable to grafting (112) showed a significant reduction in perioperative mortality rate (1.5% versus 7.6%, respectively), and the survival benefit of the TMR–CABG combination was present after 1 year of follow-up (112). At the same time, a large retrospective analysis of data from the STS National Cardiac Database as well as a study of 169 patients from the Washington Hospital Center who underwent combined TMR–CABG, showed no difference in adjusted mortality rate compared with CABG alone (113, 218). In short, a TMR–CABG combination does not appear to improve survival compared with CABG alone. In selected patients, however, such a combination may be superior to CABG alone in relieving angina.

2.11. Hybrid Coronary Revascularization: Recommendations

CLASS IIa

1. Hybrid coronary revascularization (defined as the planned combination of LIMA-to-LAD artery grafting and PCI of ≥1 non-LAD coronary arteries) is reasonable in patients with 1 or more of the following (219–225) *(Level of Evidence: B):*
   a. Limitations to traditional CABG, such as heavily calcified proximal aorta or poor target vessels for CABG (but amenable to PCI);
   b. Lack of suitable graft conduits;
   c. Unfavorable LAD artery for PCI (i.e., excessive vessel tortuosity or CTO).

CLASS IIb

Hybrid coronary revascularization (defined as the planned combination of LIMA-to-LAD artery grafting and PCI of ≥1 non-LAD coronary arteries) may be reasonable as an alternative to multivessel PCI or CABG in an attempt to improve the overall risk-benefit ratio of the procedures. *(Level of Evidence: C)*

Hybrid coronary revascularization, defined as the planned combination of LIMA-to-LAD artery grafting and PCI of ≥1 non-LAD coronary arteries (226), is intended to combine the advantages of CABG (i.e., durability of the LIMA graft) and PCI (227). Patients with multivessel CAD (e.g., LAD and ≥1 non-LAD stenoses) and an indication for revascularization are potentially eligible for this approach. Hybrid revascularization is ideal in patients in whom technical or anatomic limitations to CABG or PCI alone may be present and for whom minimizing the invasiveness (and therefore the risk of morbidity and mortality) of surgical intervention is preferred (221) (e.g., patients with

severe preexisting comorbidities, recent MI, a lack of suitable graft conduits, a heavily calcified ascending aorta, or a non-LAD coronary artery unsuitable for bypass but amenable to PCI, and situations in which PCI of the LAD artery is not feasible because of excessive tortuosity or CTO).

Hybrid coronary revascularization may be performed in a hybrid suite in one operative setting or as a staged procedure (i.e., PCI and CABG performed in 2 different operative suites, separated by hours to 2 days, but typically during the same hospital stay). Because most hospitals lack a hybrid operating room, staged procedures are usually performed. With the staged procedure, CABG before PCI is preferred, because this approach allows the interventional cardiologist to 1) verify the patency of the LIMA-to-LAD artery graft before attempting PCI of other vessels and 2) minimize the risk of perioperative bleeding that would occur if CABG were performed after PCI (i.e., while the patient is receiving DAPT). Because minimally invasive CABG may be associated with lower graft patency rates compared with CABG performed through a midline sternotomy, it seems prudent to angiographically image all grafts performed through a minimally invasive approach to confirm graft patency (221).

To date, no RCTs involving hybrid coronary revascularization have been published. Over the past 10 years, several small, retrospective series of hybrid revascularization using minimally invasive CABG and PCI have reported low mortality rates (0 to 2%) and event-free survival rates of83% to 92% at 6 to 12 months of follow-up. The few series that have compared the outcomes of hybrid coronary revascularization with standard CABG report similar outcomes at 30 days and 6 months (219–225).

3. PCI OUTCOMES

3.1. Definitions of PCI Success

The success of a PCI procedure is best defined by 3 interrelated components: angiographic findings, procedural events, and clinical outcomes.

3.1.1. Angiographic Success. A successful PCI produces sufficient enlargement of the lumen at the target site to improve coronary artery blood flow. A successful balloon angioplasty is defined as the reduction of a minimum stenosis diameter to <50% with a final TIMI flow grade 3 (visually assessed by angiography) without side branch loss, flow-limiting dissection, or angiographic thrombus (7). For coronary stents, a minimum stenosis diameter of <20% (as visually assessed by angiography) has previously been the clinical benchmark of an optimal angiographic result. Given improvements in technology and techniques, as well as recognition of the importance of an adequately deployed stent to decrease the risks of stent restenosis and thrombosis (12, 228, 229), the writing committee concluded that a minimum diameter stenosis of < 10% (with an optimal goal of as close to 0% as possible) should be the new benchmark for lesions treated with coronary stenting. As with balloon angioplasty, there should be final TIMI flow grade 3, without occlusion of a significant side branch, flow-limiting dissection, distal embolization, or angiographic thrombus. Problems with determining angiographic success include disparities between the visual assessment and computer-aided quantitative stenosis measurement and self-reporting of success in clinical reports or databases.

3.1.2. Procedural Success. A successful PCI should achieve angiographic success without associated in-hospital major clinical complications (e.g., death, MI, stroke, emergency CABG) (7, 8). Issues regarding the diagnosis and prognostic implications of procedure-related MI are discussed in Sections 3.3 and 5.10.

3.1.3. Clinical Success. In the short term, a clinically successful PCI requires both anatomic and procedural success along with relief of signs and/or symptoms of myocardial ischemia. Long-term clinical success requires that the short-term clinical success remain durable and that relief of signs and symptoms of myocardial ischemia persist >9 months after the procedure. Restenosis is the principal cause of lack of long-term clinical success after a short-term clinical success has been achieved. Restenosis is not a complication; it is the expected biological response to vascular injury. The frequency of clinically important restenosis may be judged by the frequency with which subsequent revascularization procedures are performed on target arteries after the index procedure.

3.2. Predictors of Clinical Outcome After PCI

Factors associated with increased PCI complication rates include advanced age, diabetes, CKD, ACS, congestive heart failure, and multivessel CAD (8, 230–232). Several models have been developed and refined over the past 2 decades to predict mortality with PCI (230, 233–236). At present, perhaps the best accepted system is from the ACC National Cardiovascular Data Registry (NCDR) CathPCI Risk Score system, which uses clinical variables and PCI setting to predict inpatient mortality (Appendix 4A)(236). In general, these models perform very well (C statistic: approximately 0.90), although predictive capability decreases in high-risk patients.

Models have also been developed to predict procedural success. Presently, the modified ACC/AHA score

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(230) and the SCAI score (Appendix 4B)(237) are both in use, with the latter slightly outperforming the former. Discrimination as measured by the C statistic is generally good to very good (0.70 to 0.82), depending on the outcome variable and patient population.

The angiographic SYNTAX score (238) has been developed to predict long-term risk of MACE after multivessel intervention. The SYNTAX score and its potential utility in helping guide revascularization strategies are discussed in Section 2. Composite models including angiographic and clinical variables have been developed but generally require validation in larger cohorts of patients.

3.3. PCI Complications

In an analysis of the NCDR CathPCI database of patients undergoing PCI between 2004 and 2007, the overall in-hospital mortality rate was 1.27%, ranging from 0.65% in elective PCI to 4.81% in STEMI (236). Factors associated with an increased risk of PCI-related death include advanced age, comorbidities (e.g., diabetes, CKD, congestive heart failure), multivessel CAD, high-risk lesions, and the setting of PCI (e.g., STEMI, urgent or emergency procedure, cardiogenic shock) (56, 230–232, 236).

Causes of procedural and periprocedural MI include acute artery closure, embolization and no-reflow, side branch occlusion, and acute stent thrombosis. The incidence of procedure-related MI depends to a great degree on the definition of MI used, the patient population studied, and whether or not cardiac biomarkers are routinely assessed after PCI. The definition and clinical significance of PCI-related MI have been controversial. Criteria for defining a PCI-related MI have evolved over time (8, 239, 240). The 2007 universal definition of MI (240) states that after PCI, elevations of cardiac biomarkers above the 99th percentile upper reference limit indicate periprocedural myocardial necrosis. Increases of biomarkers >3 times the 99th percentile upper reference limit were designated as defining PCI-related MI (240). According to this definition, ≥15% of patients undergoing PCI would be defined as having periprocedural MI (241, 242). Issues in procedure-related MI are discussed in Section 5.10.

The need for emergency CABG has dramatically decreased with advances in PCI technology, particularly coronary stents (243, 244). Recently the NCDR reported the rate of emergency CABG at 0.4% (244). Procedure-related indications for CABG in 1 large series included coronary dissection (27%), acute artery closure (16%), perforation (8%), and failure to cross the lesion (8%) (245). The strongest predictors of the need for emergency CABG in several analyses are cardiogenic shock (OR: 11.4), acute MI or emergency PCI (OR: 3.2 to 3.8), multivessel disease (OR: 2.3 to 2.4), and type C lesion (OR: 2.6) (243, 245). In-hospital mortality for emergency CABG ranges from 7.8% to 14% (243, 245, 246).

In a contemporary analysis from the NCDR, the incidence of PCI-related stroke was 0.22% (247). In-hospital mortality in patients with PCI-related stroke is 25% to 30% (247, 248). Factors associated with an increased risk of stroke include fibrinolytic therapy administered before PCI (OR: 4.7), known cerebrovascular disease (OR: 2.20), STEMI as the indication for PCI (OR: 3.2), use of an intra-aortic balloon pump (IABP) (OR: 2.6), older age (OR: 1.17 per 5-year increase), and female sex (247–249). Initial imaging after a stroke in 1 small series revealed hemorrhagic etiology in 18%, ischemic etiology in 58%, and no clear etiology in 24% (248). One potential algorithm for the treatment of catheterization-related stroke has been recently proposed (250). This document includes no specific recommendations for the management of PCI-related stroke but refers the reader to the AHA/American Stroke Association guidelines for the management of adults with stroke (251).

Vascular complications from PCI are primarily related to vascular access. Important femoral vascular complications include access site hematoma, retroperitoneal hematoma, pseudoaneurysm, arteriovenous fistula, and arterial dissection and/or occlusion (252). The incidence of these vascular complications in various reports generally ranges from 2% to 6% and has decreased with time (249, 253–257). Factors associated with an increased risk of vascular complication include age ≥70 years, body surface area <1.6 m^2, emergency procedures, peripheral artery disease, periprocedural use of glycoprotein (GP) IIb/IIIa inhibitors, and female sex (if not corrected for body surface area) (249, 253, 254, 257, 258). Ultrasound guidance has been used for femoral artery access to potentially decrease complications (259). As discussed in Section 5.11, vascular closure devices have not been clearly demonstrated to decrease vascular complication rates. Radial site access decreases the rate of access-related bleeding and complications compared with femoral access (255, 260). Loss of the radial pulse has been reported in ≤5% of radial procedures (261). Infrequent to rare complications occurring with the radial artery approach include compartment syndrome, pseudoaneurysm (<0.01%), and sterile abscess (occurring with previous-generation hydrophilic sheaths) (262). Radial artery spasm may occur and treatment at times may be challenging. Local hematomas may occur from small-branch vessel hydrophilic wire perforation or inexperience with wristband use.

The risk of coronary perforation is approximately 0.2%, most commonly by wire perforation during PCI for CTO or by ablative or oversized devices during PCI of heavily diseased or tortuous coronary arteries (263). The risk of tamponade and management of the perforation varies with the type of perforation (264).

Periprocedural bleeding is now recognized to be associated with subsequent mortality (265, 266), and the avoidance of bleeding complications has become an important consideration in performing PCI. The risk of bleeding is associated with patient factors (e.g., advanced age, low body mass index, CKD, baseline anemia), as well as the degree of platelet and thrombin inhibition, vascular access site, and sheath size (267–269). Issues of periprocedural bleeding are discussed in Section 4.7.

The incidence of contrast-induced acute kidney injury (AKI) or "contrast nephropathy" in published reports depends on the definition of contrast nephropathy used and the frequency of risk factors for contrast-induced AKI in the patient population studied. Important risk factors for contrast-induced AKI include advanced age, CKD, congestive heart failure, diabetes, and the volume of contrast administered. Contrast-induced AKI and strategies to prevent it are discussed in Section 4.4.

4. PREPROCEDURAL CONSIDERATIONS

T4 Table 4 contains recommendations for preprocedural considerations and interventions in patients undergoing PCI.

4.1. Cardiac Catheterization Laboratory Requirements

4.1.1. Equipment. Defibrillators are considered by The Joint Commission to be life-support equipment requiring routine assessment and completion of appropriate logs. Many hospitals require periodic inspection of consoles for ancillary devices used in coronary intervention (e.g., Doppler wires, pressure-tipped sensor wires, and IVUS catheters). Point-of-care testing devices (e.g., activated clotting time and arterial blood gas machines) require routine calibration. Duration of storage of digital cine images is often mandated by law. Operating parameters for x-ray imaging equipment are adjusted at installation and periodically assessed by a qualified physicist in cooperation with the equipment manufacturer. Familiarity with radiation dose-reducing features of catheterization laboratory equipment and assistance from a qualified physicist are important for radiation dose minimization and image optimization.

4.1.2. Staffing. An interventional cardiologist must be present in the laboratory for the duration of each procedure and is responsible for procedure outcome. Nursing and technical personnel are also required to be present in the catheterization laboratory, with specific staffing dependent on state requirements and laboratory caseload and mix. Catheterization laboratory technical staff may include nurse practitioners, registered nurses, licensed vocational or practical nurses, physician assistants, nursing assistants, radiology technicians, or catheterization laboratory technicians. All catheterization laboratory staff are usually certified in basic life support, advanced cardiovascular life support, and, where appropriate, pediatric advanced life support. Catheterization laboratory personnel have a nursing degree/certification or invasive cardiovascular credentials such as registered cardiovascular invasive specialist or American Society of Radiation technologists (305).

4.1.3. 'Time-Out' Procedures. In 2003, The Joint Commission mandated a universal protocol requiring proper preoperative identification of the patient by the members of the catheterization laboratory team, marking of the operative site, and a final time-out just before the procedure (306). Although initially intended to prevent wrong-site surgery, this has been expanded to include all invasive procedures despite limited scientific evidence of its effectiveness (307). The intent of the time-out is for all members of the team to improve patient care by collectively discussing the case. The content of a time-out includes confirmation of the correct patient, correct side and site, agreement on the procedure to be performed, correct patient position, and availability of needed equipment, supplies, and implants. The timeout may be checklist driven or conversational, depending on laboratory preferences (308). The writing committee strongly endorses the practice of conducting a time-out before all PCI procedures.

4.2. Ethical Aspects

The 3 principles of medical ethics are beneficence, autonomy, and justice. Beneficence involves the physician's duty to act in the best interests of the patient and avoid maleficence, or harm *(primum non nocere)*. Autonomy describes the physician's duty to help the patient maintain control over his or her medical treatments. Justice describes the physician's duty to treat the individual patient responsibly with due consideration of other patients and stakeholders in the healthcare system. Ethical considerations specific to PCI have been previously discussed (309) and are highlighted below:

- Place the patient's best interest first and foremost when making clinical decisions (beneficence).
- Ensure that patients actively participate in decisions affecting their care (autonomy).

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TABLE 4. Summary of Recommendations for Preprocedural Considerations and Interventions in Patients Undergoing PCI

Recommendations	COR	LOE	References
Contrast-Induced AKI			
Patients should be assessed for risk of contrast-induced AKI before PCI.	I	C	(270,271)
Patients undergoing cardiac catheterization with contrast media should receive adequate preparatory hydration.	I	B	(272–275)
In patients with CKD (creatinine clearance <60 mL/min), the volume of contrast media should be minimized.	I	B	(276–278)
Administration of N-acetyl-L-cysteine is not useful for the prevention of contrast-induced AKI.	III: No Benefit	A	(279–283)
Anaphylactoid reactions			
Patients with prior evidence of an anaphylactoid reaction to contrast media should receive appropriate prophylaxis before repeat contrast administration.	I	B	(252,284–286)
In patients with a prior history of allergic reactions to shellfish or seafood, anaphylactoid prophylaxis for contrast reaction is not beneficial.	III: No Benefit	C	(287–289)
Statins			
Administration of a high-dose statin is reasonable before PCI to reduce the risk of periprocedural MI.	IIa	A: Statin naive	(290–296)
		B: Chronic statin therapy	(297)
Bleeding risk			
All patients should be evaluated for risk of bleeding before PCI.	I	C	N/A
CKD			
In patients undergoing PCI, the glomerular filtration rate should be estimated and the dosage of renally cleared medications should be adjusted.	I	B	(298–300)
Aspirin			
Patients already on daily aspirin therapy should take 81 mg to 325 mg before PCI.	I	B	(301–304)
Patients not on aspirin therapy should be given nonenteric aspirin 325 mg before PCI.	I	B	(301,303,304)

AKI indicates acute kidney injury; CKD, chronic kidney disease; COR, class of recommendation; LOE, level of evidence; MI, myocardial infarction; N/A, not applicable; and PCI, percutaneous coronary intervention.

- Consider how decisions regarding one patient may also affect other patients and providers (justice).
- Plan and perform procedures and provide care with the intention of improving the patient's quality of life and/or decreasing the risk of mortality, independent of reimbursement considerations and without inappropriate bias or influence from industry, administrators, referring physicians, or other sources.
- Before performing procedures, obtain informed consent after giving an explanation regarding the details of the procedure and the risks and benefits of both the procedure and alternatives to the procedure.
- Plan and perform procedures according to standards of care and recommended guidelines, and deviate from them when appropriate or necessary in the care of individual patients.
- Seek advice, assistance, or consultation from colleagues when such consultation would benefit the patient.

4.2.1. Informed Consent. Obtaining informed consent for procedures is a legal and ethical necessity. Ideally, informed consent is obtained long enough before the procedure that the patient can fully consider informed consent issues and discuss them with family or other providers, avoiding any sense of coercion. Ad hoc PCI, or PCI immediately following diagnostic procedures, presents special problems. When informed consent for PCI is obtained before diagnostic catheterization is performed, it is impossible to predict the levels of risk and benefit from an ad hoc PCI (310, 311). If diagnostic catheterization reveals anatomy that poses a particularly high risk or for which the superiority of PCI compared with other strategies is unclear, the precatheterization informed consent discussion may be inadequate. In such cases, deferral of PCI until additional informed consent discussions and/or consultations occur may be appropriate, even though it inconveniences the patient and the healthcare system. It is the responsibility of the interventionalist to act in the patient's best interest in these circumstances.

Informed consent before emergency procedures is particularly difficult (312–314). The patient presenting with STEMI is usually in distress and often sedated, making true informed consent impossible. Rapid triage, transport, and treatment of STEMI patients create a pressured atmosphere that by necessity limits a prolonged and detailed informed consent process. Nevertheless, the interventionist must attempt to provide information about the risks and benefits of different strategies to the patient and family and balance the benefit of thorough discussion with the benefits of rapid intervention.

4.2.2. Potential Conflicts of Interest. Decisions about the performance and timing of PCI may pose additional ethical dilemmas. When considering whether to perform multivessel PCI in 1 stage versus 2 stages, safety and convenience for the patient must guide the decision, regardless of payment policies that maximize reimbursement when PCI is staged (311). A separate issue is self-referral, through which diagnostic catheterization often leads seamlessly to PCI by the same operator (315). The interventionist has an ethical obligation to the patient to consider all treatment options, consult with additional specialists (e.g., cardiac surgeons) when their input would be helpful to the patient, avoid unnecessary interventional procedures, and allow the patient to consult family members and other physicians (311).

4.3. Radiation Safety: Recommendation

CLASS I

1. Cardiac catheterization laboratories should routinely record relevant available patient procedural radiation dose data (e.g., total air kerma at the international reference point [$K_{a,r}$], air kerma air product [P_{KA}], fluoroscopy time, number of cine images), and should define thresholds with corresponding follow-up protocols for patients who receive a high procedural radiation dose. *(Level of Evidence: C)*

The issue of radiation exposure during imaging procedures has received increased attention, and the writing committee believes that radiation safety should be addressed in this guideline. Current standards for cardiac catheterization laboratories include the following:

- Specific procedures and policies are in place to minimize patient (and operator) risk.
- A radiation safety officer coordinates all radiation safety issues and works conjointly with the medical or health physicist.
- Patient radiation exposure is reduced to as low a level as reasonably can be achieved.
- Patients at increased risk for high procedural radiation exposure are identified.
- Informed consent includes radiation safety information, particularly for the high-risk patient.

A basic primer on the physics of x-ray imaging, essential to the safe practice of radiation dose management, has been published in an ACCF/AHA/Heart Rhythm Society/SCAI clinical competence statement (316). Appendix 4C summarizes strategies to minimize patient and operator radiation exposure. Adverse radiation effects are now well recognized as infrequent but potentially serious complications of prolonged interventional procedures (317). Fluoroscopic time does not include cine acquisition imaging and is therefore not an accurate measure of patient radiation dose. Total air kerma at the interventional reference point ($K_{a,r}$, in G_y) and air kerma area product (P_{KA}, in $Gycm^2$) are required to be reported on interventional x-ray systems since 2006.These are useful in the assessment of potential tissue adverse effects or long-term radiation sequelae, respectively, and it is reasonable to include them in the catheterization record at the conclusion of each procedure. Appendix 4D summarizes considerations for patient follow-up based on radiation dose during the procedure (317).

4.4. Contrast-Induced AKI: Recommendations

CLASS I

1. Patients should be assessed for risk of contrast-induced AKI before PCI (270, 271). *(Level of Evidence: C)*
2. Patients undergoing cardiac catheterization with contrast media should receive adequate preparatory hydration (272–275). *(Level of Evidence: B)*
3. In patients with CKD (creatinine clearance <60 mL/min), the volume of contrast media should be minimized (276–278). *(Level of Evidence: B)*

CLASS III: NO BENEFIT

1. Administration of N-acetyl-L-cysteine is not useful for the prevention of contrast-induced AKI (279–283). *(Level of Evidence: A)*

See Online Data Supplements 16 to 18 for additional data regarding contrast-induced AKI.

Contrast-induced AKI or "contrast nephropathy" is one of the leading causes of hospital-acquired AKI. Major risk factors for contrast-induced AKI include advanced age, CKD, congestive heart failure, diabetes, and the volume of contrast administered. A risk-scoring system is available to predict the risk of contrast nephropathy using these risk factors and additional variables (270). Thus far, the only strategies clearly shown to reduce the risk of contrast-induced AKI are hydration and minimizing the amount of contrast media. Other than saline hydration, measures that were believed to reduce the risk of contrast-induced AKI have been found to be neutral, to have deleterious effects, or to be characterized by heterogeneous and conflicting data.

Studies of hydration to reduce the risk of contrast-induced AKI suggest that isotonic saline is preferable to half isotonic saline, intravenous (IV) hydration is preferable to oral hydration, hydration for hours before and after exposure to contrast media is preferable to a

bolus administration of saline immediately before or during contrast media exposure, and administration of isotonic saline alone is preferable to administration of isotonic saline plus mannitol or furosemide (272–275, 320). On the basis of these studies, a reasonable hydration regimen would be isotonic crystalloid (1.0 to 1.5 mL/kg per hour) for 3 to 12 hours before the procedure and continuing for 6 to 24 hours after the procedure (272–275, 284, 320, 321).

Prior studies of N-acetyl-L-cysteine and sodium bicarbonate have produced conflicting results. Some, often small, earlier studies suggested benefit, but many other more contemporary studies and meta-analyses found no clear evidence of benefit, and there are potential issues of publication bias and poor methodology issues in several analyses (279–282, 322–332). The recently completed largest randomized study on N-acetyl-L-cysteine and contrast nephropathy in patients undergoing angiographic procedures, ACT (Acetylcysteine for Contrast-Induced Nephropathy Trial), demonstrated no benefit in primary or secondary endpoints. An updated meta-analysis using only high-quality trials similarly demonstrated no benefit (283). Taken as a whole, these studies do not support any recommendation for the use of N-acetyl-L-cysteine, they do, however, provide sufficient data to conclude that N-acetyl-L-cysteine does not prevent contrast-induced AKI in patients undergoing angiographic procedures.

The correlation between the volume of contrast media and the risk of contrast-induced AKI has been documented in several studies (276, 277). Thus, minimization of contrast media volume is important to prevent contrast-induced AKI in patients undergoing angiography. The volume of contrast already administered during diagnostic catheterization is an important factor when considering possible "ad hoc" PCI.

Comparative studies of different contrast media (e.g., low-osmolar versus iso-osmolar, one agent versus another agent) have produced variable and sometimes contradictory results (334–339). Thus, current data are insufficient to justify specific recommendations about low- and isoosmolar contrast media. This issue is discussed in detail in the 2011 UA/NSTEMI focused update (340). For a further discussion of contrast media and PCI, the reader is referred to a position statement by the SCAI (284).

4.5. Anaphylactoid Reactions: Recommendations

CLASS I

1. Patients with prior evidence of an anaphylactoid reaction to contrast media should receive appropriate steroid and antihistamine prophylaxis before repeat contrast administration (252, 284–286). *(Level of Evidence: B)*

CLASS III: NO BENEFIT

1. In patients with a prior history of allergic reactions to shellfish or seafood, anaphylactoid prophylaxis for contrast reaction is not beneficial (287–289). *(Level of Evidence: C)*

The incidence of anaphylactoid reactions to contrast media is $\leq$1%, and the incidence of severe reactions may be as low as 0.04% (284). Limited data suggest that in patients with a history of prior anaphylactoid reaction, the recurrence rate without prophylaxis is in the range of 16% to 44% (341). Adequate pretreatment of patients with prior anaphylactoid reactions reduces the recurrence rate to close to zero (284–286). A regimen of 50 mg of prednisone administered 13 hours, 7 hours, and 1 hour before the procedure (as well as 50 mg of diphenhydramine 1 hour before the procedure) has been shown to reduce the risk of recurrent anaphylactoid reaction (286). In practice, a regimen of 60 mg of prednisone the night before and morning of the procedure (as well as 50 mg of diphenhydramine 1 hour before the procedure) is often used (252). There are minimal data on the "pretreatment" of patients undergoing emergency PCI (342). One group has suggested IV steroids (e.g., 80 mg to 125 mg of methylprednisolone, 100 mg of hydrocortisone sodium succinate), as well as oral or IV diphenhydramine and possible IV cimetidine (284). For a more detailed discussion of issues related to contrast-induced anaphylactoid reactions, the reader is referred to several dedicated discussions on contrast agents (284, 341).

There are no data to suggest that those patients with seafood or shellfish allergies are at risk for an anaphylactoid reaction from exposure to contrast media. Iodine does not mediate seafood, shellfish, or contrast media reactions. The common misconception that seafood allergies and contrast reactions are cross-reactions to iodine probably arose from a survey published in 1975 in which 15% of patients with a history of contrast reaction reported a personal history of shellfish allergy, but nearly identical proportions of patients reported allergies to other foods, such as milk and egg, in the same survey (287). Pretreatment of patients with steroids based only on a history of seafood or shellfish allergy has a small but non-zero risk of adverse effect (e.g., hyperglycemia in a patient with diabetes) without any demonstrated benefit (288, 289).

4.6. Statin Treatment: Recommendation

CLASS IIa

1. Administration of a high-dose statin is reasonable before PCI to reduce the risk of periprocedural MI. *(Level of Evidence: A for statin-naive patients* [290–296]; *Level of Evidence: B for those on chronic statin therapy* [297])

See Online Data Supplement 19 for additional data regarding preprocedural statin treatment.

Statins have long-term benefits in patients with CAD (343, 344) and ACS (345, 346). The benefits of statins in ACS begin early, before substantial lipid lowering has occurred (345, 347), suggesting pleiotropic effects of statins. These might include anti-inflammatory effects, improvement of endothelial function, decrease of oxidative stress, or inhibition of thrombogenic responses (348). Statins were beneficial when pretreatment was started from 7 days to just before PCI (290–297).

4.7. Bleeding Risk: Recommendation

CLASS I

1. All patients should be evaluated for risk of bleeding before PCI. *(Level of Evidence: C)*

Periprocedural bleeding is now recognized as a major risk factor for subsequent mortality (265, 266). Bleeding may lead to mortality directly (because of the bleeding event) or through ischemic complications that occur when antiplatelet or anticoagulant agents are withdrawn in response to the bleeding. Bleeding may also be a marker of comorbidities associated with worse prognosis (e.g., occult cancer). The risk of bleeding is associated with a number of patient factors (e.g., advanced age, low body mass index, CKD, baseline anemia), as well as the degree of platelet and thrombin inhibition, vascular access site, and sheath size (267–269). The overall approach to PCI should be individualized to minimize both ischemic and bleeding risks.

Measures to minimize the risks of bleeding complications are discussed in several sections of this guideline. These include use of anticoagulation regimens associated with a lower risk of bleeding, weight-based dosing of heparin and other agents, use of activated clotting times to guide unfractionated heparin (UFH) dosing, avoidance of excess anticoagulation (349), dosing adjustments in patients with CKD (e.g., eptifibatide, tirofiban, bivalirudin) (350), use of radial artery access site (255), and avoidance of femoral vein cannulation when possible. Vascular closure devices have not been clearly demonstrated to decrease bleeding complications and are discussed in detail in Section 5.11.

4.8. PCI in Hospitals Without On-Site Surgical Backup: Recommendations

CLASS IIa

1. Primary PCI is reasonable in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished (351, 352). *(Level of Evidence: B)*

CLASS IIb

1. Elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection (352–354). *(Level of Evidence: B)*

CLASS III: HARM

1. Primary or elective PCI should not be performed in hospitals without on-site cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without appropriate hemodynamic support capability for transfer. *(Level of Evidence: C)*

See Online Data Supplement 20 for additional data regarding hospitals without on-site surgical backup.

Primary and elective PCI can be performed at hospitals without on-site cardiac surgical backup with a high success rate, low in-hospital mortality rate, and low rate for emergency CABG (351, 353, 354). The best outcomes for patients with STEMI are achieved at hospitals with 24/7 access to primary PCI (355). Criteria for the performance of PCI without on-site surgical backup have been proposed in an SCAI expert consensus document (352). Consideration of elective PCI without on-site cardiac surgical backup is thought to be appropriate only when performed by experienced operators with complication rates and outcomes equivalent or superior to national benchmarks. Accurate assessment of complication rates and patient outcomes via a regional or national data registry, so that outcomes can be compared with established benchmarks, is an important quality control component of any PCI program. Desires for personal or institutional financial gain, prestige, market share, or other similar motives are not appropriate considerations for initiation of PCI programs without on-site cardiac surgery. It is only appropriate to consider initiation of a PCI program without on-site cardiac surgical backup if this program will clearly fill a void in the healthcare needs of the community. Competition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interests of the community.

Tables 5 and 6 list the SCAI expert consensus document requirements for PCI programs without on-site surgical backup. Table 7 gives the requirements for primary PCI and emergency CABG at hospitals without on-site cardiac surgery, and Table 8 lists the requirements for patient and lesion selection and backup strategy for nonemergency PCI (352). T6 T5 T7 T8

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TABLE 5. SCAI Expert Consensus Document Personnel and Facility Requirements for PCI Programs Without On-Site Surgical Backup

Experienced nursing and technical laboratory staff with training in interventional laboratories. Personnel must be comfortable treating acutely ill patients with hemodynamic and electrical instability.
On-call schedule with operation of laboratory 24 h/d, 365 d/y.*
Experienced coronary care unit nursing staff comfortable with invasive hemodynamic monitoring, operation of temporary pacemaker, and management of IABP. Personnel capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.
Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services (e.g., respiratory care, blood bank).
Written agreements for emergency transfer of patients to a facility with cardiac surgery. Transport protocols should be developed and tested a minimum of 2 times per year.
Well-equipped and maintained cardiac catheterization laboratory with high-resolution digital imaging capability and IABP equipment compatible with transport vehicles. The capability for real-time transfer of images and hemodynamic data (via T-1 transmission line) as well as audio and video images to review terminals for consultation at the facility providing surgical backup support is ideal.
Appropriate inventory of interventional equipment, including guide catheters, balloons, and stents in multiple sizes; thrombectomy and distal protection devices; covered stents; temporary pacemakers; and pericardiocentesis trays. Pressure wire device and IVUS equipment are optimal but not mandatory. Rotational or other atherectomy devices should be used cautiously in these facilities because of the greater risk of perforation.
Meticulous clinical and angiographic selection criteria for PCI (Tables 6 and 7).
Performance of primary PCI as the treatment of first choice for STEMI to ensure streamlined care paths and increased case volumes. Door-to-balloon times should be tracked, and <90 min outlier cases should be carefully reviewed for process improvement opportunities. On-site rigorous data collection, outcomes analysis, benchmarking, quality improvement, and formalized periodic case review.
Participation in a national data registry where available, such as the ACC NCDR in the United States.

*Required for U.S. facilities but may not be possible for all facilities worldwide.

ACC indicates American College of Cardiology; IABP, intra-aortic balloon pump; IVUS, intravascular ultrasound; NCDR, National Cardiovascular Data Registry; PCI, percutaneous coronary intervention; SCAI, Society for Cardiovascular Angiography and Interventions; and STEMI, ST-elevation myocardial infarction.

Adapted with permission from Dehmer et al. (352).

TABLE 6. SCAI Expert Consensus Document Requirements for Off-Site Surgical Backup

Interventional cardiologists establish a working relationship with cardiac surgeons at the receiving facility.
1. Cardiac surgeon must have privileges at the referring facility to allow review of treatment options as time allows.
2. Cardiac surgeon and receiving hospital agree to provide cardiac surgical backup for urgent cases at all hours and for elective cases at mutually agreed hours.
3. Surgeon and receiving facility ensure that patients will be accepted based on medical condition, capacity of surgeon to provide services at the time of request, and availability of resources. If this cannot be ensured before the start of an elective procedure, the case should not be done at this time.
4. Interventional cardiologists must review with surgeons the immediate needs and status of any patient transferred for urgent surgery.
5. Hospital administrations from both facilities endorse transfer agreement.
6. Transferring and receiving facilities establish a rigorous protocol for rapid transfer of patients, including the proper personnel with appropriate experience.
7. A transport provider is available to begin transport within 20 min of the request and provide vehicle/helicopter with necessary life-sustaining equipment, including IABP and monitoring capability.
8. Transferring physician obtains consent for surgery from patient or appropriate surrogate.
9. Initial informed consent for PCI discloses that the procedure is being done without on-site surgical backup and acknowledges the possibility of risks related to transfer. The consent process should include the risk of urgent surgery (approximately 0.3%) and state that a written plan for transfer exists.
10. As part of the local continuous quality improvement program, a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of any improvement opportunities.

IABP indicates intra-aortic balloon pump; PCI, percutaneous coronary intervention; and SCAI, Society for Cardiovascular Angiography and Interventions.

Adapted with permission from Dehmer et al. (352).

5. PROCEDURAL CONSIDERATIONS

5.1. Vascular Access: Recommendation

CLASS IIa

1. The use of radial artery access can be useful to decrease access site complications (255, 260, 356–362). *(Level of Evidence: A)*

See Online Data Supplement 21 for additional data regarding radial access.

Femoral artery access remains the most commonly used approach in patients undergoing PCI in the United States. Choosing a femoral artery puncture site is facilitated by fluoroscopic landmark identification or ultrasound guidance. Low punctures have a high incidence of peripheral artery complications, whereas high punctures have an increased risk of retroperitoneal hemorrhage. In patients with a synthetic graft, arterial access is possible after the graft is a few months old and complication rates are not increased (254).

Radial site access is used frequently in Europe and Canada but not in the United States (260). A learning curve exists for the radial approach that will affect procedure time and radiation dose, with a trend toward lower procedural success rates for radial versus femoral access (255). However, compared with femoral access, radial access decreases the rate of access-related bleeding and complications (255, 260, 363). In a recent large RCT comparing radial and femoral access in patients with ACS undergoing PCI, there was no difference in the primary composite endpoint (death, MI, stroke, major bleeding), although there was a lower rate of vascular complications with the use of radial access (362).

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TABLE 7. SCAI Expert Consensus Document Requirements for Primary PCI and Emergency Aortocoronary Bypass Surgery at Hospitals Without On-Site Cardiac Surgery

Avoid intervention in patients with

- >50% diameter stenosis of left main artery proximal to infarct-related lesion, especially if the area in jeopardy is relatively small and overall LV function is not severely impaired
- Long, calcified, or severely angulated target lesions at high risk for PCI failure with TIMI flow grade 3 present during initial diagnostic angiography
- Lesions in other than the infarct artery (unless they appeared to be flow limiting in patients with hemodynamic instability or ongoing symptoms)
- Lesions with TIMI flow grade 3 that are not amenable to stenting in patients with left main or 3-vessel disease that will require coronary bypass surgery
- Culprit lesions in more distal branches jeopardizing only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention

Transfer emergently for coronary bypass surgery patients with

- High-grade left main or 3-vessel coronary disease with clinical or hemodynamic instability after successful or unsuccessful PCI of an occluded vessel and preferably with IABP support
- Failed or unstable PCI result and ongoing ischemia, with IABP support during transfer

IABP indicates intra-aortic balloon pump; LV, left ventricular; PCI, percutaneous coronary intervention; SCAI, Society for Cardiovascular Angiography and Interventions; and TIMI, Thrombolysis In Myocardial Infarction.

Adapted with permission from Dehmer et al. (352).

Radial artery access is particularly appealing in patients with coagulopathy, elevated international normalized ratio due to warfarin, or morbid obesity.

5.2. PCI in Specific Clinical Situations

5.2.1. UA/NSTEMI: Recommendations

CLASS I

1. An early invasive strategy (i.e., diagnostic angiography with intent to perform revascularization) is indicated in UA/NSTEMI patients who have refractory angina or hemodynamic or electrical instability (without serious comorbidities or contraindications to such procedures) (207, 364, 365). *(Level of Evidence: B)*
2. An early invasive strategy (i.e., diagnostic angiography with intent to perform revascularization) is indicated in initially stabilized UA/ NSTEMI patients (without serious comorbidities or contraindications to such procedures) who have an elevated risk for clinical events (207, 365–367). *(Level of Evidence: A)*
3. The selection of PCI or CABG as the means of revascularization in the patient with ACS should generally be based on the same considerations as those without ACS (53, 156, 207, 368). *(Level of Evidence: B)*

TABLE 8. SCAI Expert Consensus Document Requirements for Patient and Lesion Selection and Backup Strategy for Nonemergency PCI by Experienced Operators at Hospitals Without On-Site Cardiac Surgery

Patient risk: expected clinical risk in case of occlusion caused by procedure

High patient risk: Patients with any of the following:

- Decompensated congestive heart failure (Killip Class 3) without evidence for active ischemia, recent CVA, advanced malignancy, known clotting disorders
- LVEF <25%
- Left main stenosis (≥50% diameter) or 3-vessel disease unprotected by prior bypass surgery (>70% stenoses in the proximal segment of all major epicardial coronary arteries)
- Single-target lesion that jeopardizes >50% of remaining viable myocardium

Lesion risk: probability that procedure will cause acute vessel occlusion

Increased lesion risk: lesions in open vessels with any of the following characteristics:

- Diffuse disease (>2 cm in length) and excessive tortuosity of proximal segments
- More than moderate calcification of a stenosis or proximal segment
- Location in an extremely angulated segment (>90%)
- Inability to protect major side branches
- Degenerated older vein grafts with friable lesions
- Substantial thrombus in the vessel or at the lesion site
- Any other feature that may, in the operator's judgment, impede successful stent deployment Aggressive measures to open CTOs are also discouraged because of an increased risk of perforation.

Strategy for surgical backup based on lesion and patient risk:

- **High-risk patients with high-risk lesions** should not undergo nonemergency PCI at a facility without on-site surgery.
- **High-risk patients with non-high-risk lesions:** Nonemergency patients with this profile may undergo PCI, but confirmation that a cardiac surgeon and operating room are immediately available is necessary.
- **Non-high-risk patients with high-risk lesions** require no additional precautions.
- **Non-high-risk patients with non-high-risk lesions** require no additional precautions. Best scenario for PCI without on-site surgery.

CTO indicates chronic total occlusion; CVA, cerebrovascular accident; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; and SCAI, Society for Cardiovascular Angiography and Interventions.

Adapted with permission from Dehmer et al. (352).

CLASS III: NO BENEFIT

1. An early invasive strategy (i.e., diagnostic angiography with intent to perform revascularization) is not recommended in patients with extensive comorbidities (e.g., liver or pulmonary failure, cancer) in whom *(Level of Evidence: C)*
   a. The risks of revascularization and comorbid conditions are likely to outweigh the benefits of revascularization,
   b. There is a low likelihood of ACS despite acute chest pain, or
   c. Consent to revascularization will not be granted regardless of the findings.

The goals of coronary angiography and revascularization in UA/NSTEMI patients are to reduce the risk of death and MI and provide symptom relief. To improve prognosis, early risk stratification is essential for selection of medical and/or invasive treatment strategies. Indications for revascularization depend on the patient's clinical risk characteristics and coronary anatomy and are in general stronger in the presence of high-risk clinical presentation (e.g., dynamic electrocardiogram [ECG] changes, elevated troponin, high Global Registry of Acute Coronary Events score), recurrent symptoms, threatened viable myocardium, CKD, and larger ischemic burden (Appendix 4E). For choice of revascularization technique, the anatomical considerations are generally those used for stable CAD, although PCI may initially be performed in the index lesion to stabilize the patient (Section 2).

Contemporary studies variably comparing strategies of very early (within hours of admission), early (within 24 hours of admission), and delayed (1 to 7 days after admission) cardiac catheterization and revascularization support a strategy of *early* angiography and revascularization to reduce the risk of recurrent ischemia and MI, particularly among those at high risk (e.g., Global Registry of Acute Coronary Events score >140) (367, 369, 370), whereas a delayed approach is reasonable in low-intermediate risk patients (based on clinical course). There is no evidence that incremental benefit is derived by angiography and PCI performed within the first few hours of hospital admission (207, 367, 371–378).

5.2.2. ST-Elevation Myocardial Infarction

5.2.2.1. CORONARY ANGIOGRAPHY STRATEGIES IN STEMI: RECOMMENDATIONS

CLASS I

1. A strategy of immediate coronary angiography with intent to perform PCI (or emergency CABG) in patients with STEMI is recommended for
   a. Patients who are candidates for primary PCI (351, 379–382). *(Level of Evidence: A)*
   b. Patients with severe heart failure or cardiogenic shock who are suitable candidates for revascularization (383, 384). *(Level of Evidence: B)*

CLASS IIa

1. A strategy of immediate coronary angiography (or transfer for immediate coronary angiography) with intent to perform PCI is reasonable for patients with STEMI, a moderate to large area of myocardium at risk, and evidence of failed fibrinolysis (385, 386). *(Level of Evidence: B)*
2. A strategy of coronary angiography (or transfer for coronary angiography) 3 to 24 hours after initiating fibrinolytic therapy with intent to perform PCI is reasonable for hemodynamically stable patients with STEMI and evidence for successful fibrinolysis when angiography and revascularization can be performed as soon as logistically feasible in this time frame (387–391). *(Level of Evidence: A)*

CLASS IIb

1. A strategy of coronary angiography performed before hospital discharge might be reasonable in stable patients with STEMI who did not undergo cardiac catheterization within 24 hours of STEMI onset. *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. A strategy of coronary angiography with intent to perform PCI is not recommended in patients with STEMI in whom the risks of revascularization are likely to outweigh the benefits or when the patient or designee does not want invasive care. *(Level of Evidence: C)*

The historical reperfusion strategies of "primary PCI," "immediate PCI," "rescue PCI," "deferred PCI," "facilitated PCI," and the "pharmacoinvasive strategy" have evolved in parallel with advances in antithrombotic therapy and STEMI prehospital and hospital systems of care. The clinical challenge in primary PCI is achieving rapid time to treatment and increasing patient access to this preferred reperfusion strategy. The clinical challenge in patients treated with fibrinolytic therapy is deciding for whom and when to perform coronary angiography.

In unstable patients (e.g., severe heart failure or cardiogenic shock, hemodynamically compromising ventricular arrhythmias) not treated initially with primary PCI, a strategy of immediate coronary angiography with intent to perform PCI is implemented unless invasive management is considered futile or unsuitable given the clinical circumstances (383, 384).

In stable patients treated with fibrinolytic therapy and clinical suspicion of reperfusion failure, a strategy of immediate coronary angiography followed by PCI improves outcome in those at high risk (385, 386). Such a strategy is also implemented in patients with evidence for infarct artery reocclusion (Table 9). The T9
clinical diagnosis of failed fibrinolysis is difficult but is best made when there is <50% ST-segment resolution 90 minutes after initiation of therapy in the lead showing the greatest degree of ST-segment elevation at presentation. Given the association between bleeding events and adverse cardiac events, a reasonable approach is to select moderate- and high-risk patients for PCI and treat low-risk patients with medical therapy. ECG and clinical findings of anterior MI or

TABLE 9. Indications for Coronary Angiography in STEMI

Indications	COR	LOE	References
Immediate coronary angiography			
Candidate for primary PCI	I	A	(351,379–382)
Severe heart failure or cardiogenic shock (if suitable revascularization candidate)	I	B	(383,384)
Moderate to large area of myocardium at risk and evidence of failed fibrinolysis	IIa	B	(385,386)
Coronary angiography 3 to 24 h after fibrinolysis			
Hemodynamically stable patients with evidence for successful fibrinolysis	IIa	A	(387–391)
Coronary angiography before hospital discharge			
Stable patients	IIb	C	N/A
Coronary angiography at any time			
Patients in whom the risks of revascularization are likely to outweigh the benefits or the patient or designee does not want invasive care	III: No Benefit	C	N/A

COR indicates class of recommendation; LOE, level of evidence; N/A, not applicable; PCI, percutaneous coronary intervention; and STEMI, ST-elevation myocardial infarction.

inferior MI with right ventricular involvement or precordial ST-segment depression, as well as ongoing pain, usually predicts increased risk and the greatest potential benefit (392). Conversely, patients with symptom resolution, improving ST-segment elevation, or inferior MI localized to 3 ECG leads probably gain little benefit.

In stable patients treated with fibrinolytic therapy and clinical evidence for successful reperfusion, an early invasive strategy with cardiac catheterization performed within 24 hours decreases reinfarction and recurrent ischemic events (388, 390, 391). Because of the associated increased bleeding risk, very early (<2 to 3 hours) catheterization after administration of fibrinolytic therapy with intent to perform revascularization should be reserved for patients with evidence of failed fibrinolysis and significant myocardial jeopardy for whom immediate angiography and revascularization would be appropriate (393).

5.2.2.2. PRIMARY PCI OF THE INFARCT ARTERY: RECOMMENDATIONS

CLASS I

1. Primary PCI should be performed in patients within 12 hours of onset of STEMI (379–382). *(Level of Evidence: A)*
2. Primary PCI should be performed in patients with STEMI presenting to a hospital with PCI capability within 90 minutes of first medical contact as a systems goal (394, 395). *(Level of Evidence: B)*
3. Primary PCI should be performed in patients with STEMI presenting to a hospital without PCI capability within 120 minutes of first medical contact as a systems goal (396–398). *(Level of Evidence: B)*
4. Primary PCI should be performed in patients with STEMI who develop severe heart failure or cardiogenic shock and are suitable candidates for revascularization as soon as possible, irrespective of time delay (383, 384). *(Level of Evidence: B)*
5. Primary PCI should be performed as soon as possible in patients with STEMI and contraindications to fibrinolytic therapy with isch-emic symptoms for less than 12 hours (399, 400). *(Level of Evidence: B)*

CLASS IIa

1. Primary PCI is reasonable in patients with STEMI if there is clinical and/or electrocardiographic evidence of ongoing ischemia between 12 and 24 hours after symptom onset (401–403). *(Level of Evidence: B)*

CLASS IIb

1. Primary PCI might be considered in asymptomatic patients with STEMI and higher risk presenting between 12 and 24 hours after symptom onset. *(Level of Evidence: C)*

CLASS III: HARM

1. PCI should not be performed in a noninfarct artery at the time of primary PCI in patients with STEMI without hemodynamic compromise (404–408). *(Level of Evidence: B)*

Primary PCI is preferred to fibrinolytic therapy when time-to-treatment delays are short and the patient presents to a high-volume, well-equipped center staffed with expert interventional cardiologists and skilled support staff. Compared with fibrinolytic therapy in RCTs, primary PCI produces higher rates for infarct artery patency, TIMI flow grade 3, and lower rates for recurrent ischemia, reinfarction, emergency repeat revascularization procedures, intracranial hemorrhage, and death (379). Early, successful PCI also greatly decreases the complications of STEMI that result from longer ischemic times or unsuccessful fibrinolytic therapy, allowing earlier hospital discharge and resumption of daily activities. The greatest

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TABLE 10. Indications for PCI in STEMI

Indications	COR	LOE	References
Primary PCI*			
STEMI symptoms within 12 h	I	A	(379–382)
Severe heart failure or cardiogenic shock	I	B	(383,384)
Contraindications to fibrinolytic therapy with ischemic symptoms <12 h	I	B	(399,400)
Clinical and/or electrocardiographic evidence of ongoing ischemia between 12 and 24 h after symptom onset	IIa	B	(401–403)
Asymptomatic patients presenting between 12 and 24 h after symptom onset and higher risk	IIb	C	N/A
Noninfarct artery PCI at the time of primary PCI in patients without hemodynamic compromise	III: Harm	B	(404–408)
Delayed or elective PCI in patients with STEMI			
Clinical evidence for fibrinolytic failure or infarct artery reocclusion	IIa	B	(385,386)
Patent infarct artery 3 to 24 h after fibrinolytic therapy	IIa	B	(390,391)
Ischemia on noninvasive testing	IIa	B	(410,411)
Hemodynamically significant stenosis in a patent infarct artery >24 h after STEMI	IIb	B	(413–417)
Totally occluded infarct artery >24 h after STEMI in a hemodynamically stable asymptomatic patient without evidence of severe ischemia	III: No Benefit	B	(418–420)

*Systems goal of performing primary PCI within 90 min of first medical contact when the patient presents to a hospital with PCI capability (394, 395)(Class *I; LOE: B)* and within 120 min when the patient presents to a hospital without PCI capability (396–398) (Class *I; LOE:* B).
COR indicates class of recommendation; LOE, level of evidence; N/A, not applicable; PCI, percutaneous coronary intervention; and STEMI, ST-elevation myocardial infarction.

mortality benefit of primary PCI is in high-risk patients. PCI outcomes may not be as successful with prolonged time-to-treatment or low-volume hospitals and operators (Table 10).

Several reports have shown excellent outcomes for patients with STEMI undergoing interhospital transfer where first medical contact-to-door balloon time modestly exceeded the systematic goal of <90 minutes (396–398, 409). In these reports, the referring hospital and the receiving hospital established a transfer protocol that minimized transfer delays, and outcomes were similar to those of direct-admission patients. On the basis of these results, the PCI and STEMI guideline writing committees have modified the first medical contact-to-device time goal from 90 minutes to 120 minutes for interhospital transfer patients (397), while emphasizing that systems should continue to strive for times ≤90 minutes. Hospitals that cannot meet these criteria should use fibrinolytic therapy as their primary reperfusion strategy.

PCI of a noninfarct artery at the time of primary PCI in stable patients is associated with worse clinical outcomes unless the patient is in cardiogenic shock where PCI of a severe stenosis in a coronary artery supplying a large territory of myocardium might improve hemodynamic stability (404, 406, 408). Delayed PCI can be performed in noninfarct arteries at a later time if clinically indicated (410–412).

5.2.2.3. DELAYED OR ELECTIVE PCI IN PATIENTS WITH STEMI: RECOMMENDATIONS

CLASS IIa

1. PCI is reasonable in patients with STEMI and clinical evidence for fibrinolytic failure or infarct artery reocclusion (385, 386). *(Level of Evidence: B)*
2. PCI is reasonable in patients with STEMI and a patent infarct artery 3 to 24 hours after fibrinolytic therapy (390, 391). *(Level of Evidence: B)*
3. PCI is reasonable in patients with STEMI who demonstrate ischemia on noninvasive testing (410, 411). *(Level of Evidence: B)*

CLASS IIb

1. PCI of a hemodynamically significant stenosis in a patent infarct artery greater than 24 hours after STEMI may be considered as part of an invasive strategy (413–417). *(Level of Evidence: B)*

CLASS III: NO BENEFIT

1. PCI of a totally occluded infarct artery greater than 24 hours after STEMI should not be performed in asymptomatic patients with 1- or 2-vessel disease if patients are hemodynamically and electrically stable and do not have evidence of severe ischemia (418–420). *(Level of Evidence: B)*

Studies and meta-analyses suggest potential benefit for PCI in fibrinolytic failure (385, 386). In stable

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patients treated with fibrinolytic therapy and clinical evidence for successful reperfusion, an early invasive strategy with cardiac catheter-ization performed within 24 hours decreases reinfarction and recurrent ischemic events (388, 390, 391).

PCI for a hemodynamically significant stenosis in a patent infarct artery >24 hours after STEMI as part of a revascularization strategy improves outcome (410, 411, 413–417). PCI of an occluded infarct artery 1 to 28 days after MI in asymptomatic patients without evidence of myocardial ischemia has no incremental benefit beyond optimal medical therapy with aspirin, beta blockers, angiotensin-converting enzyme inhibitors, and statins in preserving LV function and preventing subsequent cardiovascular events (418–420). It is important to note that elective PCI of an occluded infarct artery has not been studied in patients with New York Heart Association functional class III or IV heart failure, rest angina, serum creatinine >2.5 mg/dL, left main or 3-vessel CAD, clinical instability, or severe inducible ischemia on stress testing in an infarct zone that is not akinetic or dyskinetic.

5.2.3. Cardiogenic Shock: Recommendations

CLASS I

1. PCI is recommended for patients with acute MI who develop cardiogenic shock and are suitable candidates (384, 421–423). *(Level of Evidence: B)*
2. A hemodynamic support device is recommended for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy (384, 424–427). *(Level of Evidence: B)*

See Online Data Supplement 22 for additional data regarding cardiogenic shock.

Cardiogenic shock is the leading cause of in-hospital mortality complicating STEMI. Revascularization is the only treatment proven to decrease mortality rates (384, 421–423). Although revascularization is almost always accomplished through PCI, selected patients with severe 3-vessel or left main disease can benefit from emergency CABG. Revascu-larization attempts may be futile and not indicated in cases of severe multiorgan failure (427). Patient selection for revascularization is more important in the elderly, but several observational reports demonstrate acceptable outcomes in patients with few comorbidities and a reasonable potential for survival (428–431). Patients who present to hospitals without PCI capability are usually emergently transported to a PCI center, because mortality without transfer is markedly elevated (432).

5.2.3.1. PROCEDURAL CONSIDERATIONS FOR CARDIOGENIC SHOCK. Patients with cardiogenic shock should receive standard pharmacological therapies, including aspirin, a $P2Y_{12}$ receptor antagonist, and anticoagulation (427, 433). Inotropic and vasopressor therapy improves perfusion pressure. Historically, negative inotropes and vasodilators are avoided. IV GP IIb/IIIa inhibitors have been shown to provide benefit in observational studies but not in 1 small RCT (433).

Endotracheal intubation and mechanical ventilation with positive end-expiratory pressure is usually necessary in patients with respiratory failure. Placement of a temporary pacemaker is indicated for patients with bradycardia or high-degree atrioventricular heart block. A pulmonary artery catheter can provide information to dose and titrate inotropes and pressors. Further hemodynamic support is available with IABP counterpulsation or percutaneous LV assist devices, although no data support a reduction in mortality rates (434).

Contrast medium injections should be minimized. Orthogonal angiograms of the left coronary artery and a left anterior oblique angiogram of the right coronary artery are usually sufficient to identify the infarct artery (435). Although most patients undergoing revascularization will receive a stent as part of the procedure, there are conflicting data on the impact of stenting over balloon angioplasty. Some studies reveal lower mortality rates (436–438), whereas others reveal no benefit (439) or higher mortality rates (440). There are no data comparing the choice ofBMS versus DES in cardiogenic shock; however, BMS are often used because compliance with long-term DAPT is often unclear in the emergency setting.

In patients with multivessel disease, revascularization of the noninfarct artery may be necessary to maximize myocardial perfusion. Alternatively, in patients with multivessel disease and particularly left main disease, emergency CABG as a primary reperfusion strategy may be preferred (50, 441). Refractory cardiogenic shock unresponsive to revascularization may necessitate institution of more intensive cardiac support with a ventricular assist device or other hemodynamic support devices to allow for myocardial recovery or subsequent cardiac transplantation in suitable patients.

5.2.4. Revascularization Before Noncardiac Surgery: Recommendations

CLASS IIa

1. For patients who require PCI and are scheduled for elective noncardiac surgery in the subsequent 12 months, a strategy of balloon angioplasty, or BMS implantation followed by 4 to 6 weeks of DAPT, is reasonable (442–448). *(Level of Evidence: B)*
2. For patients with DES who must undergo urgent surgical procedures that mandate the discontinuation of DAPT, it is reasonable to continue aspirin if possible and restart the $P2Y_{12}$ inhibitor as soon as possible in the immediate postoperative period (444). *(Level of Evidence: C)*

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CLASS III: HARM

1. Routine prophylactic coronary revascularization should not be performed in patients with stable CAD before noncardiac surgery (449, 450). *(Level of Evidence: B)*
2. Elective noncardiac surgery should not be performed in the 4 to 6 weeks after balloon angioplasty or BMS implantation or the 12 months after DES implantation in patients in whom the $P2Y_{12}$ inhibitor will need to be discontinued perioperatively (208, 447, 451, 452). *(Level of Evidence: B)*

The 2007 and 2009 ACC/AHA Guidelines on Perioperative Cardiovascular Evaluation and Care for Noncardiac Surgery gave detailed recommendations for the evaluation of patients undergoing noncardiac surgery (444). Patients with evidence of ACS should receive standard therapy, including early revascularization, to minimize the risk of adverse events. Patients with known significant left main or 3-vessel CAD who would otherwise benefit from revascularization in terms of survival or symptomatic relief also generally undergo revascularization before elective noncardiac surgery.

Two RCTs (449, 450) found no benefit with routine preoperative revascularization before noncardiac surgery. Noncardiac surgery early after coronary stenting, particularly in the first 4 weeks, is associated with a high risk of stent thrombosis and death (444, 446, 448). When emergency surgery is necessary, the patient should proceed to surgery without prior PCI. When surgery is required within 30 days and coronary revascularization is required before surgery, many clinicians perform balloon angioplasty alone to avoid the need for DAPT. In situations where preoperative revascularization is required and surgery can be deferred for at least 30 days, many clinicians use BMS and discontinue DAPT after 30 days. If surgery is elective and can be deferred for 1 year, most clinicians would consider DES to reduce the long-term risk of restenosis. A dilemma occurs when a patient has undergone PCI and then unexpectedly requires noncardiac surgery. Many patients can undergo surgery on DAPT, where the risk-benefit ratio will favor continued dual antiplatelet inhibition. If it is necessary to hold $P2Y_{12}$ inhibitor therapy, most clinicians will still continue aspirin uninterrupted during the perioperative period if the bleeding risk is not prohibitive. When the risk of delaying surgery or performing surgery while the patient is on DAPT exceeds the risk of stent thrombosis from stopping DAPT, the $P2Y_{12}$ inhibitor is stopped before surgery and resumed as soon as possible afterward. No $P2Y_12$ inhibitor "bridging" strategy (e.g., GP IIb/IIIa inhibitor, antithrombin therapy) has been validated.

5.3. Coronary Stents: Recommendations

CLASS I

1. Before implantation of DES, the interventional cardiologist should discuss with the patient the need for and duration of DAPT and the ability of the patient to comply with and tolerate DAPT (212). *(Level of Evidence: C)*
2. DES are useful as an alternative to BMS to reduce the risk of restenosis in cases in which the risk of restenosis is increased and the patient is likely to be able to tolerate and comply with prolonged DAPT *(Level of Evidence: A for elective PCI* [453,453a,454–456]; *Level of Evidence: C for UA/NSTEMI* (453); *Level of Evidence: A for STEMI* [453,456–459]).
3. Balloon angioplasty or BMS should be used in patients with high bleeding risk, inability to comply with 12 months of DAPT, or anticipated invasive or surgical procedures within the next 12 months, during which time DAPT may be interrupted (208, 460–462). *(Level of Evidence: B)*

CLASS III: HARM

1. PCI with coronary stenting should not be performed if the patient is not likely to be able to tolerate and comply with DAPT (208–211). *(Level of Evidence: B)*
2. DES should not be implanted if the patient is not likely to be able to tolerate and comply with prolonged DAPT or this cannot be determined before stent implantation (208, 460–462). *(Level of Evidence: B)*

Coronary stent implantation is commonly performed during PCI to prevent recoil, abrupt closure, and late restenosis (463, 464). BMS are composed of either stainless steel or cobalt chromium alloys. Because the risk of stent thrombosis is greatest within the first 30 days after implantation, the use of DAPT is required for 30 days after implantation of BMS (208).

In the United States, 4 types of DES are currently approved: sirolimus-eluting stents, paclitaxel-eluting stents, zotarolimus-eluting stents, and everolimus-eluting stents. DES vary according to stent scaffold material and design, drug content, and the polymer used for drug elution; however, several common clinical features are present. First, sirolimus-eluting stents, paclitaxel-eluting stents, and zotarolimus-eluting stents have been demonstrated in RCTs to be associated with a reduced need for repeat revascularization and no increase in death or MI compared with BMS at 4 years' follow-up (465). Everolimus-eluting stents have been demonstrated in RCTs to be associated with a lower need for repeat revascularization than paclitaxel-

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eluting stents, and, by inference, a lower risk for repeat revascularization than BMS (466, 467), with no increase in death or MI at 2-year follow-up (468). Second, each of these stents is presumed to be associated with delayed healing based on pathologic studies and longer periods of risk for thrombosis compared with BMS and require longer duration of DAPT (469). In the RCTs that led to the U.S. Food and Drug Administration (FDA) approval of these stents, the recommended minimum duration of DAPT therapy was 3 to 6 months. Recently, the consensus of clinical practice has been 12 months of DAPT following DES implantation to avoid late (after 30 days) thrombosis (208), based on observational studies of paclitaxel-eluting stents and sirolimus-eluting stents that indicate lower risk of late stent thrombosis with >6 months of therapy (212). Extending DAPT beyond 1 year is considered reasonable by some practitioners based on observational data analysis (212), but RCTs to determine whether longer DAPT is associated with reduction in stent thrombosis risk have not been completed. Finally, DES therapy is more expensive than BMS. Cost-effectiveness analysis has shown a reduction in total cost associated with DES because of avoidance of repeat procedures, yet it may be reasonable to consider use of BMS in patient subsets in which the risk of restenosis is low (470).

This risk-benefit profile is most favorable for DES over BMS when the risk of restenosis with BMS is high (Table 11). Pooled and meta-analyses have demonstrated that in patients with diabetes, use of DES decreases the risk of restenosis compared with BMS (471, 472). DES may be more appealing for unprotected left main PCI, given the rate and clinical consequences of restenosis in this location (473–475). The risk of stent thrombosis is higher in populations or lesion types excluded from RCTs of DES (e.g., STEMI, smaller arteries [<2.5 mm diameter], longer lesions, bifurcations) (210, 465). Importantly, these features also predict both stent thrombosis (476) and restenosis in BMS (477). The greatest risk of stent thrombosis is within the first year, ranging from 0.7% to 2.0%, depending on patient and lesion complexity. Late stent thrombosis risk after 1 year with DES is observed at a rate of 0.2% to 0.4% per year (210, 478).

Compared with balloon angioplasty, routine BMS implantation during primary PCI decreases risk for target-vessel revascularization and possibly reduces MI rates but does not reduce mortality rates (479). More recent primary PCI studies and meta-analyses have demonstrated lower restenosis rates without increased risk of adverse stent outcome with DES compared with BMS. Although stent thrombosis rates in trials ofSTEMI are higher than in trials of elective PCI, the rates of stent thrombosis are not higher with DES compared with BMS in STEMI (453, 456–459).

TABLE 11. Clinical Situations Associated With DES or BMS Selection Preference

DES Generally Preferred Over BMS (Efficacy Considerations)	BMS Preferred Over DES (Safety Considerations)
• Left main disease	• Unable to tolerate or comply with DAPT
• Small vessels	• Anticipated surgery requiring discontinuation of DAPT within 12 mo
• In-stent restenosis	• High risk of bleeding
• Bifurcations	
• Diabetes	
• Long lesions	
• Multiple lesions	
• Saphenous vein grafts	

BMS indicates bare-mental stent(s); DAPT, dual antiplatelet therapy; and DES, drug-eluting stent(s).

The greatest risk for DES thrombosis is early discontinuation of DAPT (208, 460–462). It is therefore important to determine that the patient will likely be able to tolerate and comply with DAPT before implantation of DES. Therefore, DES should not be used in the presence of financial barriers to continuing prolonged DAPT, social barriers that may limit patient compliance, or medical issues involving bleeding risks or the need for invasive or surgical procedures in the following year that would interrupt antiplatelet therapy. The need for use of long-term warfarin and the associated increased risk ofbleeding with long-term "triple therapy" is also a consideration in deciding on DES versus BMS (480).

Patients implanted with most contemporary coronary stents can undergo magnetic resonance imaging (MRI) examination any time after implantation (481, 482). The effect of the MRI examination on heating of the drug or polymer coating used in DES is unknown. There is no indication for antibiotic prophylaxis before dental or invasive procedures in patients with coronary stents (483).

5.4. Adjunctive Diagnostic Devices

5.4.1. FFR: Recommendation

CLASS IIa

1. FFR is reasonable to assess angiographic intermediate coronary lesions (50% to 70% diameter stenosis) and can be useful for guiding revascularization decisions in patients with SIHD (12, 97, 484–486). *(Level of Evidence: A)*

See Online Data Supplement 23 for additional data regarding FFR.

The limitations of coronary angiography for determination of lesion severity have been well described. Angiography may under- or overestimate lesion stenosis. Various physiologic measurements can be made in the catheterization laboratory, including

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coronary flow reserve and FFR. The correlation of ischemia on stress testing with FFR values of <0.75 has been established in numerous comparative studies with high sensitivity (88%), specificity (100%), positive predictive value (100%), and overall accuracy (93%) (487). The 5-year outcomes for patients with medical therapy based on an FFR >0.75 were superior compared with PCI in the DEFER (Deferral Versus Performance of Balloon Angioplasty in Patients Without Documented Ischemia) study (485). The FAME (Fractional Flow Reserve Versus Angiography for Multivessel Evaluation) study identified the benefit for deferring PCI in patients with multivessel disease and lesion FFR >0.80, with reduced rates of cardiac events at both 1 and 2 years (97, 486). Whereas both FFR and IVUS have been used for assessment of intermediate angiographic stenosis with favorable outcomes, FFR may reduce the need for revascularization when compared with IVUS (488). Although IVUS is often considered in the assessment ofequivocal left main stenosis, FFR may be similarly effective (484).

5.4.2. IVUS: Recommendations

CLASS IIa

1. IVUS is reasonable for the assessment of angiographically indeterminant left main CAD (489–491). *(Level of Evidence: B)*
2. IVUS and coronary angiography are reasonable 4 to 6 weeks and 1 year after cardiac transplantation to exclude donor CAD, detect rapidly progressive cardiac allograft vasculopathy, and provide prognostic information (492–494). *(Level of Evidence: B)*
3. IVUS is reasonable to determine the mechanism of stent restenosis (495). *(Level of Evidence: C)*

CLASS IIb

1. IVUS may be reasonable for the assessment of non-left main coronary arteries with angiographically intermediate coronary stenoses (50% to 70% diameter stenosis) (489, 496, 497). *(Level of Evidence: B)*
2. IVUS may be considered for guidance of coronary stent implantation, particularly in cases of left main coronary artery stenting (490, 495, 498). *(Level of Evidence: B)*
3. IVUS may be reasonable to determine the mechanism of stent thrombosis (495). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. IVUS for routine lesion assessment is not recommended when revascularization with PCI or CABG is not being contemplated. *(Level of Evidence: C)*

IVUS provides a unique coronary artery assessment of lesion characteristics, minimal and maximal lumen diameters, cross-sectional area, and plaque area. Diagnostic uses for IVUS include the assessment of angiographic indeterminant coronary artery stenoses, determination of the mechanism of stent restenosis or thrombosis, and postcardiac transplantation surveillance of CAD (488, 490–492, 499). For left main coronary artery stenoses, a minimal lumen diameter of <2.8 mm or a minimal lumen area of <6mm^2 suggests a physiologically significant lesion for which patients may benefit from revascularization. A minimal lumen area >7.5 mm^2 suggests that revascularization may be safely deferred (490). A minimal lumen area between 6 and 7.5 mm^2 requires further physiological assessment, such as measurement of FFR (487, 500). For non-left main stenoses, minimal lumen diameter >2.0 mm and minimal lumen area > 4.0 mm^2 correlate with low event rates (489). However, in smaller-diameter arteries (minimal lumen area <3.0 mm^2), measurement of FFR may more accurately reflect a significant stenosis (488). Studies correlating IVUS measures with ischemia have not specified the size of coronary arteries for which such correlations are valid (488, 489, 497).

IVUS assessment after stent thrombosis may serve to identify stent underexpansion or malapposition (499). IVUS is superior to angiography in the early detection of the diffuse, immune-mediated, cardiac allograft vasculopathy; recommendations about the use of IVUS for this purpose were published in 2010 by the International Society of Heart and Lung Transplantation (492). Whereas IVUS has been an important research tool in interventional cardiology, most clinical studies of IVUS have not been able to demonstrate that its routine use results in a reduction of MACE or restenosis rates (498, 501, 502). IVUS has been inappropriately used in clinical practice to justify implanting stents in mildly diseased segments that may require no intervention (503).

5.4.3. Optical Coherence Tomography. Compared with IVUS, optical coherence tomography has greater resolution (10 to 20 micronmeter axially) but more limited depth of imaging (1 to 1.5 mm) (504, 505). Unlike IVUS, optical coherence tomography requires that the artery be perfused with saline solution or crystalloid during image acquisition and therefore does not permit imaging of ostial lesions. Clinical studies have shown low optical coherence tomography complication rates (506, 507), similar to those of IVUS (508). The excellent resolution of optical coherence tomography permits detailed in vivo 2-dimensional imaging of plaque morphological characteristics (e.g., calcification, lipid, thrombus, fibrous cap thickness, and plaque ulceration or rupture) (508–510) and evaluation of the arterial response to stent implantation (e.g., stent strut neointimal thickness and apposition) (511–513) and

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may be of value in clinical research. The appropriate role for optical coherence tomography in routine clinical decision making has not been established.

5.5. Adjunctive Therapeutic Devices

5.5.1. Coronary Atherectomy: Recommendations

CLASS IIa

1. Rotational atherectomy is reasonable for fibrotic or heavily calcified lesions that might not be crossed by a balloon catheter or adequately dilated before stent implantation (514, 515). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. Rotational atherectomy should not be performed routinely for de novo lesions or in-stent restenosis (516–519). *(Level of Evidence: A)*

Rotational atherectomy in RCTs was associated with higher rates of MACE at 30 days and no reduction in restenosis. It has a limited role in facilitating the dilation or stenting of lesions that cannot be crossed or expanded with PCI (520, 521). Devices for directional coronary atherectomy are no longer marketed in the United States.

5.5.2. Thrombectomy: Recommendation

CLASS IIa

1. Aspiration thrombectomy is reasonable for patients undergoing primary PCI (522–524). *(Level of Evidence: B)*

The benefit of thrombectomy in patients with STEMI appears to be dependent on the type of thrombectomy technique used (522–526). No clinical benefit for routine rheolytic thrombectomy (AngioJet device, MEDRAD Interventional, Minneapolis, MN and Pittsburgh, PA) has been demonstrated in primary PCI (524–526). Two RCTs (522, 523) and a meta-analysis (524) support the use of manual aspiration thrombectomy during primary PCI to improve microvascular reperfusion and decrease MACE. It is not known whether a strategy of selective thrombus aspiration in patients with a large thrombus burden might be equivalent to routine thrombus aspiration.

5.5.3. Laser Angioplasty: Recommendations

CLASS IIb

1. Laser angioplasty might be considered for fibrotic or moderately calcified lesions that cannot be crossed or dilated with conventional balloon angioplasty (527). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. Laser angioplasty should not be used routinely during PCI (516, 518, 528). *(Level of Evidence: A)*

RCTs of laser angioplasty have not demonstrated improved clinical or angiographic PCI outcomes, although some practitioners think that laser angioplasty may be of use in the treatment of lesions that are difficult to dilate with balloon angioplasty (527).

5.5.4. Cutting Balloon Angioplasty: Recommendations

CLASS IIb

1. Cutting balloon angioplasty might be considered to avoid slippage-induced coronary artery trauma during PCI for in-stent restenosis or ostial lesions in side branches (529). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. Cutting balloon angioplasty should not be performed routinely during PCI (516, 529, 530). *(Level of Evidence: A)*

Although some small, single-center trials have suggested that cutting balloon angioplasty was more efficacious than balloon angioplasty, it was not found to be safer or more effective in several large trials (516, 529, 531). When balloon dilation is required for in-stent restenosis, however, cutting balloons are less likely to slip and may offer a technical advantage over conventional balloons (529). Scoring balloons have been used by some cardiologists as an alternative to cutting balloons, but no RCTs have been reported (531).

5.5.5. Embolic Protection Devices: Recommendation

CLASS I

1. Embolic protection devices (EPDs) should be used during saphenous vein graft (SVG) PCI when technically feasible (532–535). *(Level of Evidence: B)*

The incidence of MACE doubles in SVG PCI compared with native-artery PCI (536). A distal balloon occlusion EPD decreased the 30-day composite outcome of death, MI, emergency CABG, or target-lesion revascularization (9.6% versus 16.5%) in the only RCT (532). Subsequent noninferiority comparisons have demonstrated similar benefit with proximal occlusion and distal filter EPDs, with benefit limited to reduction in periprocedural MI (534, 535) (Section 5.10). Distal EPDs do not improve survival or reinfarction rates in patients undergoing native-artery PCI (524, 537).

5.6. Percutaneous Hemodynamic Support Devices: Recommendation

CLASS IIb

1. Elective insertion of an appropriate hemodynamic support device as an adjunct to PCI may be

reasonable in carefully selected high-risk patients. *(Level of Evidence: C)*

IABP counterpulsation is frequently used as an adjunct to PCI in hemodynamically unstable patients (538, 539). In single-center series, the routine prophylactic use of IABP during PCI in high-risk patients was associated with lower mortality and fewer major complications compared with rescue use of IABP (540, 541). In the only RCT in high-risk PCI patients (BCIS-1 [Balloon Pump-Assisted Coronary Intervention Study]) (542), there was no difference in the primary composite outcome between routine and provisional use of IABP. There were also no differences in major secondary endpoints except major procedural complications (e.g., prolonged hypotension, ventricular tachycardia/ fibrillation, cardiopulmonary arrest), which were lower in the routine IABP group. Bleeding and access site complication rates tended to be higher in the routine IABP group. The "bailout" rate of IABP insertion in the provisional IABP group was 12%, mostly for procedural hypotension (542). A meta-analysis of IABP therapy in patients with STEMI did not show improved outcomes with the use of IABP (434).

The Impella Recover LP 2.5 System (Abiomed, Aachen, Germany/Danvers, Massachusetts) is a 12.5 Fr catheter that is inserted percutaneously through a 13 Fr femoral artery sheath and placed across the aortic valve into the left ventricle, through which a transaxial blood pump provides flows of up to 2.5 L/min. This has been used in patients with cardiogenic shock (543, 544) as well as elective PCI (545). The hemodynamic effects of the Impella 2.5 have been studied in high-risk PCI patients, demonstrating beneficial LV unloading effect (decreased end-diastolic pressure and wall stress) with no change in global or systolic LV function (546). The PROTECT I (A Prospective Feasibility Trial Investigating the Use of the IMPELLA Recover LP 2.5 System in Patients Undergoing High-Risk PCI) trial in 20 patients undergoing high-risk PCI with the Impella 2.5 system concluded that this device was safe, easy to implant, and hemodynamically effective (547). The Europella Registry included 144 patients undergoing high-risk PCI and reported the safety, feasibility, and potential usefulness of the device and that RCTs were warranted (548). The randomized PROTECT II (A Prospective, Multicenter, Randomized Controlled Trial of the IMPELLA Recover LP 2.5 System Versus Intra Aortic Balloon Pump in Patients Undergoing Non Emergent High Risk PCI) trial, which was designed to demonstrate superiority ofImpella over IABP in terms of 1-month adverse events, was halted for futility after interim analysis of study results (549).

The TandemHeart (CardiacAssist, Inc, Pittsburgh, PA) is a left atrial to aorta catheter-based system that includes a centrifugal blood pump providing flows of up to 4 L/min. This device uses a 21 Fr cannula percutaneously inserted into the femoral vein for transseptal access of the left atrium with a 15 Fr catheter placed in the contralateral femoral artery and positioned above the aortic bifurcation. An extracorporeal pump then returns oxygenated blood from the left atrium to the arterial system, thereby unloading the left ventricle (550, 551). The hemodynamic effects have been studied in patients undergoing high-risk PCI (552). Several small studies have addressed the clinical efficacy of the TandemHeart in high-risk patients undergoing PCI (551, 553–556). In a single-center report of 68 patients undergoing high-risk PCI using either TandemHeart or Impella Recover 2.5, success rates (>90%) and vascular complications (7%) were similar (553).

High-risk patients may include those undergoing unprotected left main or last-remaining-conduit PCI, those with severely depressed EF undergoing PCI of a vessel supplying a large territory, and/or those with cardiogenic shock. Patient risk, hemodynamic support, ease of application/ removal, and operator and laboratory expertise are all factors involved in consideration of use of these devices. With devices that require large cannula insertion, the risk of vascular injury and related complications are important considerations regarding necessity and choice of device.

5.7. Interventional Pharmacotherapy

5.7.1. Procedural Sedation. The term *conscious sedation* is falling out of favor with the recognition that there is a spectrum of procedural sedation levels. Most patients undergoing PCI fall under the definition of either minimal sedation (anxiolysis) or moderate sedation (depressed consciousness with the ability to respond purposefully to verbal commands) (557). Nonetheless, an underlying principle of procedural sedation is that the physician should be prepared to manage one level of sedation deeper than the level intended. Thus, cardiologists should be cognizant of the principles of managing deep sedation (depressed consciousness without easy arousal that may require assistance in maintaining airway patency or spontaneous ventilation).

A full review of procedural sedation is beyond the scope of this document, but practice guidelines for sedation and analgesia by nonanesthesiologists, along with The Joint Commission standards, provides a reasonable framework. These guidelines outline several general principles (558, 559). Before the procedure the patient should be assessed for predictors of difficult

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intubation or a history of prior difficult intubation. The patient should be monitored by someone dedicated to observing the level and effects of sedation. Level of consciousness, respiratory rate, blood pressure, cardiac rhythm, and oxygen saturation by pulse oximetry should be monitored. Available equipment should include a high-flow oxygen source, suction, airway management equipment, a defibrillator, resuscitation drugs, and reversal agents appropriate for the drugs being used. A free-flowing IV line should be established. Supplemental oxygen is usually administered, even in the absence of preexisting hypoxia, to provide a margin of safety.

Agents used for sedation are best given in incremental doses, allowing adequate time for the development and assessment of peak effect. The most commonly used agents are listed in Appendix 4F.

5.7.2. Oral Antiplatelet Therapy: Recommendations

CLASS I

1. Patients already taking daily aspirin therapy should take 81 mg to 325 mg before PCI (301–304). *(Level of Evidence: B)*
2. Patients not on aspirin therapy should be given non-enteric aspirin 325 mg before PCI (301, 303, 304). *(Level of Evidence: B)*
3. After PCI, use of aspirin should be continued indefinitely (560–563). *(Level of Evidence: A)*
4. A loading dose of a $P2Y_{12}$ receptor inhibitor should be given to patients undergoing PCI with stenting (564–568) *(Level of Evidence: A)*. Options include
   a. Clopidogrel 600 mg (ACS and non-ACS patients) (564–566) *(Level of Evidence: B)*
   b. Prasugrel 60 mg (ACS patients) (567) *(Level of Evidence: B)*
   c. Ticagrelor 180 mg (ACS patients) (568) *(Level of Evidence: B)*
5. The loading dose of clopidogrel for patients undergoing PCI after fibrinolytic therapy should be 300 mg within 24 hours and 600 mg more than 24 hours after receiving fibrinolytic therapy (565, 569). *(Level of Evidence: C)*
6. Patients should be counseled on the need for and risks of DAPT before placement of intracoronary stents, especially DES, and alternative therapies should be pursued if patients are unwilling or unable to comply with the recommended duration of DAPT (208). *(Level of Evidence: C)*
7. The duration of $P2Y_{12}$ inhibitor therapy after stent implantation should generally be as follows:
   a. In patients receiving a stent (BMS or DES) during PCI for ACS, $P2Y_{12}$ inhibitor therapy should be given for at least 12 months. Options include clopidogrel 75 mg daily (570), prasugrel 10 mg daily (567), and ticagrelor 90 mg twice daily (568). *(Level of Evidence: B)*
   b. In patients receiving DES for a non-ACS indication, clopidogrel 75 mg daily should be given for at least 12 months if patients are not at high risk of bleeding (208, 212, 571). *(Level of Evidence: B)*
   c. In patients receiving BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 month and ideally up to 12 months (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks) (208, 572). *(Level of Evidence: B)*

CLASS IIa

1. After PCI, it is reasonable to use aspirin 81 mg per day in preference to higher maintenance doses (302, 573–576). *(Level of Evidence: B)*
2. If the risk of morbidity from bleeding outweighs the anticipated benefit afforded by a recommended duration of $P2Y_{12}$ inhibitor therapy after stent implantation, earlier discontinuation (e.g., <12 months) of $P2Y_{12}$ inhibitor therapy is reasonable. *(Level of Evidence: C)*

CLASS IIb

1. Continuation of DAPT beyond 12 months may be considered in patients undergoing DES implantation (567, 568). *(Level of Evidence: C)*

CLASS III: HARM

1. Prasugrel should not be administered to patients with a prior history of stroke or transient ischemic attack (567). *(Level of Evidence: B)*

Aspirin reduces the frequency of ischemic complications after PCI. Although the minimum effective aspirin dosage in the setting of PCI has not been established, aspirin 325 mg given at least 2 hours, and preferably 24 hours, before PCI is recommended (302, 303), after which aspirin 81 mg daily should be continued indefinitely.

Several investigations have explored various loading doses of clopidogrel before or during PCI. Compared with a 300-mg loading dose, doses of either 600 mg or 900 mg achieve greater degrees of platelet inhibition with fewer low responders (577). A meta-analysis of 7 studies that included 25,383 patients undergoing PCI demonstrated that intensified loading of clopidogrel with 600 mg reduces the rate of MACE without an increase in major bleeding compared with 300 mg (578). Another study suggested that a 600-mg loading dose of clopidogrel is associated with improvements in procedural angiographic endpoints and 1-year clinical outcomes in patients with STEMI who undergo

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primary PCI compared with a 300-mg dose (579). There is no benefit with increasing the loading dose to 900 mg compared with 600 mg (577). Clopidogrel 75 mg daily should be given for a minimum of 4 weeks after balloon angioplasty or BMS implantation (a minimum of 2 weeks if increased bleeding risk is present) (580) and for at least 12 months after DES implantation (unless the risk of bleeding outweighs the anticipated benefit). Patients should be counseled on the need for and risks of DAPT before stent implantation, especially DES implantation, and alternative therapies pursued (BMS or balloon angioplasty) if they are unwilling or unable to comply with the recommended duration of DAPT.

The efficacy of clopidogrel pretreatment remains controversial. Although some studies have suggested that pretreatment with clopidogrel is associated with decreased platelet aggregation and a significantly lower incidence of periprocedural MI after elective PCI, others have suggested no benefit to pretreatment compared with administration of the drug in the catheterization laboratory (572, 581, 582).

When prasugrel was compared with clopidogrel in patients with ACS in TRITON-TIMI 38 (Trial to Assess Improvement in Therapeutic Outcomes by Optimizing Platelet Inhibition with Prasugrel-Thrombolysis In Myocardial Infarction), prasugrel was associated with a significant 2.2% reduction in absolute risk and a 19% reduction in relative risk in the composite endpoint of cardiovascular death, nonfatal MI, or nonfatal stroke, and a significant increase in the rate of TIMI major hemorrhage (1.8% versus 2.4%) (567). Prasugrel is contraindicated in patients with a history of transient ischemic attack or stroke. Patients weighing <60 kg have an increased risk of bleeding on the 10 mg daily maintenance dose. The package insert suggests that consideration should be given to lowering the maintenance dose to 5 mg daily, although the effectiveness and safety of the 5-mg dose has not been studied. Prasugrel is not recommended for patients >75 years of age because of the increased risk of fatal and intracranial bleeding and lack of benefit, except in patients with diabetes or a history of prior MI. Prasugrel should not be started in patients likely to undergo urgent CABG. Prasugrel has not been studied in elective PCI, and thus no recommendation can be made regarding its use in this clinical setting.

Ticagrelor reversibly binds the $P2Y_{12}$ receptor. Unlike clopidogrel or prasugrel, ticagrelor is not a thienopyridine. It also does not require metabolic conversion to an active metabolite. Compared with clopidogrel in patients with ACS in the PLATO (Platelet Inhibition and Patient Outcomes) trial, ticagrelor was associated with a significant 1.9% reduction in absolute risk and a 16% reduction in relative risk in the primary composite endpoint of vascular death, nonfatal MI, or nonfatal stroke (568). Importantly, a significant reduction in vascular mortality and all-cause mortality was observed. Although CABG-related bleeding was not significantly increased with ticagrelor compared with clopidogrel, a significantly greater incidence of major bleeding was observed in patients not undergoing CABG. Ticagrelor was associated with higher rates of transient dyspnea and bradycardia compared with clopidogrel, although only a very small percentage of patients discontinued the study drug because of dyspnea. Based on post hoc analysis of the PLATO study, specifically the results in the U.S. patient cohort, a black box warning states that maintenance doses of aspirin above 100 mg reduce the effectiveness of ticagrelor and should be avoided. After any initial dose, ticagrelor should be used with aspirin 75 mg to 100 mg per day (583). Given the twice-daily dosing and reversible nature of the drug, patient compliance may be a particularly important issue to consider and emphasize. Ticagrelor has not been studied in elective PCI or in patients who received fibrinolytic therapy; thus, no recommendations about its use in these clinical settings can be made.

5.7.3. IV Antiplatelet Therapy: Recommendations STEMI

CLASS IIa

1. In patients undergoing primary PCI treated with UFH, it is reasonable to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban), whether or not patients were pretreated with clopidogrel (584–590). *(For GP IIb/IIIa inhibitor administration in patients not pretreated with clopidogrel, Level of Evidence: A; for GP IIb/IIIa inhibitor administration in patients pretreated with clopidogrel, Level of Evidence: C)*

CLASS IIb

1. In patients undergoing primary PCI with abciximab, it may be reasonable to administer intracoronary abciximab (589, 591–604). *(Level of Evidence: B)*

CLASS III: NO BENEFIT

1. Routine precatheterization laboratory (e.g., ambulance or emergency department) administration of GP IIb/IIIa inhibitors as part of an upstream strategy for patients with STEMI undergoing PCI is not beneficial (605–612). *(Level of Evidence: B)*

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UA/NSTEMI

CLASS I

1. In UA/NSTEMI patients with high-risk features (e.g., elevated tro-ponin level) not treated with bivalirudin and not adequately pre-treated with clopidogrel, it is useful at the time of PCI to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban) in patients treated with UFH (613–618). *(Level of Evidence: A)*

CLASS IIa

1. In UA/NSTEMI patients with high-risk features (e.g., elevated troponin level) treated with UFH and adequately pretreated with clopidogrel, it is reasonable at the time of PCI to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban) (616, 619). *(Level of Evidence: B)*

SIHD

CLASS IIa

1. In patients undergoing elective PCI treated with UFH and not pretreated with clopidogrel, it is reasonable to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban) (619–621). *(Level of Evidence: B)*

CLASS IIb

1. In patients undergoing elective PCI with stent implantation treated with UFH and adequately pretreated with clopidogrel, it might be reasonable to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban) (619, 622–624). *(Level of Evidence: B)*

See Online Data Supplement 24 for additional data regarding IV antiplatelet therapy.

In the era before DAPT, trials of adequately dosed GP IIb/IIIa inhibitors in patients undergoing balloon angioplasty and coronary stent implantation demonstrated a reduction in the incidence of composite ischemic events with GP IIb/IIIa treatment, primarily through a reduction of enzymatically defined MI (613, 615, 618, 620, 621). Earlier RCTs of GP IIb/IIIa inhibitors were generally conducted in patients treated with UFH. In some trials, use of GP IIb/IIIa inhibitors are associated with some increased bleeding risk, and trials of these agents have generally excluded patients at high risk of bleeding (e.g., coagulopathy) (584, 587–589, 613–618, 620–626). Thus, recommendations about use of GP IIb/IIIa inhibitors are best construed as applying to those patients not at high risk of bleeding complications. Abciximab, double-bolus eptifibatide (180 mcg/kg bolus followed 10 minutes later by a second 180 mcg/kg bolus), and high-bolus dose tirofiban (25 mcg/kg) all result in a high degree of platelet inhibition (627–629), have been demonstrated to reduce ischemic complications in patients undergoing PCI (608, 609, 613, 615, 618–621), and appear to lead to comparable angiographic and clinical outcomes (630, 631).

Trials of GP IIb/IIIa inhibitors in the setting of STEMI and primary PCI were conducted in the era before routine stenting and DAPT. The results of these and more recent trials, as well as several meta-analyses, have yielded mixed results (584–590). Therefore, it is reasonable to administer GP IIb/IIIa inhibitors in patients with STEMI undergoing PCI, although these agents cannot be definitively recommended as routine therapy. These agents might provide more benefit in selective use, such as in patients with large anterior MI and/or large thrombus burden. Trials of precatheterization laboratory (e.g., ambulance or emergency room) administered GP IIb/IIIa inhibitors in patients with STEMI undergoing PCI, with or without fibrinolytic therapy, have generally shown no clinical benefit, and GP IIb/IIIa inhibitor use in this setting may be associated with an increased risk of bleeding (605–610, 612). Studies of intracoronary GP IIb/IIIa inhibitor administration (predominantly using abciximab) consist of several small RCTs, retrospective analyses, retrospective and prospective registries, cohort analyses, and case reports. Although most of these published studies have reported some benefit of intracoronary administration in terms of acute angiographic parameters, infarct size, left ventricle myocardial salvage, and composite clinical endpoints, several other studies have not detected any benefit with intracoronary administration (589, 591–604).

Trials of GP IIb/IIIa inhibitors in patients with UA/NSTEMI undergoing PCI demonstrated reduced ischemic outcomes, particularly in those with high-risk features such as positive biomarkers. Most trials were conducted in a prior PCI era and without $P2Y_{12}$ inhibitor pretreatment (613, 615, 618, 632, 633), although several trials have also demonstrated benefit in patients with high-risk features pretreated with clopidogrel (616, 619). In most older studies of stable patients undergoing balloon angioplasty or coronary stenting, treatment with GP IIb/IIIa inhibitors resulted in a reduction of composite ischemic events, primarily enzymatically defined MI (613–618, 620, 621, 634, 635). More contemporary trials of patients pretreated with a thienopyridine have not demonstrated any benefit with GP IIb/IIIa inhibitor therapy in patients with stable symptoms undergoing elective PCI (619, 622–624).

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TABLE 12. Dosing of Parenteral Anticoagulants During PCI

Drug	Patient Has Received Prior Anticoagulant Therapy	Patient Has Not Received Prior Anticoagulant Therapy
UFH	• IV GPI planned: additional UFH as needed (e.g., 2,000 to 5,000 U) to achieve an ACT of 200 to 250 s • No IV GPI planned: additional UFH as needed (e.g., 2,000 to 5,000 U) to achieve an ACT of 250 to 300 s for HemoTec, 300 to 350 s for Hemochron	• IV GPI planned: 50 to 70 U/kg bolus to achieve an ACT of 200 to 250 s • No IV GPI planned: 70 to 100 U/kg bolus to achieve target ACT of 250 to 300 s for HemoTec, 300 to 350 s for Hemochron
Enoxaparin	• For prior treatment with enoxaparin, if the last SC dose was administered 8 to 12 h earlier or if only 1 SC dose of enoxaparin has been administered, an IV dose of 0.3 mg/kg of enoxaparin should be given. • If the last SC dose was administered within the prior 8 h, no additional enoxaparin should be given.	0.5 to 0.75 mg/kg IV bolus
Bivalirudin	For patients who have received UFH, wait 30 min, then give 0.75 mg/kg IV bolus, then 1.75 mg/kg per h IV infusion.	0.75 mg/kg bolus, 1.75 mg/kg per h IV infusion
Fondaparinux	For prior treatment with fondaparinux, administer additional IV treatment with an anticoagulant possessing anti-IIa activity, taking into account whether GPI receptor antagonists have been administered.	N/A
Argatroban	200 mcg/kg IV bolus, then 15 mcg/kg per min IV infusion	350 mcg/kg bolus, then 15 mcg/kg per min IV infusion

ACT indicates activated clotting time; IV, intravenous; GPI, glycoprotein inhibitor; N/A, not applicable; PCI, percutaneous coronary intervention; SC, subcutaneous; and UFH, unfractionated heparin.

5.7.4. Anticoagulant Therapy

5.7.4.1. USE OF PARENTERAL ANTICOAGULANTS DURING PCI: RECOMMENDATION

CLASS I

1. An anticoagulant should be administered to patients undergoing PCI. *(Level of Evidence: C)*

Anticoagulant therapy prevents thrombus formation at the site of arterial injury, on the coronary guidewire, and in the catheters used for PCI (8). With rare exceptions (636), all PCI studies have used some form of anticoagulant. It is the consensus of the writing committee that PCI be performed with the use of some form of anticoagulant therapy. Suggested dosing regimens of parenteral agents used in PCI are given in Table 12. Recommendations for antiplatelet and antithrombin pharmacotherapy in PCI are given in Table 13.

5.7.4.2. UFH: RECOMMENDATION

CLASS I

1. Administration of IV UFH is useful in patients undergoing PCI. *(Level of Evidence: C)*

As the only anticoagulant available for PCI for many years, UFH became the standard of care by default (8). The dose of UFH for PCI has been based on empiricism and experience from RCTs. Suggested UFH dosing regimens are given in Table 12. When UFH is used during PCI, most cardiologists assess the degree of anticoagulation by measuring the activated clotting time. Although measurements are useful to show that an anti-IIa anticoagulant has been given, the value of the activated clotting time in current practice has been questioned. Although studies in the balloon angioplasty era did demonstrate a relationship between activated clotting time levels and ischemic complications (653–655), more recent analyses from the coronary stent era have not found a clear relationship between activated clotting time and outcomes (349, 656, 657). There may, however, be a modest relation between bleeding and activated clotting time levels (349, 657). In addition, not only are there differences between activated clotting time levels measured by Hemochron and HemoTec devices, but both devices have less than optimal precision (658). Thus, although traditional target activated clotting time levels are included in this document, the utility of measured activated clotting time levels in current practice should be considered uncertain.

Most cardiologists remove femoral sheaths when the activated clotting time falls to <150 to 180 seconds or when the activated partial thromboplastin time falls to <50 seconds. Full-dose anticoagulation is no longer used after successful PCI procedures. Almost all large clinical trials have enrolled patients who underwent transfemoral PCI, but recent small studies assessing the transradial approach have used similar doses of UFH (659) and similar activated clotting time target levels (660).

5.7.4.3. ENOXAPARIN: RECOMMENDATIONS

CLASS I

1. An additional dose of 0.3 mg/kg IV enoxaparin should be administered at the time of PCI to patients who have received fewer than 2 therapeutic

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TABLE 13. Recommendations for Antiplatelet and Antithrombin Pharmacotherapy at the Time of PCI

	COR	LOE	References	Relevant Caveats/Comments
Oral antiplatelet agents				
Aspirin	I	B	(301–304, 560–563)	N/A
$P2Y_{12}$ inhibitors	I	A	(564–568)	• A loading dose of a $P2Y_{12}$ inhibitor should be given to patients undergoing PCI with stenting.
• Clopidogrel	I	B	(564–566)	• 600-mg loading dose now recommended.
• Prasugrel	I	B	(567)	• Contraindicated in patients with prior TIA/CVA: ***Class III: Harm; LOE: B.*** • Generally not recommended in patients >75 y of age (Section 5.7.2). • Consideration of using a lower maintenance dose in patients weighing <60 kg suggested by FDA (Section 5.7.2).
• Ticagrelor	I	B	(568)	• Issues of patient compliance may be especially important.
GP IIb/IIIa inhibitors (abciximab, double-bolus eptifibatide, high-bolus dose tirofiban)				
• No clopidogrel pretreatment	STEMI: IIa	A	(584–590)	• UA/NSTEMI recommendation applies to those with high-risk features. • GPI use in STEMI may be most appropriate in those with large anterior MI and/or large thrombus burden. • IC abciximab administration in STEMI: ***Class IIb; LOE: B.*** • Precatheterization laboratory GPI administration in STEMI: ***Class III: No Benefit; LOE: B.*** • Recommendations apply to those not at high risk for bleeding complications.
	UA/NSTEMI: I	A	(613–618)	
	SIHD: IIa	B	(619–621)	
• Clopidogrel pretreatment	STEMI: IIa	C	(584–590)	
	UA/NSTEMI: IIa	B	(616, 619)	
	SIHD: IIb	B	(619, 622–624)	
Antithrombin agents				
UFH	I	C	N/A	• Dosing based on whether or not GPI was administered.
Bivalirudin	I	B	(625, 637–645)	• Lower bleeding rates associated with bivalirudin are mitigated when used concomitantly with a GPI.
Enoxaparin	IIb	B	(646–650)	• Recommendations apply to administration of IV enoxaparin at the time of PCI for those who have not received prior antithrombin therapy or who have received "upstream" SC enoxaparin therapy for UA/NSTEMI. • An additional dose of 0.3 mg/kg IV enoxaparin should be administered at the time of PCI to patients who have received <2 therapeutic SC doses (e.g., 1 mg/kg) or received the last SC enoxaparin dose 8 to 12 h before PCI: ***Class I; LOE: B.*** • Patients treated with SC enoxaparin within 12 h of PCI should not receive additional treatment with UFH during PCI ("stacking"): ***Class III: Harm; LOE: B.***
Anti-Xa inhibitors				
Fondaparinux	III: Harm	C	(651, 652)	• PCI should not be performed with fondaparinux as the sole antithrombin agent in patients treated with upstream fondaparinux. An additional anticoagulant with anti-IIa activity should be administered.

ACT indicates activated clotting time; COR, class of recommendation; CVA, cerebrovascular accident; FDA, U.S. Food and Drug Administration; GP, glycoprotein; GPI, glycoprotein IIb/IIIa inhibitor; IC, intracoronary; IV, intravenous; LOE, level of evidence; MI, myocardial infarction; N/A, not applicable; PCI, percutaneous coronary intervention; SC, subcutaneous; SIHD, stable ischemic heart disease; STEMI, ST-elevation myocardial infarction; TIA, transient ischemic attack; UA/NSTEMI, unstable angina/non-ST-elevation myocardial infarction; and UFH, unfractionated heparin.

subcutaneous doses (e.g., 1 mg/kg) or received the last subcutaneous enoxaparin dose 8 to 12 hours before PCI (649, 661–664). *(Level of Evidence: B)*

CLASS IIb

1. Performance of PCI with enoxaparin may be reasonable in patients either treated with "upstream" subcutaneous enoxaparin for UA/ NSTEMI or who have not received prior antithrombin therapy and are administered IV enoxaparin at the time of PCI (646–650). *(Level of Evidence: B)*

CLASS III: HARM

1. UFH should not be given to patients already receiving therapeutic subcutaneous enoxaparin (649, 665). *(Level of Evidence: B)*

Trials of enoxaparin relevant to PCI include both studies in which patients with UA/NSTEMI were started on upstream subcutaneous enoxaparin therapy that was continued up to the time of PCI and trials in which patients who had received no prior antithrombin therapy were treated with IV enoxaparin at the time of PCI (646–650, 661–663, 666). In the SYNERGY

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(Superior Yield of the New strategy of Enoxaparin, Revascularization and Glycoprotein IIb/IIIa Inhibitors) trial, there was an increased incidence of bleeding in those treated with upstream enoxaparin, later attributed at least in part to the fact that some patients being treated with enoxaparin were also administered UFH at the time of PCI (so-called "stacking") (649, 665). Almost all patients undergoing elective PCI who are administered enoxaparin (0.5 mg/kg IV) will have a peak anti-Xa level > 0.5 IU/mL (647). Most clinical studies have used a regimen of 0.5 to 0.75 mg IV (667). Several studies have used this regimen in elective patients and those with STEMI (646). Patients who have received multiple doses of subcutaneously administered enoxaparin who undergo PCI within 8 hours of the last subcutaneous dose generally have adequate degrees ofanticoagulation to undergo PCI, but the degree of anticoagulation may diminish in the 8- to 12-hour period after the last subcutaneous dose. In such patients, as well as in patients who have received only 1 subcutaneous dose of enoxaparin, the addition of enoxaparin (0.3 mg/kg IV) at the time of PCI provides an additional degree of anticoagulation and has become standard practice (648, 661–664). Patients who undergo PCI >12 hours after the last subcutaneous dose are usually treated with full-dose de novo anticoagulation using an established regimen (e.g., full-dose UFH or bivalirudin).

5.7.4.4. BIVALIRUDIN AND ARGATROBAN: RECOMMENDATIONS

CLASS I

1. For patients undergoing PCI, bivalirudin is useful as an anticoagulant with or without prior treatment with UFH (625, 637–645). *(Level of Evidence: B)*
2. For patients with heparin-induced thrombocytopenia, it is recommended that bivalirudin or argatroban be used to replace UFH (668, 669). *(Level of Evidence: B)*

Bivalirudin is being increasingly used in clinical practice (670) as evidence emerges from clinical trials across the spectrum of CAD (638–644). In individual trials and meta-analyses, the use of bivalirudin has been associated with reduced bleeding compared with UFH plus a GP IIb/IIIa inhibitor, although concerns about ischemic events have emerged in individual studies (625, 637–645). Longer-term follow-up of the major bivalirudin trials, however, suggests that small or nominal increases in ischemic events have not translated into long-term consequences and that treatment at or before the time of PCI with clopidogrel may mitigate any increased early ischemic risk (637–645). Thus, a treatment strategy of bivalirudin compared with heparin (or enoxaparin) plus GP IIb/IIIa inhibitor appears to lower the risk of bleeding complications. The lower bleeding rates associated with bivalirudin (compared with UFH plus a GP IIb/IIIa inhibitor) are mitigated when used concomitantly with a GP IIb/IIIa inhibitor (639). A strategy of use of provisional GP IIb/IIIa inhibitor in patients treated with bivalirudin is widely accepted (639, 643, 644).

In patients with heparin-induced thrombocytopenia (671, 672), a direct-thrombin inhibitor (argatroban) has been approved as an alternative parenteral anticoagulant to be used during PCI (668). The use of bivalirudin for heparin-induced thrombocytopenia has been reported as well (669).

5.7.4.5. FONDAPARINUX: RECOMMENDATION

CLASS III: HARM

1. Fondaparinux should not be used as the sole anticoagulant to support PCI. An additional anticoagulant with anti-IIa activity should be administered because of the risk of catheter thrombosis (651, 652). *(Level of Evidence: C)*

Fondaparinux, a pentasaccharide, is an indirect factor Xa inhibitor but has no effect on thrombin. On the basis of reports of catheter thrombosis when fondaparinux is used alone during primary PCI (651, 652), the writing committee recommends that an anticoagulant with anti-IIa activity be used in patients undergoing PCI (651, 652). One study suggested that clinical outcomes were better when fondaparinux was replaced during PCI by a standard dose of UFH (85 U/kg, 60 U/kg with GP IIb/IIIa inhibitors) rather than by a low dose (50 U/kg) (673).

5.7.5. No-Reflow Pharmacological Therapies: Recommendation

CLASS IIa

1. Administration of an intracoronary vasodilator (adenosine, calcium channel blocker, or nitroprusside) is reasonable to treat PCI-related no-reflow that occurs during primary or elective PCI (674–689). *(Level of Evidence: B)*

See Online Data Supplement 25 for additional data regarding no-reflow therapies.

No-reflow is a broad term used to describe 2 distinct entities. The first is "interventional no-reflow" attributed to vasospasm and downstream embolization of debris dislodged during PCI, usually in the setting of atherectomy, thrombus, or degenerated SVGs. The second entity is suboptimal reperfusion of an infarct artery, attributed to endothelial injury in addition to embolization and vasospasm. Angiographic no-reflow is the most obvious sequela of the same

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pathophysiology that produces abnormal TIMI frame counts and TIMI blush scores, so these measures are often used interchangeably. The principal clinical sequela of no-reflow is myonecrosis. Efforts to prevent no-reflow overlap with strategies to reduce MI size and prevent periprocedural MI.

In the setting of MI, several drugs have been shown to reduce the incidence of no-reflow. Evidence for a beneficial effect on no-reflow exists for abciximab, adenosine, nicorandil, and nitroprusside (674, 675, 680, 682, 683, 685, 687, 688, 690). However, their adoption into clinical practice has depended on their effect on hard clinical endpoints such as infarct size and mortality. These benefits, and consequentially the use of these agents, have been limited.

For interventional no-reflow, several therapies have proven effective after no-reflow has started. These include adenosine, calcium channel blockers, and nitroprusside (676, 678, 679, 681, 684, 686, 689, 691). There are fewer data to support the use of epinephrine (692). No-reflow after rotational atherectomy was less common with nicorandil compared with verapamil infusions in 3 studies (693–695), and an infusion of nicorandil/adenosine during rotational atherectomy prevented no-reflow in 98% of patients (677). Trials of pre-PCI intracoronary verapamil, nicardipine, and adenosine have reported them to be safe but have not demonstrated reductions in post-PCI no-reflow (696–698). Mechanical devices to prevent interventional and myocardial infarct reperfusion no-reflow are also covered in Section 5.5.5.

5.8. PCI in Specific Anatomic Situations

5.8.1. CTOs: Recommendation

CLASS IIa

1. PCI of a CTO in patients with appropriate clinical indications and suitable anatomy is reasonable when performed by operators with appropriate expertise (699–703). *(Level of Evidence: B)*

See Online Data Supplements 26 to 28 for additional data regarding CTOs.

Approximately one third of patients with suspected CAD who undergo coronary angiography have $\geq$ 1 CTO (defined as occlusion of a duration >3 months) (704). Although stress-induced ischemia can be elicited in the majority of patients with CTO despite the presence of collaterals (706, 707), only 8% to 15% of these patients undergo PCI (708, 709). The disparity between the frequency of CTOs and percutaneous treatment underscores not only the technical and procedural complexities of this lesion subtype but also the clinical uncertainties regarding which patients benefit from CTO revascularization. Studies suggest that patients who undergo successful, rather than failed, recanalization of CTOs fare better in terms of symptom status and need for CABG (699), as well as LV function (710). However, the impact of successful CTO recanalization on long-term survival remains unsettled (701, 711, 712). The decision to try PCI for a CTO (versus continued medical therapy or surgical revascularization) requires an individualized risk-benefit analysis encompassing clinical, angiographic, and technical considerations. Consultation with a cardiothoracic surgeon and use of the Heart Team approach in cases of CTO in which a large territory is subtended and/or multivessel CAD is present are frequently done.

From a technical perspective, successful recanalization of CTOs has steadily increased over the years because of adoption of dedicated wires, novel techniques, and increased operator experience (702). In patients who undergo successful CTO recanalization, use of DES significantly reduces the need for repeated target-vessel revascularization, compared with BMS and balloon angioplasty, without compromising safety (703, 713–719).

5.8.2. SVGs: Recommendations

CLASS I

1. EPDs should be used during SVG PCI when technically feasible (532–535). *(Level of Evidence: B)*

CLASS III: NO BENEFIT

1. Platelet GP IIb/IIIa inhibitors are not beneficial as adjunctive therapy during SVG PCI (212, 571, 720, 721). *(Level of Evidence: B)*

CLASS III: HARM

1. PCI is not recommended for chronic SVG occlusions (722–724). *(Level of Evidence: C)*

See Online Data Supplement 29 for additional data regarding SVG.

Adverse cardiac event rates are doubled after SVG PCI compared with native-artery PCI (536). A distal balloon occlusion EPD decreased the 30-day composite outcome of death, MI, emergency CABG, or target-lesion revascularization (9.6% versus 16.5%) in the only RCT comparing embolic protection with no embolic protection (532). Subsequent noninferiority comparisons have demonstrated similar benefit with proximal occlusion and distal filter EPDs, with benefit limited to reduction in periprocedural MI (534, 535). PCI in chronic SVG occlusion is associated with low success rates, high complication rates, and poor long-term patency rates (722, 723). Restenosis and target-vessel revascularization rates are lower with DES compared with BMS, although mortality and stent thrombosis rates are similar (725). The use of covered stents is

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limited to the treatment of the uncommon complication of SVG perforation. Balloon angioplasty for distal SVG anastomotic stenoses has low restenosis rates (724), so stenting is commonly reserved at this location for suboptimal balloon angioplasty results or restenosis. Routine GP IIb/IIIa inhibitor therapy has not proven beneficial in SVG PCI (720). Fibrinolytic therapy is no longer used for thrombus-containing lesions, but rheolytic or manual aspiration thrombectomy is sometimes employed.

5.8.3. Bifurcation Lesions: Recommendations

CLASS I

1. Provisional side-branch stenting should be the initial approach in patients with bifurcation lesions when the side branch is not large and has only mild or moderate focal disease at the ostium (726–729). *(Level of Evidence: A)*

CLASS IIa

1. It is reasonable to use elective double stenting in patients with complex bifurcation morphology involving a large side branch where the risk of side-branch occlusion is high and the likelihood of successful side-branch reaccess is low (730–733). *(Level of Evidence: B)*

Side-branch occlusion or severe stenosis after stenting the main artery in coronary bifurcation PCI occurs in 8% to 80% of unselected patients (732, 734). The frequency of side-branch occlusion is related to complex bifurcation morphology (severe and/or long side-branch ostial stenosis, large plaque burden in the side-branch ostium, and/or unfavorable side-branch angulation) (732, 735, 736). Side-branch occlusion after PCI is associated with Q-wave and non-Q-wave MI (734, 735). Therefore, preservation of physiologic flow in the side branch after PCI is important (736). There are 2 bifurcation PCI strategies: provisional stenting (stenting the main vessel with additional balloon angioplasty or stenting of the side branch only in the case of an unsatisfactory result) and elective double stenting of the main vessel and the side branch. When there is an unsatisfactory result in the side branch from the provisional stent in the main branch, sometimes balloon angioplasty alone in the side branch will improve the result and stenting the side branch is not necessary. Some experts have suggested that using the side-branch balloon alone will distort the main branch stent and thus this always needs to be a kissing balloon inflation.

In patients with low-risk bifurcation lesions (minimal or moderate ostial side-branch disease [<50% diameter stenosis] of focal length [5 to 6 mm]), provisional stenting yields similar clinical outcome to elective double stenting, with lower incidence of periprocedural biomarker elevation (726–729). Conversely, in patients with high-risk bifurcations, elective double stenting is associated with a trend toward higher angiographic success rates, lower in-hospital MACE, and better long-term patency of the side branch compared with provisional stenting (193). Culotte, Crush, and T-stent techniques have been studied in RCTs (726–729, 737). Use of DES yields better outcomes than BMS (738), and sirolimus-eluting stents yield better outcomes than paclitaxel-eluting stents (739–742). Clinical evidence supports the use of final kissing balloon inflation after elective double stenting (743).

5.8.4. Aorto-Ostial Stenoses: Recommendations

CLASS IIa

1. IVUS is reasonable for the assessment of angiographically indeterminant left main CAD (744, 745). *(Level of Evidence: B)*
2. Use of DES is reasonable when PCI is indicated in patients with an aorto-ostial stenosis (746, 747). *(Level of Evidence: B)*

Aorto-ostial stenoses of native coronary arteries (left main coronary artery and right coronary artery) are most commonly caused by atherosclerosis, but they can also occur in patients with congenital malformations, radiation exposure, vasculitides, and aortic valve replacement. The angiographic diagnosis of aorto-ostial disease is not always straightforward, especially in the ostial left main coronary artery, where eccentricity and angulation can be mistaken for stenosis (490, 748). Aorto-ostial disease can be evaluated with IVUS (744, 745); FFR (with IV adenosine) has also been used (484, 749). The treatment of aorto-ostial stenoses with balloon angioplasty has been associated with lower procedural success rates, more frequent in-hospital complications, and a greater likelihood of late restenosis (750). Although atherectomy devices (directional atherectomy, rotational atherectomy, and excimer laser angioplasty) have improved acute angiographic results over balloon angioplasty, restenosis has remained a limitation (751). In patients with aorto-ostial stenoses undergoing PCI, use of DES has been shown to reduce restenosis compared with BMS (176, 746, 752).

5.8.5. Calcified Lesions: Recommendation

CLASS IIa

1. Rotational atherectomy is reasonable for fibrotic or heavily calcified lesions that might not be crossed by a balloon catheter or adequately dilated before stent implantation (514, 515, 520). *(Level of Evidence: C)*

The presence of coronary calcification is a marker for significant CAD and increased long-term mortality

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(753). Calcified coronary lesions are not a homogenous entity, and their response to PCI varies according to severity of calcification. Severely calcified lesions respond poorly to balloon angioplasty (230, 754), and when stents are implanted in such lesions, an incomplete and asymmetrical stent expansion occurs in the majority of cases (755). Attempts to remedy the underexpanded stents with aggressive high-pressure balloon dilatation may result in coronary artery rupture (756). All the published prospective RCTs that evaluated the various catheter-based coronary interventional devices excluded patients with severely calcified lesions. Therefore, the evidence base for best PCI practices in patients with severely calcified lesions comes from nonrandomized single-arm studies. Among the various adjunct devices that are used to facilitate PCI in severely calcified lesions, only rotational atherectomy has been shown to have potential utility (514, 757). Although rotational atherectomy increases the chances of angiographic success in severely calcified lesions, its use as a stand-alone device has not led to a reduction in restenosis (520, 521, 758). Several retrospective studies have shown that in patients with severely calcified lesions, the use of rotational atherectomy before implantation of BMS (514)or DES(515)is safe. Intermediate-term patency is more favorable with DES than BMS (759).

5.9. PCI in Specific Patient Populations

Several specific patient subsets with higher risks for PCI, and at times higher absolute clinical benefit, have traditionally been underrepresented in RCTs and are described below.

5.9.1. Elderly. The elderly constitute a growing proportion of patients considered for PCI (760). In 1 series examining trends over a 25-year period, the proportion of patients undergoing PCI who were 75 to 84 years of age doubled, and those >85 years of age increased 5-fold (761). Age is one of the strongest predictors of mortality after PCI (762), and elderly patients present with a substantially higher clinical risk profile (760). Nonetheless, the angiographic success rates and clinical benefits of PCI in elderly patients are similar to younger patients (763). In fact, the absolute benefit is typically greater because of higher absolute risk of adverse outcomes in these patients (764). However, increased risks of complications such as major bleeding and stroke mandate careful consideration of the benefits and risks of PCI in elderly patients (373).

5.9.2. Diabetes. Patients with diabetes represent approximately one third of patients undergoing PCI in the United States. Restenosis, which had been a major limitation of PCI, is significantly reduced in patients with diabetes treated with DES compared with BMS (471). However, there are no definitive data from RCTs supporting different clinical outcomes for different types of DES (765), with a recent meta-analysis of 35 RCTs involving 3,852 patients with diabetes unable to find major differences between patients receiving sirolimus-eluting stents or paclitaxel-eluting stents (472). Numerous analyses and clinical studies have evaluated how the presence of diabetes may impact the clinical outcome of patients undergoing PCI and decisions about PCI or CABG (14, 116, 163, 164, 186). These studies and the approach to revascularization decisions in diabetes are addressed in Section 4.

Diabetes is an important risk factor for the development of contrast-induced AKI. Strategies to reduce the risk of contrast-induced AKI in patients with diabetes are discussed in Section 4.4.

5.9.3. Women. Cardiovascular disease is the leading cause of death in women in the United States and Europe (766), and an estimated 35% of PCIs in the United States are performed in women (767, 768). Women undergoing PCI usually have more risk factors (including hypertension, advanced age, elevated cholesterol, and more significant and diffuse CAD) compared with men (769). Women with STEMI are also less likely to receive early medical treatments and experience longer delays to reperfusion therapy (770, 771). In subgroup analyses of clinical trials, use of DES appears to be similarly efficacious in women and men (772).

5.9.4. CKD: Recommendation

CLASS I

1. In patients undergoing PCI, the glomerular filtration rate should be estimated and the dosage of renally cleared medications should be adjusted (298–300). *(Level of Evidence: B)*

CKD is an independent risk factor for the development and progression of CAD (773, 774), and is also associated with worse prognosis after MI or PCI (369, 775). A glomerular filtration rate of <60 mL/min per 1.73 m^2 of body surface area should be considered abnormal. Patients with CKD undergoing PCI have a higher risk ofcomplications, including bleeding (776), AKI, and death (236, 777), but CKD is not a strong predictor of restenosis after BMS or DES (778). Strategies to reduce the risk of contrast-induced AKI in patients with CKD are discussed in Section 4.4. Platelet dysfunction and overdosing of antiplatelet and antithrombin drugs (350) in patients with CKD contribute to the increased risk of bleeding. The Cockcroft-Gault formula is commonly used as a surrogate marker for estimating creatinine clearance, which in turn estimates glomerular filtration rate (298, 299, 779, 780).

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Medications that require dosage adjustments in patients with CKD include eptifibatide, tirofiban, bivalirudin, enoxaparin, and fondaparinux (781).

5.9.5. Cardiac Allografts. Cardiac allograft vasculopathy is a major cause of death in cardiac transplant recipients after their first year of survival (782). In general, revascularization for cardiac allograft vasculopathy with PCI is only palliative, with no evidence supporting benefit in regard to long-term survival or avoidance of retransplantation. The restenosis rate after PCI in patients with cardiac allograft vasculopathy is high, although stent implantation reduces early and midterm reste-nosis compared with balloon angioplasty. DES have been shown to have a tendency to lower restenosis rates compared with BMS (783, 784). Thus, many clinicians perform stenting with DES or BMS in cardiac transplant patients with discrete lesions who have an abnormal stress test or symptoms suggestive of myocardial ischemia.

5.10. Periprocedural MI Assessment: Recommendations

CLASS I

1. In patients who have signs or symptoms suggestive of MI during or after PCI or in asymptomatic patients with significant *persistent* angiographic complications (e.g., large side-branch occlusion, flow-limiting dissection, no-reflow phenomenon, or coronary thrombosis), creatinine kinase-MB and troponin I or T should be measured. *(Level of Evidence: C)*

CLASS IIb

1. Routine measurement of cardiac biomarkers (creatinine kinase-MB and/or troponin I or T) in all patients after PCI may be reasonable. *(Level of Evidence: C)*

Major events leading to ischemia or MI after PCI include acute closure, embolization and no-reflow, side-branch occlusion, and acute stent thrombosis. Issues surrounding the routine assessment of cardiac biomarkers after PCI are complex, especially given that the definition of PCI-related MI has evolved over the years and most events are asymptomatic. The most recent consensus definition of MI considers troponin elevations of 3 times the upper limit of normal as a PCI-related MI in patients with normal baseline levels; this is further classified as a type 4a MI (240). This definition is supported by studies with delayed-enhancement MRI confirming that there is irreversible injury in the myocardium associated with biomarker elevations and that the size of this injury correlates with the degree of elevation (785). Furthermore, a meta-analysis of 15 observational studies found that troponin elevations at any level were linked with worse in-hospital and long-term outcomes; elevations >3 times the upper limit of normal predicted even worse outcomes (242). Other observational data, however, have raised concerns about whether the relationship is causal (786, 787). A recent study found creatinine kinase-MB to correlate better with MRI-detected MI than troponin level (788). Definitions of PCI-related MI are being reevaluated by the Task Force for the Redefinition of Myocardial Infarction. Although there may be value for individual operators and hospitals to routinely measure cardiac biomarkers to track rates of PCI-related MI, at present there are not compelling data to recommend this for all PCI procedures.

5.11. Vascular Closure Devices: Recommendations

CLASS I

1. Patients considered for vascular closure devices should undergo a femoral angiogram to ensure their anatomic suitability for deployment. *(Level of Evidence: C)*

CLASS IIa

1. The use of vascular closure devices is reasonable for the purposes of achieving faster hemostasis and earlier ambulation compared with the use of manual compression (257, 789–791). *(Level of Evidence: B)*

CLASS III: NO BENEFIT

1. The routine use of vascular closure devices is not recommended for the purpose of decreasing vascular complications, including bleeding (256, 257, 789–792). *(Level of Evidence: B)*

See Online Data Supplement 30 for additional data regarding vascular closure devices.

Vascular (arteriotomy) closure devices have been extensively reviewed (790), most recently in a 2010 AHA scientific statement (257), which issued several formal recommendations. The results of 4 meta-analyses have found that vascular closure devices decrease time to hemostasis compared with manual compression but do not decrease vascular complications, bleeding complications, or the need for blood transfusions (256, 789, 791, 793). Future studies of vascular closure devices need to be randomized, include "high-risk" patients and "high-risk" anatomy, use blinded endpoint adjudication as much as possible, use well-defined and comprehensive complication endpoints, and be adequately powered to

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detect clinically important endpoints, particularly bleeding and vascular complications.

6. POSTPROCEDURAL CONSIDERATIONS

Postprocedural considerations in patients undergoing PCI are discussed below and summarized in Table 14. Some recommendations and text regarding DAPT in Section 5.7.2 are intentionally repeated in this section for reader ease of use.

T14

6.1. Postprocedural Antiplatelet Therapy: Recommendations

CLASS I

1. After PCI, use of aspirin should be continued indefinitely (560–563). *(Level of Evidence: A)*
2. The duration of $P2Y_{12}$ inhibitor therapy after stent implantation should generally be as follows:
   a. In patients receiving a stent (BMS or DES) during PCI for ACS, $P2Y_{12}$ inhibitor therapy should be given for at least 12 months. Options include clopidogrel 75 mg daily (570), prasugrel 10 mg daily (567), and ticagrelor 90 mg twice daily (568). *(Level of Evidence: B)*
   b. In patients receiving DES for a non-ACS indication, clopidogrel 75 mg daily should be given for at least 12 months if the patient is not at high risk of bleeding (208, 212, 571). *(Level of Evidence: B)*
   c. In patients receiving BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 month and ideally up to 12 months (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks) (572). *(Level of Evidence: B)*
3. Patients should be counseled on the importance of compliance with DAPT and that therapy should not be discontinued before discussion with their cardiologist (208). *(Level of Evidence: C)*

CLASS IIa

1. After PCI, it is reasonable to use aspirin 81 mg per day in preference to higher maintenance doses (302, 573–576). *(Level of Evidence: B)*
2. If the risk of morbidity from bleeding outweighs the anticipated benefit afforded by a recommended duration of $P2Y_{12}$ inhibitor therapy after stent implantation, earlier discontinuation (e.g., <12 months) of $P2Y_{12}$ inhibitor therapy is reasonable. *(Level of Evidence: C)*

CLASS IIb

1. Continuation of clopidogrel, prasugrel, or ticagrelor beyond 12 months may be considered in patients undergoing placement of DES (567, 568). *(Level of Evidence: C)*

Continued treatment with the combination of aspirin and a $P2Y_{12}$ inhibitor antagonist after PCI appears to reduce MACE (570, 572). On the basis of RCT protocols, secondary prevention measures, and expert consensus opinion, aspirin 81 mg daily should be given indefinitely after PCI.

Likewise, $P2Y_{12}$ inhibitors should be given for a minimum of1 month after BMS (minimum 2 weeks for patients at significant increased risk of bleeding) (580) and for 12 months after DES and ideally in all patients who are not at high risk of bleeding.

The 2009 STEMI/PCI guidelines update (10) listed the recommendation "if the risk of morbidity because of bleeding outweighs the anticipated benefit afforded by thienopyridine therapy, earlier discontinuation *should be considered*" as a Class I recommendation, although the language used, in part, was consistent with a Class IIa recommendation. To clarify the intent ofthe recommendation, as well as to acknowledge the inherent difficulties in weighing bleeding and stent thrombosis risks, the recommendation is designated a Class IIa recommendation, using the phrase "earlier discontinuation *is reasonable*." Recommendations regarding $P2Y_12$ inhibitor discontinuation before elective or urgent CABG are provided in the "2011 ACCF/AHA Guideline for Coronary Artery Bypass Graft Surgery" (824).

6.1.1. PPIs and Antiplatelet Therapy: Recommendations

CLASS I

1. PPIs should be used in patients with a history of prior gastrointestinal (GI) bleeding who require DAPT (794). *(Level of Evidence: C)*

CLASS IIa

1. Use of PPIs is reasonable in patients with an increased risk of GI bleeding (e.g., advanced age, concomitant use of warfarin, steroids, nonsteroidal anti-inflammatory drugs, *Helicobacter pylori* infection) who require DAPT (794). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. Routine use of a PPI is not recommended for patients at low risk of GI bleeding, who have much less potential to benefit from prophylactic therapy (794). *(Level of Evidence: C)*

See Online Data Supplement 31 for additional data regarding the clopidogrel—PPI interaction.

PPIs are often prescribed prophylactically when clopi-dogrel is started to prevent GI complications such

TABLE 14. Postprocedural Recommendations for Patients Undergoing PCI

Recommendations		COR	LOE	References
Aspirin				
After PCI, use of aspirin should be continued indefinitely.		I	A	(560–563)
After PCI, it is reasonable to use aspirin 81 mg/d in preference to higher maintenance doses.		IIa	B	(302,573–576)
$P2Y_{12}$ inhibitors				
In patients receiving a stent (BMS or DES) during PCI for ACS, $P2Y_{12}$ inhibitor therapy should be given for at least 12 mo. Options include clopidogrel 75 mg/d, prasugrel 10 mg/d, and ticagrelor 90 mg twice daily.		I	B	(567,568,570)
In patients receiving DES for a non-ACS indication, clopidogrel 75 mg/d should be given for at least 12 mo if patients are not at high risk of bleeding.		I	B	(208,212,571)
In patients receiving BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 mo and ideally up to 12 mo (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 wk).		I	B	(572)
Patients should be counseled on the importance of compliance with DAPT and that therapy should not be discontinued before discussion with their cardiologist.		I	C	(208)
PPIs should be used in patients with a history of prior GI bleeding who require DAPT.		I	C	(794)
If the risk of morbidity from bleeding outweighs the anticipated benefit afforded by a recommended duration of $P2Y_{12}$ inhibitor therapy after stent implantation, earlier discontinuation (e.g., <12 mo) of $P2Y_{12}$ inhibitor therapy is reasonable.		IIa	C	N/A
Use of PPIs is reasonable in patients with an increased risk of GI bleeding (e.g., advanced age, concomitant use of warfarin, steroids, NSAIDs, *Helicobacter pylori* infection) who require DAPT.		IIa	C	(794)
Continuation of clopidogrel, prasugrel, or ticagrelor beyond 12 mo may be considered in patients undergoing placement of DES.		IIb	C	N/A
Routine use of a PPI is not recommended for patients at low risk of GI bleeding, who have much less potential to benefit from prophylactic therapy.		III: No Benefit	C	(794)
Exercise testing				
For patients entering a formal cardiac rehabilitation program after PCI, treadmill exercise testing is reasonable.		IIa	C	(567,568)
Routine periodic stress testing of asymptomatic patients after PCI without specific clinical indications should not be performed.		III: No Benefit	C	(795)
Cardiac rehabilitation				
Medically supervised exercise programs (cardiac rehabilitation) should be recommended to patients after PCI, particularly for patients at moderate to high risk, for whom supervised exercise training is warranted.		I	A	(796–804)
Secondary prevention (recommendations included from the 2011 AHA/ACCF Secondary Prevention and Risk Reduction Therapy Guideline) (805)				
Lipid management with lifestyle modification and lipid-lowering pharmacotherapy	Lifestyle modification	I	B	(806,807)
	Statin therapy	I	A	(344,806,808–810,810a)
	Statin therapy which lowers LDL cholesterol to <100 mg/dL and achieves at least a 30% lowering of LDL cholesterol	I	C	(344,806,808–810,810a)
	Statin therapy which lowers LDL cholesterol to <70 mg/dL in very high-risk* patients	IIa	B	(345,808–810,810a,811,812)
Blood pressure control (with a blood pressure goal of <140/90 mm Hg)	Lifestyle modification	I	B	(813–817)
	Pharmacotherapy	I	A	(813,818,819)
Diabetes management (e.g., lifestyle modification and pharmacotherapy) coordinated with the patient's primary care physician and/or endocrinologist		I	C	N/A
Complete smoking cessation		I	A	(820–823)

*Presence of established cardiovascular disease plus 1) multiple major risk factors (especially diabetes), 2) severe and poorly controlled risk factors (especially continued cigarette smoking), 3) multiple risk factors of the metabolic syndrome (especially high triglycerides >200 mg/dL plus non-HDL cholesterol ≥130 mg/dL with low HDL cholesterol [<40 mg/dL]), and 4) acute coronary syndromes.

ACS indicates acute coronary syndromes; BMS, bare-metal stent(s); COR, class of recommendation; DAPT, dual antiplatelet therapy; DES, drug-eluting stent(s); GI, gastrointestinal; HDL, high-density lipoprotein; LDL, low-density lipoprotein; LOE, level of evidence; N/A, not applicable; NSAID, nonsteroidal anti-inflammatory drug; PCI, percutaneous coronary intervention; and PPI, proton pump inhibitor.

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as ulceration and bleeding due to DAPT (825). There is pharmacodynamic evidence that omeprazole interferes with clopidogrel metabolism (826, 827), but there is no clear evidence implicating other PPIs. However, even with omeprazole, there are no convincing data supporting an important clinical drug-drug interaction (826). The FDA communication about an ongoing safety review of clopidogrel advises that healthcare providers avoid the use of clopidogrel in patients with impaired *CYP2C19* function due to known genetic variation or drugs that inhibit *CYP2C19* activity. The FDA notes that there is no evidence that other drugs that reduce stomach acid, such as histamine-2 receptor antagonists (except cimetidine) or antacids, interfere with clopidogrel responsiveness. The COGENT (Clopidogrel and the Optimization of Gastrointestinal Events) trial randomized patients with DAPT to clopidogrel and omeprazole or clopidogrel and placebo, and while there was no difference in cardiovascular events between the 2 groups, GI events were halved in those randomized to omeprazole (828). It is reasonable to carefully evaluate the indication for PPI therapy in patients treated with clopidogrel, based on the presence or absence of the risk factors discussed above (794). The need for GI protection increases with the number of risk factors for bleeding. Prior upper GI bleeding is the strongest and most consistent risk factor for GI bleeding on antiplatelet therapy. Patients with ACS and prior upper GI bleeding are at substantial cardiovascular risk, so DAPT with concomitant use of a PPI may provide the optimal balance of risk and benefit. It should be noted that PPIs, by decreasing adverse GI effects related to clopidogrel, might decrease patients' discontinuation of clopidogrel. In patients in whom there is a clear indication for PPI therapy, some clinicians may choose to use a PPI other than omeprazole.

6.1.2. Clopidogrel Genetic Testing: Recommendations

CLASS IIb

1. Genetic testing might be considered to identify whether a patient at high risk for poor clinical outcomes is predisposed to inadequate platelet inhibition with clopidogrel (829). *(Level of Evidence: C)*
2. When a patient predisposed to inadequate platelet inhibition with clopidogrel is identified by genetic testing, treatment with an alternate $P2Y_{12}$ inhibitor (e.g., prasugrel or ticagrelor) might be considered (829). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. The routine clinical use of genetic testing to screen patients treated with clopidogrel who are undergoing PCI is not recommended (829). *(Level of Evidence: C)*

On March 12, 2010, the FDA approved a new label for clopidogrel with a "boxed warning" about the diminished effectiveness of clopidogrel in patients with impaired ability to convert the drug into its active metabolite (829). Patients with decreased *CYP2C19* function because of genetic polymorphisms metabolize clopidogrel poorly and have higher rates of cardiovascular events after ACS and PCI than patients with normal *CYP2C19* function. The warning also notes that tests are available to identify patients with genetic polymorphisms and that alternative treatment strategies should be considered for patients who are poor metabolizers. The clopidogrel boxed warning leaves the issue of whether to perform *CYP2C19* testing up to the individual physician. It does not specifically require genetic testing or other changes in evaluation or treatment and does not imply that there are solid evidence-based reasons for such actions. Rather, it serves to inform clinicians of genetic variations in response to clopidogrel and to emphasize that clinicians should use this knowledge to make decisions about how to treat individual patients. At the present time, the evidence base is insufficient to recommend routine genetic testing in patients undergoing PCI. There may be a potential role for genetic testing for patients undergoing elective high-risk PCI procedures (e.g., unprotected left main, bifurcating left main, or last patent coronary artery).

6.1.3. Platelet Function Testing: Recommendations

CLASS IIb

1. Platelet function testing may be considered in patients at high risk for poor clinical outcomes (829). *(Level of Evidence: C)*
2. In patients treated with clopidogrel with high platelet reactivity, alternative agents, such as prasugrel or ticagrelor, might be considered (829). *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. The routine clinical use of platelet function testing to screen patients treated with clopidogrel who are undergoing PCI is not recommended (829). *(Level of Evidence: C)*

Platelet function testing to tailor antiplatelet therapy has received considerable interest. The GRAVITAS (Gauging Responsiveness With A VerifyNow Assay-Impact On Thrombosis And Safety) trial and several other ongoing trials test the concept that tailoring antiplatelet therapy based on platelet responsiveness assessed in an ex vivo $P2Y_{12}$ assay will improve cardiovascular outcomes (830). In GRAVITAS, treatment with high-dose clopidogrel for 6 months in patients with high platelet reactivity on standard-dose

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clopidogrel was not beneficial. At the present time, the evidence base is insufficient to recommend routine platelet function testing. The results of 2 ongoing trials (DANTE [Dual Antiplatelet Therapy Tailored on the Extent of Platelet Inhibition] and ARCTIC [Double Randomization of a Monitoring Adjusted Antiplatelet Treatment Versus a Common Antiplatelet Treatment for DES Implantation, and Interruption Versus Continuation of Double Antiplate-let Therapy, One Year After Stenting]) will provide further information on the issue (www.clinicaltrials.gov).

6.2. Stent Thrombosis

The majority of stent thrombosis occurs early (0 to 30 days after PCI). In broad clinical practice, the expected rate of early stent thrombosis is <1%, and beyond 30 days it is 0.2% to 0.6% per year (210, 831). Acute stent thrombosis often presents as STEMI, and emergency revascularization is indicated. Acute stent thrombosis is associated with mortality rates of 20% to 45% (832). Survivors are also at risk of recurrent stent thrombosis (833).

Mechanical and pharmacological factors are the most frequent cause of acute stent thrombosis. After the usual measures to restore flow in the infarct-related artery, it is important to consider the etiology of stent thrombosis as it pertains to further therapy and avoidance of recurrence. IVUS may identify factors such as an undersized stent, incomplete stent apposition, residual stenosis, or dissection and can guide subsequent treatment. The most common cause of acute stent thrombosis is nonadherence to DAPT; however, resistance to aspirin or thienopyridines and pro-thrombotic states such as congenital or acquired thrombophilic states (malignancy) are additional risk factors (834, 835).

Given the poor prognosis of stent thrombosis and the uncertainties surrounding treatment, the importance of prevention must be emphasized. This includes ensuring compliance with DAPT and adequate stent sizing and expansion (836).

6.3. Restenosis: Recommendations

CLASS I

1. Patients who develop clinical restenosis after balloon angioplasty should be treated with BMS or DES if anatomic factors are appropriate and if the patient is able to comply with and tolerate DAPT (837). *(Level of Evidence: B)*
2. Patients who develop clinical restenosis after BMS should be treated with DES if anatomic factors are appropriate and the patient is able to comply with and tolerate DAPT (838–840). *(Level of Evidence: A)*

CLASS IIa

1. IVUS is reasonable to determine the mechanism of stent restenosis (495). *(Level of Evidence: C)*

CLASS IIb

1. Patients who develop clinical restenosis after DES may be considered for repeat PCI with balloon angioplasty, BMS, or DES containing the same drug or an alternative antiproliferative drug if anatomic factors are appropriate and the patient is able to comply with and tolerate DAPT (495). *(Level of Evidence: C)*

6.3.1. Background and Incidence. After balloon angioplasty, mechanisms contributing to restenosis include smooth muscle cell migration and proliferation, platelet deposition, thrombus formation, elastic recoil, and negative arterial remodeling. Stents block elastic recoil and negative remodeling, and the predominant mechanism for restenosis after stent implantation is neointimal hyperplasia. Restenosis rates vary, depending on whether angiographic restenosis (defined as >50% diameter stenosis at follow-up angiography) or clinical restenosis (symptomatic and requiring target-lesion revascularization or target-vessel revascularization) is measured, as well as on patient characteristics, coronary anatomy considerations, and device type (balloon angioplasty, BMS, or DES). The incidence of angiographic restenosis rates for uncomplicated lesions treated in RCTs ranges from 32% to 42% after balloon angioplasty (463, 464) and from 16% to 32% after BMS (463, 464), and is generally <10% after DES (454, 841). Less than half of patients with angiographic restenosis present with symptomatic, clinically relevant restenosis at 1-year follow-up, and a pooled analysis of 6,186 patients from 6 trials of BMS showed target-lesion revascularization was performed in 12% and target-vessel revascularization in 14% at 1 year (842, 843). Patients with clinical restenosis typically present with recurrent exertional angina, but 5% to 10% of patients present with acute MI and 25% with UA (844, 845).

Factors associated with an increased risk of restenosis in various models include clinical setting (STEMI, ACS, daily angina), patient characteristics (diabetes, age <55 to 60 years, prior PCI, male sex, multivessel CAD), lesion location (unprotected left main, SVG), and procedural characteristics (minimum stent diameter ≤2.5 mm, total stent length ≥40 mm) (778, 846).

PCI strategies for treating restenosis after balloon angioplasty, BMS, and DES are reviewed in the following sections. In addition to repeat PCI, intensified medical therapy or CABG are often also reasonable strategies, dependent on initial treatment (e.g., balloon

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angioplasty, BMS), pattern of restenosis, likelihood of recurrent restenosis, ability to intensify medical therapy, suitability for CABG, and patient preference. Repeat PCI with BMS or DES is not appropriate if the patient is not able to comply with and tolerate DAPT.

6.3.2. Restenosis After Balloon Angioplasty. For clinical restenosis after balloon angioplasty, stent implantation is superior to repeat balloon angioplasty or atheroablation devices. The REST (REstenosis STent) study showed that target-lesion revascularization rates were 10% for stent-treated patients and 27% for balloon-treated patients (p=0.001) (837).

6.3.3. Restenosis After BMS. In-stent restenosis is classified according to these angiographic characteristics: Pattern I includes focal lesions $\leq$10 mm in length; Pattern II is in-stent restenosis >10 mm within the stent; Pattern III includes in-stent restenosis >10 mm extending outside the stent; and Pattern IV is totally occluded in-stent restenosis (847). Treatment of in-stent restenosis with balloon angioplasty, repeat BMS, or atheroablation devices for Patterns I to IV resulted in 1-year target-lesion revascularization rates of 19%, 35%, 50%, and 83%, respectively. For clinical restenosis after BMS, repeat stenting with DES is preferred. Studies have demonstrated lower recurrent restenosis rates with DES compared with BMS or vascular brachytherapy (495, 838–840).

6.3.4. Restenosis After DES. Clinical restenosis after placement of DES is becoming increasingly common due to the large numbers of patients who have been treated with DES. The predominant angiographic pattern for DES in-stent restenosis is focal ($\leq$10 mm in length). Several biologic, mechanical, and technical factors may contribute to DES in-stent restenosis, including drug resistance, hypersensitivity, stent underexpansion, stent strut fracture, nonuniform stent strut coverage, gap in stent coverage, and residual uncovered atherosclerotic lesion. IVUS might be considered to determine the cause for in-stent restenosis and help guide treatment strategy. Interventionists may treat focal DES restenosis with balloon angioplasty and treat nonfocal DES restenosis with BMS, CABG, or repeat DES with the same or an alternative antiproliferative drug (848, 849). Small, observational cohort studies have demonstrated angiographic restenosis rates of 25% to 30% with repeat DES either with the same or an alternative drug (495, 849, 850). There are no RCTs, and the most appropriate treatment of restenosis of DES remains unknown.

6.4. Clinical Follow-Up

At the time of discharge, patients are instructed to contact their physician or seek immediate medical attention if symptoms recur. Most physicians will give the patient instructions on return to work and timing of return to full activities. The importance of strict compliance with aspirin and $P2Y_{12}$ inhibitor therapy is ideally emphasized to the patient at the time of discharge and during follow-up visits.

Secondary prevention measures after PCI are an essential part of long-term therapy, reducing both future morbidity and mortality associated with CAD, and are discussed in Section 6.5. A follow-up visit after PCI is usually scheduled to assess the patient's clinical status, the patient's compliance with secondary prevention therapies, and the success of secondary prevention measures (e.g., blood pressure control, low-density lipoprotein levels, smoking cessation). Routine, periodic stress testing of asymptomatic patients is not considered part of standard patient follow-up.

6.4.1. Exercise Testing: Recommendations

CLASS IIa

1. In patients entering a formal cardiac rehabilitation program after PCI, treadmill exercise testing is reasonable. *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. Routine periodic stress testing of asymptomatic patients after PCI without specific clinical indications should not be performed (795). *(Level of Evidence: C)*

Treadmill exercise testing before cardiac rehabilitation provides information about peak exercise capacity and heart rate, helping to stratify patients for the level of supervision during training, and seems reasonable for this purpose (851); nuclear imaging to assess ischemia in this context usually adds little.

The role of exercise testing to evaluate restenosis is much less certain. Although the presence of symptoms may not be a reliable means of detecting restenosis, there is no evidence that the detection of silent restenosis leads to improved outcome (852, 853). Routine testing of all patients after PCI will also lead to many false-positive tests, particularly in the era of DES. As restenosis rates decline from 30% to 10%, the false-positive rate of stress imaging increases from 37% to 77% (854). A recent analysis of a national health insurance claims database and accompanying editorial find that stress testing after PCI is likely overused and rarely leads to repeat revascularization (855, 856). In summary, there is no proven benefit or indication for routine periodic stress testing in patients after PCI, and, thus, it is not indicated (8, 851). In cases in which there is a clear clinical indication for stress testing in a patient after PCI, exercise ECG alone is an insensitive predictor of restenosis (857, 858); therefore, stress

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imaging is the preferred stress test (8). In cases of recurrent angina after PCI in which the pretest likelihood of restenosis is high and repeat revascularization based on symptoms is likely indicated, most practitioners will proceed directly to cardiac catheterization rather than first obtain stress imaging.

6.4.2. Activity and Return to Work. The timing of return to physical activity depends on the presenting condition as well as previous functional status. For STEMI, for example, daily walking is encouraged immediately, and driving can begin within 1 week after uncomplicated MI if allowed by local motor vehicle laws (859). Sexual activity usually can be resumed within days, provided exercise tolerance is adequate, normally assessed by the ability to climb a flight of stairs (859). Similar recommendations have been issued for UA/NSTEMI (860). Patients with UA who have undergone successful revascularization and are otherwise doing well may return to physical activity on an accelerated schedule, usually within a few days (860).

Return to work is more complex. Return to work rates after MI range from 63% to 94% and are confounded by factors such as job satisfaction, financial stability, and company policies (861). The physical demands and degree of stress of a particular job require that recommendations be individualized. In the PAMI-2 (Primary Angioplasty in Myocardial Infarction) trial, patients were encouraged to return to work 2 weeks after primary PCI for STEMI, and no adverse events were reported (862). In the RITA (Randomized Intervention Treatment of Angina) trial, revascularization with PCI led to earlier return to work compared with CABG, and subsequent employment rates were associated with relief of angina (105). Many practitioners use graded exercise treadmill testing to determine the safety of activity and return to work by measuring the metabolic equivalent of task (MET) level achieved and comparing that level to energy levels required to perform different activities (863).

6.4.3. Cardiac Rehabilitation: Recommendation

CLASS I

1. Medically supervised exercise programs (cardiac rehabilitation) should be recommended to patients after PCI, particularly for moderate- to high-risk patients for whom supervised exercise training is warranted (796–804). *(Level of Evidence: A)*

Participation in cardiac rehabilitation is associated with significant reductions in all-cause mortality (OR: 0.80, 95% CI: 0.68 to 0.93) and cardiac mortality (796, 797). Reports from community-based surveys, which in general enroll older and higher-risk patients than clinical trials, have confirmed that participation in comprehensive rehabilitation is independently associated with a reduction in recurrent MI and reduced mortality (799). Cardiac rehabilitation is also associated with improvements in exercise tolerance, cardiac symptoms, lipid levels, cigarette smoking cessation rates (in conjunction with a smoking cessation program), stress levels, improved medical regimen compliance, and improved psychosocial well-being (800). Cardiac rehabilitation is cost-effective as well (864). Physician referral may be the most powerful predictor of patient participation in a cardiac rehabilitation program (865).

6.5. Secondary Prevention

The treatment of the patient does not end with PCI; secondary prevention measures are a critical component of patient management. Important secondary prevention measures were presented in detail in the "2006 AHA/ACC Guidelines for Secondary Prevention for Patients With Coronary and Other Atherosclerotic Vascular Disease" (562) and have recently been updated in the "AHA/ACCF Secondary Prevention and Risk Reduction Therapy for Patients With Coronary and Other Atherosclerotic Vascular Disease: 2011 Update" (805). The reader is referred to this document for detailed discussions of secondary prevention. Among the important recommendations are the following:

- Lipid management with lifestyle modification *(Class I; Level of Evidence: B)* (805–807) and statin therapy are recommended. *(Level of Evidence: A)* (344, 806, 808–810, 810a) An adequate statin dose should be employed which reduces low-density lipoprotein cholesterol to <100 mg/dL AND achieves at least a 30% lowering of low-density lipoprotein cholesterol. *(Class I; Level of Evidence: C)* (806–810, 810a) It is reasonable to treat patients with statin therapy which lowers low-density lipoprotein cholesterol to <70 mg/dL in very high-risk* patients. *(Class IIa; Level of Evidence: C)* (345,808–810,810a,811,812) Patients who have triglycerides ≥200 mg/dL should be treated with statins to lower non-high-density lipoprotein cholesterol to <130 mg/dL. *(Class I; Level of Evidence: B)* (344, 809, 810, 866) In patients who are very high risk* and have triglycerides ≥200 mg/dL, a non-high-density lipoprotein cholesterol goal of <100 mg/dL is reasonable. *(Class IIa; Level of Evidence: C)* (344, 809, 810, 866).

*Presence of established cardiovascular disease plus 1) multiple major risk factors (especially diabetes), 2) severe and poorly controlled risk factors (especially continued cigarette smoking), 3) multiple risk factors of the metabolic syndrome (especially high triglycerides ≥200 mg/dL plus non-high-density lipoprotein cholesterol ≥130 mg/dL with low high-density lipoprotein cholesterol [40 mg/dL]), and 4) acute coronary syndromes.

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- Blood pressure control with lifestyle modification *(Class I; Level of Evidence: B)* (813–817) and pharmacotherapy *(Class I; Level of Evidence: A)* (805, 813, 818, 819), with the goal of blood pressure <140/90 mm Hg.
- Diabetes management (e.g., lifestyle modification and pharmacotherapy), coordinated with the patient's primary care physician and/or endocrinologist. *(Class I; Level of Evidence: C)* (805)
- Advising patients on the need for complete smoking cessation. *(Class I; Level of Evidence: A)* (805, 820–823)

7. QUALITY AND PERFORMANCE CONSIDERATIONS

7.1. Quality and Performance: Recommendations

CLASS I

1. Every PCI program should operate a quality-improvement program that routinely 1) reviews quality and outcomes of the entire program; 2) reviews results of individual operators; 3) includes risk adjustment; 4) provides peer review of difficult or complicated cases; and 5) performs random case reviews. *(Level of Evidence: C)*
2. Every PCI program should participate in a regional or national PCI registry for the purpose of benchmarking its outcomes against current national norms. *(Level of Evidence: C)*

PCI quality and performance considerations are defined by attributes related to structure, processes, and risk-adjusted outcomes. Structural attributes include elements such as equipment, supplies, staffing, institutional and operator-level volumes, and the availability of electronic medical records. Processes include strategies for the appropriate patient, protocols for pre- and postprocedural care, appropriate procedural execution and management of complications, and participation in databases and registries for benchmarking performance of the program and individual operator. Risk-adjusted outcomes are the end result of these structures and processes of care, and when available are more reliable measures of quality than the institutional and individual operator volumes discussed in Section 7.4.

PCI process and outcomes assessments can be used for internal quality-improvement efforts and public reporting. Public reporting of institutional risk-adjusted outcomes is becoming more common. Although operator-level outcomes can be assessed and risk adjusted, the results are much less reliable due to lack of statistical power resulting from lower volumes. Any public reporting must use statistical methods that meet the high criteria established by the AHA Work Group (867).

7.2. Training

The cognitive knowledge and technical skill required to perform PCI continue to grow. Details on the training required for interventional cardiology are found in the most recent ACCF Core Cardiology Training Statement (868).

7.3. Certification and Maintenance of Certification: Recommendation

CLASS IIa

1. It is reasonable for all physicians who perform PCI to participate in the American Board of Internal Medicine interventional cardiology board certification and maintenance of certification program. *(Level of Evidence: C)*

The American Board of Internal Medicine established interventional cardiology board certification in 1999 as an "added qualification" to the cardiovascular disease board certification. Since 1990 all certificates from the American Board of Internal Medicine are time limited for a 10-year period and require all diplomats to participate in maintenance of certification to maintain their board-certified status. Maintenance of certification in interventional cardiology requires physicians to document a minimum of 150 interventional cases over the 2 years before expiration of the current certification, complete self-assessment modules of their medical knowledge, participate in practice-based quality-improvement activities, and pass a secure, knowledge-based examination (869–871). For those who cannot meet the case volume requirement, an alternative option is to submit a log of 25 consecutive cases including patient characteristics and procedural outcomes. The maintenance of certification process is likely to change, as the American Board of Internal Medicine intends to evolve maintenance of certification from an episodic event that occurs once every 10 years to a more continuous process of continuous professional development.

7.4. Operator and Institutional Competency and Volume: Recommendations

CLASS I

1. Elective/urgent PCI should be performed by operators with an acceptable annual volume (≥75 procedures) at high-volume centers (>400 procedures) with on-site cardiac surgery (872, 873). *(Level of Evidence: C)*

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2. Elective/urgent PCI should be performed by operators and institutions whose current risk-adjusted outcomes statistics are comparable to those reported in contemporary national data registries. *(Level of Evidence: C)*
3. Primary PCI for STEMI should be performed by experienced operators who perform more than 75 elective PCI procedures per year and, ideally, at least 11 PCI procedures for STEMI per year. Ideally, these procedures should be performed in institutions that perform more than 400 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year (872, 874–877). *(Level of Evidence: C)*

CLASS IIa

1. It is reasonable that operators with acceptable volume (≥75 PCI procedures per year) perform elective/urgent PCI at low-volume centers (200 to 400 PCI procedures per year) with on-site cardiac surgery (872). *(Level of Evidence: C)*
2. It is reasonable that low-volume operators (<75 PCI procedures per year) perform elective/urgent PCI at high-volume centers (>400 PCI procedures per year) with on-site cardiac surgery. Ideally, operators with an annual procedure volume of fewer than 75 procedures per year should only work at institutions with an activity level of more than 600 procedures per year. Operators who perform fewer than 75 procedures per year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume of at least 150 procedures per year. *(Level of Evidence: C)*

CLASS IIb

1. The benefit of primary PCI for STEMI patients eligible for fibrinolysis when performed by an operator who performs fewer than 75 procedures per year (<11 PCIs for STEMI per year) is not well established. *(Level of Evidence: C)*

CLASS III: NO BENEFIT

1. It is not recommended that elective/urgent PCI be performed by low-volume operators (<75 procedures per year) at low-volume centers (200 to 400 procedures per year) with or without on-site cardiac surgery. An institution with a volume of fewer than 200 procedures per year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer this service (872). *(Level of Evidence: C)*

Older observational evidence supported a volume-outcome relationship in PCI at both the institutional and operator level (873). However, this relationship is complicated and may be inconsistent across low-volume institutions or operators. More recent data on primary PCI suggest that operator experience may modify the volume-outcome relationship at the institutional level (876, 878). Risk-adjusted outcomes remain preferable to institutional and individual operator volumes as quality measures.

Operator and hospital volume recommendations have been carried over from the 2005 PCI guideline. However, the writing committee recognizes that these volume recommendations are controversial. In addition, after extensive review of all relevant data, the writing committee believes that the LOE in support of all the above recommendations is best categorized as LOE C rather than LOE B as it has been in prior guidelines for some recommendations. We encourage the ACCF/AHA/ACP Clinical Competence and Training writing group for PCI and other expert writing groups to review this issue so that new recommendations can be considered by the next PCI guideline writing committee.

7.5. Participation in ACC NCDR or National Quality Database

Assessment of PCI quality and outcomes is important both at the level of the entire program and at the level of the individual physician. This requires collection of clinical and procedural data for PCI that allows regular comparison of risk-adjusted outcomes and complications with national benchmarks. The ACC NCDR CathPCI Registry is an example of a national registry to fulfill the goals of assessing and benchmarking quality and outcomes.

8. FUTURE CHALLENGES

Although this latest guideline reflects significant advancements in the field of PCI, there remain future challenges to the formulation and updating of guidelines for PCI. The proliferation of studies comparing the many newer drugs and devices with older therapies (or other newer therapies), often using different or novel study endpoints, endpoint definitions, and noninferiority designs, pose increasing challenges to objectively evaluating newer therapies and generating recommendations for their use. Numerous potential advances in the field of PCI, including intracoronary stem cell infusions for chronic and acute ischemic heart disease, designer drugs, novel intracoronary imaging technologies such as optical coherence tomography and virtual histology, new stent composition and designs (e.g., drug-eluting, biodegradable, bifurcation), and drug-eluting balloons were considered for formal evaluation by the current writing committee, but it was thought that

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there were insufficient data at present to formulate any formal recommendations on these topics. These and other emerging technologies and treatments will need to be addressed in future PCI guidelines.

Finally, with this proliferation of new technology, the amount of data generated in the evaluation of these potential therapeutic advances will grow dramatically, adding significant challenges to future guideline generations. Of note, the Web site www.clinicaltrials.gov currently lists several hundred PCI-related clinical trials.

Staff

American College of Cardiology Foundation

David R. Holmes, Jr., MD, FACC, President

John C. Lewin, MD, Chief Executive Officer

Janet Wright, MD, FACC, Senior Vice President, Science and Quality

Charlene May, Senior Director, Science and Clinical Policy

Erin A. Barrett, MPS, Senior Specialist, Science and Clinical Policy

American College of Cardiology Foundation/ American Heart Association

Lisa Bradfield, CAE, Director, Science and Clinical Policy

Sue Keller, BSN, MPH, Senior Specialist, Evidence-Based Medicine

Jesse M. Welsh, Specialist, Science and Clinical Policy

Debjani Mukherjee, MPH, Associate Director, Evidence-Based Medicine

American Heart Association

Ralph L. Sacco, MS, MD, FAAN, FAHA, President

Nancy Brown, Chief Executive Officer

Rose Marie Robertson, MD, FAHA, Chief Science Officer

Gayle R. Whitman, PhD, RN, FAHA, FAAN, Senior Vice President, Office of Science Operations

Mark D. Stewart, MPH, Science and Medicine Advisor, Office of Science and Medicine

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APPENDIX 1. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—2011 ACCF/AHA/SCAI GUIDELINE FOR PERCUTANEOUS CORONARY INTERVENTION

Committee Member	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness	Voting Recusals by Section Number*
Glenn N. Levine *(Chair)*	Baylor College of Medicine—Professor of Medicine; Director, Cardiac Care Unit	None	None	None	None	None	None	None
Eric R. Bates *(Vice Chair)*	University of Michigan—Professor of Medicine	• Bristol-Myers Squibb • Daiichi-Sankyo • Datascope • Eli Lilly • Merck • Sanofi-aventis	None	None	None	None	None	5.7.2 5.7.3 5.7.4.1 5.7.4.2 5.7.4.3 5.7.4.4 5.7.4.5 6.1 6.1.2 6.1.3
James C. Blankenship *(Vice Chair)*	Geisinger Medical Center—Director of Cardiology and Cardiac Catheterization Laboratories	None	None	None	• Abiomed • AstraZeneca • Boston Scientific • Conor Medsystems • Kai Pharmaceutical • Schering-Plough	None	None	2.1 2.2 2.3 2.9.7 2.11 5.2.4 5.3 5.4.1 5.4.2 5.8.4 6.3
Steven R. Bailey	University of Texas Medical Center—Professor of Medicine and Radiology	• Volcano	None	None	• Boston Scientific	None	None 5.4.2	5.4.1
John A. Bittl	Munroe Heart—Interventional Cardiologist	None	None	None	None	None	None	None
Bojan Cercek	Cedars-Sinai Medical Center—Director, Coronary Care Unit	None	None	None	None	None	None	None
Charles E. Chambers	Penn State Milton S. Hershey Medical Center—Professor of Medicine and Radiology	None	None	None	None	None	None	None
Stephen G. Ellis	Cleveland Clinic Foundation—Section Head, Invasive and Interventional Cardiology	• Abbott Vascular • Boston Scientific • Cordis • Daiichi-Sankyo • Eli Lilly	None	None	• Abbott Vascular	None	None	2.2 2.11 5.7.2 6.1
Robert A. Guyton	Emory Clinic, Inc.—Professor and Chief, Division of Cardiothoracic Surgery	None	None	None	• Edwards Lifesciences	None	None	2.1 2.2 2.3 2.9.7 2.11 5.2.4 5.3 5.5.5 6.2 6.3
Steven M. Hollenberg	Cooper University Hospital—Director, Coronary Care Unit	• Eisai	None	None	None	None	None	5.7.4.3
Umesh N. Khot	CV Research Innovations, LLC—President/CEO	None	None	• Merck†	None	None	None	4.6 5.7.3

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Committee Member	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness	Voting Recusals by Section Number*
Richard A. Lange	University of Texas Health Science Center at San Antonio—Professor of Medicine	None	None	None	None	None	None	None
Laura Mauri	Brigham and Women's Hospital— Associate Professor of Medicine, Harvard Medical School	• Abbott	None	None	• Lutonix	• Abbott	• Defendant, Conor, interpretation of clinical trial results, 2010	2.9.7
		• Conor Medsystems (Johnson & Johnson)				• Abiomed • Boston Scientific • Bristol-Myers Squibb		5.2.3 5.3 5.4.2 5.5.1
		• Cordis • Medtronic				• Conor Medsystems		5.5.2 5.5.4
						• Cordis • Daiichi-Sankyo • Eli Lilly • Medtronic Cardiovascular • Sanofi-aventis		5.5.5 5.6 5.7.2 5.7.3 5.8.2 5.8.4 5.8.5 5.11 6.1 6.1.2 6.1.3 6.2
Roxana Mehran	Columbia University Medical Center— Associate Professor of Medicine; Director, Data Coordinating Analysis Center	• Abbott Vascular • Abiomed • AlphaMedical • AstraZeneca • Bracco • BMS/sanofi-aventis • DataScope • Eli Lilly/ Daichii-Sankyo • Guerbet • The Medicines Company • Medtronic Vascular • St. Jude	None	None	None	None	None	4.7 5.1 5.2.4 5.3 5.4.1 5.4.2 5.5.1 5.5.2 5.6 5.7.2 5.7.3 5.7.4.1 5.7.4.2 5.7.4.3 5.7.4.4 5.7.4.5 5.8.3 5.8.4 5.11 6.1 6.1.1 6.1.2 6.1.3

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APPENDIX 1. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—2011 ACCF/AHA/SCAI GUIDELINE FOR PERCUTANEOUS CORONARY INTERVENTION (continued)

Committee Member	Employer/Title	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness	Voting Recusals by Section Number*
Issam D. Moussa	Mayo Clinic—Professor of Medicine; Chair, Division of Cardiovascular Diseases	None	None	None	None	None	None	None
Debabrata Mukherjee	Texas Tech University—Chief, Cardiovascular Medicine	None	None	None	None	None	None	None
Brahmajee K. Nallamothu	University of Michigan—Assistant Professor of Medicine	None	None	None	None	None	None	None
Henry H. Ting	Mayo Clinic—Professor of Medicine; Assistant Dean for Quality	None	None	None	None	None	None	None

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APPENDIX 2. REVIEWER RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—2011 ACCF/AHA/SCAI GUIDELINE FOR PERCUTANEOUS CORONARY INTERVENTION

Peer Reviewer	Representation	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Deepak L. Bhatt	Official Reviewer—AHA	None	None	None	• AstraZeneca* • Bristol-Myers Squibb • Eisai* • Eli Lilly • Ethicon* • The Medicines Company* • PLx Pharma† • Sanofi-aventis*	None	None
Mauricio G. Cohen	Official Reviewer—AHA	• AstraZeneca* • Momenta Pharma • Xoma	• Terumo Medical	None	• Invitrox*	None	None
John P. Erwin III	Official Reviewer— ACCF/AHA Task Force on Performance Measures	None	None	None	None	None	None
Kirk Garratt	Official Reviewer—SCAI	• Boston Scientific • Cordis/Johnson & Johnson • The Medicines Company	• Boston Scientific • BMS/sanofi-aventis* • Daiichi-Sankyo/Eli Lilly* • Medtronic • The Medicines Company	• Abbott Vascular • Boston Scientific	None	None	None
Steven L. Goldberg	Official Reviewer—SCAI	• AGA	• Bristol-Myers Squibb • Sanofi-aventis	None	None	None	• Plaintiff, patient litigation, 2010
Alice K. Jacobs	Official Reviewer—ACCF/AHA Task Force on Practice Guidelines	None	None	• Wyeth*	• Abbott Vascular* • Abiomed* • Accumetrics* • Cardiovascular Research Foundation (DSMB)† • Harvard Clinical Research Institute† • TIMI Study Group (DSMB)†	None	None
G. B. John Mancini	Official Reviewer—ACCF Board of Governors	• GlaxoSmithKline • Merck • Pfizer • Sanofi-aventis	None	None	• Merck*	None	None
W. Douglas Weaver	Official Reviewer— ACCF Board of Trustees	None	None	None	• Boehringher Ingelheim (DSMB) • Boston Scientific (DSMB) • Duke Clinical Research Institute (Johnson & Johnson/Schering Plough)* • GlaxoSmithKline • NHLBI (DSMB) • TIMI Study Group (Johnson & Johnson/ Bayer—DSMB)		
Thomas M. Bashore	Content Reviewer	None	None	None	None	None	None
Christopher E. Buller	Content Reviewer	• Abbott Vascular • Toshiba Medical	None	None	• Novartis • Regado Biosciences	None	None
James A. Burke	Content Reviewer— ACCF Interventional Scientific Council	None	None	None	None	None	None

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APPENDIX 2. REVIEWER RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—2011 ACCF/AHA/SCAI GUIDELINE FOR PERCUTANEOUS CORONARY INTERVENTION (continued)

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John G. Byrne	Content Reviewer—ACCF Surgeons' Scientific Council	• Edwards Lifesciences	None	>None	None	None	None
T. Bruce Ferguson	Content Reviewer—ACCF Surgeons' Scientific Council	None	None	None	• Novadaq Technologies*	None	None
Victor A. Ferrari	Content Reviewer	None	None	None	• NHLBI (DSMB)† • National Institute for Aging/NIH (DSMB)†	None	None
John G. Harold	Content Reviewer	None	None	None	None	None	None
Biswajit Kar	Content Reviewer	None	None • Medtronic†	None	• AstraZeneca† • Boston Scientific†	• VA Cooperative Study†	None
Morton J. Kern	Content Reviewer	• Infraredex • Merit Medical*	• St. Jude Medical* • Volcano Therapeutics*	None	None	None	None
Spencer B. King III	Content Reviewer	• Celonova Biosciencest	None	None	• Merck (DSMB) • Wyeth (DSMB)	None	None
Frederick G. Kushner	Content Reviewer	None	None	None	• Novartist	None	None
David J. Maron	Content Reviewer	None	None	• Cardiovascular Care Affiliates*	None	None	• Plaintiff, acute coronary syndrome, 2010
Douglass A. Morrison	Content Reviewer	None	None	None	None	None	None
Thomas C. Piemonte	Content Reviewer—ACCF Board of Governors	None	None	None	None	None	• Defendant, stent perforation, 2010
Peter K. Smith	Content Reviewer	• Eli Lilly	None	None	None	None	None
Sidney C. Smith	Content Reviewer	None	None	None	None	None	None
Richard W. Snyder	Content Reviewer—ACCF Board of Governors	None	None	None	None	• Hospital Corporation of America	None
Patrick L. Whitlow	Content Reviewer	• Edwards Lifesciences* • eValve* • Medtronic*	None	None	None	• ICON	None
David O. Williams	Content Reviewer	• Light Lab/St. Jude Medical	None	None	None	None	None
R. Scott Wright	Content Reviewer	• Hoffman LaRoche*	None	None	None	None	None

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†No financial benefit.

ACCF indicates American College of Cardiology Foundation; AHA, American Heart Association; DSMB, data safety and monitoring board; NHLBI, National Heart, Lung, and Blood Institute; NIH, National Institutes of Health; SCAI, Society for Cardiovascular Angiography and Interventions; and TIMI, Thrombolysis In Myocardial Infarction.

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APPENDIX 3. ABBREVIATION LIST

ACS = acute coronary syndromes
AKI = acute kidney injury
BMS = bare-metal stent(s)
CABG = coronary artery bypass graft surgery
CAD = coronary artery disease
CKD = chronic kidney disease
CTO = chronic total occlusion
DAPT = dual antiplatelet therapy
DES = drug-eluting stent(s)
ECG = electrocardiogram
EF = ejection fraction
EPD = embolic protection device
FDA = U.S. Food and Drug Administration
FFR = fractional flow reserve
GDMT = guideline-directed medical therapy
GI = gastrointestinal
GP = glycoprotein
IABP = intra-aortic balloon pump
IV = intravenous
IVUS = intravascular ultrasound
LAD = left anterior descending
LIMA = left internal mammary artery
LV = left ventricular
LVEF = left ventricular ejection fraction
MACE = major adverse cardiac event
MI = myocardial infarction
MRI = magnetic resonance imaging
NCDR = National Cardiovascular Data Registry
PCI = percutaneous coronary intervention
PPI = proton pump inhibitor
RCT = randomized controlled trial
SIHD = stable ischemic heart disease
STEMI = ST-elevation myocardial infarction
SVG = saphenous vein graft
TIMI = Thrombolysis In Myocardial Infarction
TMR = transmyocardial laser revascularization
UA/NSTEMI = unstable angina/non-ST-elevation myocardial infarction
UFH = unfractionated heparin

APPENDIX 4. ADDITIONAL TABLES/FIGURES

APPENDIX 4A. The NCDR CathPCI Risk Score System

Variable	Scoring Response Categories				Risk Score Calculation	
					Total Points	Risk of In-Patient Mortality (%)
Age	<60	≥60, <70	≥70, <80	≥80	0	0.0
	0	4	8	14	5	0.1
Cardiogenic shock	No	Yes			10	0.1
	0	25			15	0.2
Prior CHF	No	Yes			20	0.3
	0	5			25	0.6
Peripheral vascular disease	No	Yes			30	1.1
	0	5			35	2.0
Chronic lung disease	No	Yes			40	3.6
	0	4			45	6.3
GFR	<30	30-60	60-90	>90	50	10.9
	18	10	6	0	55	18.3
NYHA functional class IV	No	Yes			60	29.0
	0	4			65	42.7
PCI status (STEMI)	Elective	Urgent	Emergent	Salvage	70	57.6
	12	15	20	38	75	71.2
PCI status (no STEMI)	Elective	Urgent	Emergent	Salvage	80	81.0
	0	8	20	42	85	89.2
					90	93.8
					95	96.5
					100	98.0

CathPCI indicates catheterization percutaneous coronary intervention; CHF, congestive heart failure; GFR, glomerular filtration rate; NCDR, National Cardiovascular Data Registry; NYHA, New York Heart Association; and STEMI, ST-elevation myocardial infarction. Reproduced with permission from Peterson et al. (236).

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APPENDIX 4B. The SCAI Lesion Classification System

Type I lesions (highest success expected, lowest risk)
1. Does not meet criteria for C lesion
2. Patent

Type II lesions
1. Meets any of these criteria for ACC/AHA C lesion
   - Diffuse (>2 cm length)
   - Excessive tortuosity of proximal segment
   - Extremely angulated segments, >90°
   - Inability to protect major side branches
   - Degenerated vein grafts with friable lesions
2. Patent

Type III lesions
1. Does not meet criteria for C lesion
2. Occluded

Type IV lesions
1. Meets any of these criteria for ACC/AHA C lesion
   - Diffuse (>2 cm length)
   - Excessive tortuosity of proximal segment
   - Extremely angulated segments, >90°
   - Inability to protect major side branches
   - Degenerated vein grafts with friable lesions
   - Occluded for >3 mo
2. Occluded

ACC indicates American College of Cardiology; AHA, American Heart Association; and SCAI, Society for Cardiovascular Angiography and Interventions. Reprinted with permission from Krone et al. (879).

APPENDIX 4C. Strategies to Reduce Radiation Exposure to Patient and Operator

Precautions to minimize exposure to patient and operator
- Use radiation only when imaging is necessary to support clinical care
- Minimize use of cine
- Minimize use of steep angles of x-ray beam
- Minimize use of magnification modes
- Minimize frame rate of fluoroscopy and cine
- Keep the image receptor close to the patient
- Utilize collimation to the fullest extent possible
- Monitor radiation dose in real time to assess patient risk-benefit during procedure

Precautions to specifically minimize exposure to operator
- Use and maintain appropriate protective garments
- Maximize distance of operator from x-ray source and patient
- Keep above-table and below-table shields in optimal position at all times
- Keep all body parts out of field of view at all times

Precautions to specifically minimize exposure to patient
- Keep table height as high as comfortably possible for operator
- Vary imaging beam angle to minimize exposure to any single skin area
- Keep patient's extremities out of beam

APPENDIX 4D. Patient Care Consideration Based on Procedural Radiation Dose

$K_{a,r}$*	P_{KA}†	FT‡	Action
>5 Gray	>500 Gray cm^2	>60 min	Physician charts documentation about why exposure at this level occurred, documents whether multiple skin entry angles were used, assesses risk, educates patient about potential for skin injury, and arranges for appropriate follow-up within 30 d. Phone calls may be sufficient with an office visit arranged if issues/questions arise or a potential tissue injury is suspected.
≥10 Gray			Physician contacts radiation safety officer/medical physicist. The radiation safety officer/medical physicist should perform a detailed analysis of PSD. Document a) FOV, b) skin entrance port number, c) known geometry, with a "rough" geometric setup required. Educate patient about the potential for skin injury and document this in chart. Schedule an office visit in 2 to 4 wk.
PSD§ >15 Gray			If calculated PSD is indeed >15 Gray, the physician and/or radiation safety officer/medical physicist should contact hospital risk management within 24 h. Report the event to the Joint Commission and as needed to the appropriate State Department of Health.

*$K_{a,r}$ is total air kerma at reference point
†P_{KA} is air kerma-area product
‡FT is total fluoroscopy time, does not include cine
§PSD is peak skin dose, which requires calculations made by a qualified physicist.
FOV indicates field of view; and FT, fluoroscopy time.
Adapted with permission from Chambers et al. (317).

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APPENDIX 4E. General Considerations in Deciding Between Early Invasive Strategy and Initial Conservative Strategy

Early Invasive Strategy Generally Preferred	Initial Conservative Strategy Generally Preferred or Reasonable
• Recurrent angina or ischemia at rest or with low-level activities despite intensive medical therapy	• Low-risk score (e.g., GRACE, TIMI)
• Elevated cardiac biomarkers (TnT or TnI)	• Absence of high-risk features
• New or presumably new ST-segment depression	• High risk for catheterization-related complications
• Signs or symptoms of heart failure	• Patient not a candidate for revascularization (with either PCI or CABG)
• Hemodynamic instability	• Patient prefers conservative therapy
• High-risk score (e.g., GRACE, TIMI)	
• Sustained ventricular tachycardia	
• PCI within 6 mo	
• Prior CABG	
• Diabetes mellitus	
• Mild to moderate renal dysfunction	
• Reduced LV function (LVEF <40%)	

CABG indicates coronary artery bypass graft surgery; GRACE, Global Registry of Acute Coronary Events; LV, left ventricular; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; TIMI, Thrombolysis In Myocardial Infarction; TnI, troponin I; and TnT, troponin T.

APPENDIX 4F. Agents for Procedural Sedation and Analgesia

Drug	Clinical Effects	Dose	Onset	Duration	Comments
Midazolam	Sedation, anxiolysis. No analgesia.	Initial 0.5 to 1 mg IV, then titrated.	2 to 3 min	45 to 60 min	Reduce dose when used in combination with opioids. May produce paradoxical excitement. Reversible with flumazenil.
Fentanyl	Analgesia	50 mcg IV. May repeat every 3 min, titrate to effect.	3 to 5 min	30 to 60 min	Reduce dosing when combined with benzodiazepines. Reversible with naloxone.
Etomidate	Sedation, anxiolysis. No analgesia.	Sedation: 0.1 mg/kg IV; repeat if inadequate response.	<1 min	5 to 15 min	Respiratory depression may occur; institutional guidelines vary about administration to nonintubated patients by nonanesthesiologists. May cause myoclonus, nausea, and vomiting. Adrenocortical suppression occurs but is rarely of clinical significance. Not reversible.
Propofol	Sedation, anxiolysis. No analgesia.	Load 1 mg/kg IV; may administer additional 0.5 mg/ kg doses as needed to enhance or prolong sedation.	<1 min	5 to 15 min	Frequent hypotension and respiratory depression; institutional guidelines vary concerning administration to nonintubated patients by nonanesthesiologists. Avoid with egg or soy allergies. Not reversible.
Reversal Agents					
Naloxone	Opioid reversal	0.4 to 2 mg IV	2 min	20 to 40 min	If shorter acting than reversed drug, serial doses may be required.
Flumazenil	Benzodiazepine reversal	0.2 mg IV. May repeat every 1 min up to 1 mg.	1 to 2 min	30 to 60 min	If shorter acting than reversed drug, serial doses may be required. Do not use in patients receiving long-term benzodiazepines, cyclosporine, isoniazid, lithium, propoxyphene, theophylline, or tricyclic antidepressants.

IV indicates intravenous.

Executive Summary

Catheterization and Cardiovascular Interventions 69:471–478 (2007)

EXECUTIVE SUMMARY

The Current Status and Future Direction of Percutaneous Coronary Intervention Without On-Site Surgical Backup: An Expert Consensus Document from the Society for Cardiovascular Angiography and Interventions

Gregory J. Dehmer,[1]* MD, James Blankenship,[2] MD, Thomas P. Wharton Jr.,[3] MD, Ashok Seth,[4] MD, MBBS, DSc, Douglass A. Morrison,[5] MD, PhD, Carlo DiMario,[6] MD, David Muller,[7] MD, Mirle Kellett,[8] MD, and Barry F. Uretsky,[9] MD

*The full-length version of this article can be found on the **Catheterization and Cardiovascular Interventions** website (http://www.mrw.interscience.wiley.com/suppmat/1522-1946/suppmat/index.html) and on the SCAI website at www.scai.org.*

PREAMBLE

The Society for Cardiovascular Angiography and Interventions (SCAI) coauthored and cosponsored with the American College of Cardiology (ACC) and the American Heart Association (AHA) the percutaneous coronary intervention (PCI) guidelines update, released in November 2005 [1]. This guideline update continued to designate elective PCI without on-site surgery as a Class III indication, and primary PCI for ST-segment elevation myocardial infarction (STEMI) as a class IIb indication in the absence of on-site surgery. The performance of PCI without on-site surgical backup is currently the subject of debate. Although providing the highest quality of care and best outcomes to patients should always be the primary goal, debate on this topic has the potential to supersede quality of patient care issues. Within this context, SCAI developed this Expert Consensus document to determine the current status of PCI without on-site surgery not only in the United States, but globally, and make recommendations regarding the performance of PCI in this circumstance. The focus of this document is to provide a structure that provides the highest quality care to patients undergoing PCI in any circumstance.

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[1]Texas A&M School of Medicine, Scott & White Clinic, Temple, Texas
[2]Geisinger Medical Center, Danville, Pennsylvania
[3]Exeter Hospital and Exeter Cardiovascular Associates, Exeter, New Hampshire
[4]Max Devki Devi Heart & Vascular Institute, Saket, New Delhi, India
[5]Yakima Heart Center, Yakima, Washington
[6]Royal Brompton Hospital, London, United Kingdom
[7]St. Vincent's Hospital, Melbourne, Australia
[8]Maine Medical Center, Portland, Maine
[9]Sparks Health System, Fort Smith, Arkansas
See Appendix Table

Endorsed by the following societies: Asian Pacific Society of Interventional Cardiology, Belgian Working Group of Interventional Cardiology, Brazilian Society for Interventional Cardiology, British Cardiovascular Intervention Society, Working Group on Interventional Cardiology of the Bulgarian Cardiology Society, Cardiac Society of Australia and New Zealand, Egyptian Society of Cardiology Working Group on Interventional Cardiology, Interventional Council of the Cardiological Society of India, Italian Society of Interventional Cardiology, Working Group on Interventional Cardiology of the Latvian Society of Cardiology, Polish Working Group on Interventional Cardiology of the Polish Cardiology Society, Sociedad Venezolana de Cardiología Intervencionista (Venezuelan Society of Interventional Cardiology).

*Correspondence to: Gregory J. Dehmer, MD, FSCAI, Professor of Medicine, Texas A&M School of Medicine, Director, Cardiology Division, Scott & White Clinic, 2401 South 31st Street, Temple, Texas 76508. E-mail: president@scai.org

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BACKGROUND

Over the past 20 years, the use and indications for PCI have greatly expanded. It is now well-recognized that PCI is safer and the need for urgent coronary artery bypass graft (CABG) surgery greatly reduced [2]. Primary PCI, when available, has eclipsed fibrinolytic therapy for reperfusion in the treatment of STEMI [3], but is adversely affected by time delays in initiating the PCI procedure [4]. Studies examining patient transport to PCI hospitals have shown suboptimal initial door-to-balloon times, especially in the United States [5]. Efforts to provide primary PCI services locally at community hospitals without on-site cardiac surgery have developed and demonstrate outcomes comparable to facilities that have on-site cardiac surgery [6]. Because it is difficult to sustain a PCI program solely on STEMI patients, elective PCIs are also being performed at facilities without on-site surgery [7], enhancing the debate regarding PCI without on-site surgery.

PREVALENCE AND TRENDS OF PCI WITHOUT ON-SITE SURGERY

Data on the prevalence of PCI performed without on-site surgical backup in the United States are not easily found and are changing rapidly. Data gathered from several sources and believed accurate as of July 2006 indicate primary PCI programs without on-site surgical backup exist in all but 10 states (Alaska, Arkansas, Delaware, Georgia, Mississippi, North Dakota, Rhode Island, South Dakota, Vermont, and Wyoming) plus the District of Columbia. Facilities performing both primary and elective PCI without on-site surgery currently exist in 28 states. A large (n = 18,000) randomized trial of elective PCI without on-site surgery (The Atlantic Cardiovascular Patient Outcomes Research Team Elective Angioplasty Study) is currently enrolling patients and includes facilities in several states where elective PCI without on-site backup has been prohibited.

The exact number of patients receiving PCI at facilities without on-site surgery is unknown. Data from facilities reporting to the CathPCI Registry™ of the ACC-National Cardiovascular Data Registry (ACC-NCDR®) show an increase in the number of both primary and elective PCIs performed without on-site surgical backup [8]. In 2005, 75 of the 463 facilities reporting to the ACC-NCDR were performing PCI without on-site surgical backup.

PCI without on-site surgical backup is being performed in 35 of 39 (90%) countries responding to requests for information and appears to be increasing. For example, 7% of PCI procedures performed in the United Kingdom in 1996 were at facilities without on-site cardiac surgery. By 2004, this increased to 15% with 26% of the PCI centers in the United Kingdom operating without on-site cardiac surgery.

EXISTING GUIDELINES AND COMPETENCY DOCUMENTS

ACC/AHA/SCAI Guidelines

In the 2005 update of this guideline, primary PCI without on-site surgical backup remained a Class IIb indication, and elective PCI without on-site surgery remained a Class III indication. Many other programmatic recommendations were made [1].

European Society of Cardiology Guidelines

In contrast to the ACC/AHA/SCAI guidelines, the 2005 European Society of Cardiology (ESC) guidelines do not comment on PCI without on-site cardiac surgery or issues related to institutional or operator competency [9].

British Cardiac Society and British Cardiovascular Intervention Society Guidelines

The British Cardiac Society and British Cardiovascular Intervention Society (BCIS) guideline, published in 2005, acknowledges and approves PCI without on-site surgical backup and emphasizes a common standard applied across facilities with and without on-site surgical backup so as to avoid two levels of service provision [10].

German Guidelines

The only German guidelines found were published in 1987 [11] and thus may not be relevant today. However, there is substantial evidence that PCI without on-site surgical backup is widely performed in Germany.

The Cardiac Society of Australia and New Zealand Guidelines

Policy statements on support facilities and on the performance of coronary angiography and PCI at rural sites in Australia and New Zealand were published (online) in 2003 and 2005, respectively [12,13]. The Cardiac Society of Australia and New Zealand (CSANZ) guidelines state that PCI is preferably performed in hospitals with on-site surgical support, but acknowledge that the requirements for on-site cardiac surgical facilities may be omitted in certain circumstances, and that appropriately trained individuals can perform coronary interventional procedures safely in hospitals without on-site surgical

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backup. Furthermore, these documents acknowledge that rural patients have reduced access to diagnostic angiography and interventional procedures and further state that providing these services as close to the patient's place of residence as possible facilitates equity of access, which should result in improved quality of care.

Spanish Society of Cardiology Guidelines

Published in 1999 [14], these guidelines are specific for PCI at hospitals without on-site cardiac surgery. PCI performance without on-site cardiac surgery is not prohibited, provided a program meets certain requirements.

Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista

Guidelines from the Brazilian Society of Cardiac Hemodynamics and Intervention (Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista) [15] were published in 2003. They use a scheme similar to the ACC/AHA/SCAI guidelines [1] and classify elective PCI without on-site surgical backup as Class III. Primary PCI for STEMI in the absence of on-site surgery is a Class IIa indication; their guidelines do not have a IIb category.

Belgian Working Group on Invasive Cardiology Guidelines

Published in 2003, these guidelines acknowledge the increasing safety and diminishing risk of PCI but conclude that "the current standard practice for elective PCI remains the presence of on-site surgical standby" [16].

PEER-REVIEWED LITERATURE OF PCI WITHOUT ON-SITE SURGERY

There are over 30 published papers or abstracts reporting PCI results without on-site surgical backup. All published data for both primary and elective PCI were derived from retrospective reviews or registries, and thus are subject to unintentional bias and other methodological concerns. These are summarized and referenced in the on-line version of this document. These studies span a time period from 1990 to 2006, and thus incorporate changing treatment paradigms, including fibrinolytic therapy before PCI, glycoprotein IIb/IIIa inhibitors, and coronary artery stents. The total patient number within some of these reports is not easily derived because the studies listed are expanding experiences within the same registry; thus, simple aggregation of outcome data is not appropriate or meaningful. The more recent reports show that both primary and elective PCI without on-site surgical backup are performed with a high success rate, low in-hospital mortality rate, and a low rate of urgent cardiac surgery.

BEST PRACTICES FOR PCI WITHOUT ON-SITE SURGERY

Although no randomized or controlled studies exist and despite the current ACC/AHA/SCAI guideline recommendation, PCI without on-site surgery is being performed in many states and is accepted in many countries throughout the world. Moreover, data from many countries, including the United States, indicate that the use of PCI without on-site surgery is growing [8]. The purpose of this document is neither to challenge the ACC/AHA/SCAI guideline recommendations nor to support PCI without on-site surgery backup. However, with the reality that PCI without on-site surgery is growing, it is both appropriate and necessary to define the best standards of practice such that facilities and physicians operate within the highest possible quality standards.

Qualifications of the Physician

Simply performing a high volume of cases does not guarantee technical expertise or sound judgment on the part of the physician. More important than a specific case volume threshold is the accurate assessment of complication rates and patient outcomes. Recommendations for physicians performing PCI at facilities without on-site surgery include the following:

a. Only operators with complication rates and outcomes equivalent or superior to national benchmarks should perform PCI procedures with or without on-site surgery. The operator also must actively participate in a facility's quality improvement program. In addition to involvement in local continuous quality improvement efforts, participation in a national data registry if available and appropriate continuing medical education is mandatory.
b. A proven record of satisfactory outcomes is of greater importance than simply meeting an arbitrary case volume requirement. However, operators must have sufficient prior experience to allow assessment of their judgment and quality. The initial operators at a facility without on-site backup should not begin performing PCI in such facilities until they have a lifetime experience of >500 PCIs as primary operator after completing fellowship. Interventional cardiologists joining those already engaged in PCI without on-site surgery with <500 cases of lifetime experience should be mentored and monitored by existing physicians until it is determined and certi-

TABLE I. Personnel and Facility Requirements for PCI Programs Without On-Site Surgical Backup

Experienced nursing and technical laboratory staff with training in interventional laboratories. Personnel must be comfortable treating acutely ill patients with hemodynamic and electrical instability.
On-call schedule with operation of laboratory 24 hr/day, 365 days/year[a].
Experienced coronary care unit nursing staff, comfortable with invasive hemodynamic monitoring, temporary pacemaker operation, and intraaortic balloon pump management. Personnel capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.
Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services (e.g., respiratory care, blood bank, etc.).
Written agreements for the emergency transfer of patients to a facility with cardiac surgery. Transport protocols should be developed and tested a minimum of twice per year.
Well-equipped and maintained cardiac catheterization laboratory with high-resolution digital imaging capability and intraaortic balloon pump equipment compatible with transport vehicles. The ability for the real-time transfer of images and hemodynamic data (via T-1 transmission line) as well as audio and video images to review terminals for consultation at the facility providing surgical backup support is ideal.
Appropriate inventory of interventional equipment, including guide catheters, balloons, and stents in multiple sizes, thrombectomy and distal protection devices, covered stents, temporary pacemakers, pericardiocentesis trays. Pressure wire device and intravascular ultrasound equipment are optimal but not mandatory. Rotational or other atherectomy devices should be used cautiously in these facilities due to the greater risk of perforation.
Meticulous clinical and angiographic selection criteria for PCI (Tables II and III).
Performance of primary PCI as the treatment of first choice for STEMI to ensure streamlined care paths and increased case volumes. Door-to-balloon times should be tracked and be $\leq$90 min. Outlier cases should be carefully reviewed for process improvement opportunities.
On-site rigorous data collection, outcomes analysis, benchmarking, quality improvement, and formalized periodic case review.
Participation in a national data registry where available, such as the American College of Cardiology-National Cardiovascular Data Registry® in the United States.

CABG, coronary artery bypass graft; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation acute myocardial infarction.
[a]Required for the United States facilities, but this may not be possible for all facilities world-wide.
Adapted from Ref. 6.

TABLE II. Recommendations for Primary PCI and Emergency Aortocoronary Bypass Surgery at Hospitals Without On-Site Cardiac Surgery

Avoid intervention in:
Patients with >50% stenosis of left main artery proximal to infarct-related lesion especially if the area in jeopardy is relatively small and the overall LV function is not severely impaired.
Long, calcified or severely angulated target lesions at high-risk for PCI failure with TIMI grade 3 flow present during initial diagnostic angiography.
Lesions in other than the infarct artery (unless they appeared to be flow-limiting in patients with hemodynamic instability or ongoing symptoms).
Lesions with TIMI grade 3 flow that are not amenable to stenting in patients with left main or three-vessel disease that will require coronary bypass surgery.
Culprit lesions in more distal branches jeopardizing only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention.
Transfer emergently for coronary bypass surgery patients with:
High-grade left main or three-vessel coronary disease with clinical or hemodynamic instability after successful or unsuccessful PCI of an occluded vessel and preferably with intra-aortic balloon pump support.
Failed or unstable PCI result and ongoing ischemia, with intra-aortic balloon pump support during transfer.

LV, left ventricular; PCI, percutaneous coronary intervention; TIMI, Thrombolysis in Myocardial Infarction.
Adapted from Ref. 6.

fied formally by that hospital that their skills and judgment are excellent and outcomes equivalent or superior to the national benchmarks.

c. Operators performing PCI without on-site surgery should perform $\geq$100 total PCIs per year, including $\geq$18 primary PCIs per year. These numbers exceed those currently recommended in the ACC/AHA/SCAI guidelines to reflect the opinion of this writing group that a greater experience level is appropriate for PCI in this setting.
d. In the United States, board certification in interventional cardiology by the American Board of Internal Medicine is strongly recommended for all physicians performing PCI.

Facilities and Support Personnel

It is essential that all support personnel have adequate education regarding the management of PCI patients before, during, and after the procedure. This knowledge should include potential procedural complications and their management and the drug therapies used in PCI patients (Table I).

Facilities performing both primary and elective procedures without on-site surgery should perform a minimum of 200 PCI/year. Programs with <200 PCI/year should be reviewed on an individual basis. They should remain open only if they are in geographically isolated or under-served areas and their performance metrics are equivalent to accepted benchmarks. We recommend that each country or state review this issue, and establish an absolute minimum annual case volume below which a PCI program must close under any circumstance. In the United States, this minimum should be 150 PCI/year for a program offering both primary and elective PCIs and this must include a minimum of 36 primary PCI/year. Programs offering only primary PCIs must perform a minimum of 36 primary PCIs/year to remain operational. At the present time in the United States, there is no justification for a PCI

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TABLE III. Recommendations for Patient and Lesion Selection and Backup Strategy for Nonemergent PCI at Hospitals Without On-site Cardiac Surgery and by Operators Performing ≥100 PCIs/Year

Patient Risk: expected clinical risk in case of occlusion caused by procedure.

High Patient Risk: Patients with any of the following:

- decompensated congestive heart failure (Killip Class 3) without evidence for active ischemia, recent CVA, advanced malignancy, known clotting disorders;
- left ventricular ejection fraction ≤25%;
- left main stenosis (≥50%) or three-vessel disease unprotected by prior bypass surgery (>70% stenoses in the proximal segment of all major epicardial coronary arteries);
- single target lesion that jeopardizes over 50% of remaining viable myocardium.

Lesion Risk: probability that procedure will cause acute vessel occlusion.

Increased Lesion Risk: lesions in open vessels with any of the following characteristics:

- diffuse disease (>2 cm in length) and excessive tortuosity of proximal segments;
- more than moderate calcification of a stenosis or proximal segment;
- location in an extremely angulated segment (>90°);
- inability to protect major side branches;
- degenerated older vein grafts with friable lesions;
- substantial thrombus in the vessel or at the lesion site;
- any other feature that may, in the operator's judgment, impede successful stent deployment.
- aggressive measures to open chronic total occlusions are also discouraged due to an increased risk of perforation.

Strategy for Surgical Backup Based on Lesion and Patient Risk:

High-Risk Patient with High-Risk Lesion should not undergo nonemergent PCI at a facility without on-site surgery.

High-Risk Patient with Not High-Risk Lesion: nonemergent patients with this profile may undergo PCI, but confirmation that a cardiac surgeon and operating room is immediately available is necessary.

Not High-Risk Patient with High-Risk Lesion requires no additional precautions.

Not High-Risk Patient with Not High-Risk Lesion requires no additional precautions. Best scenario for PCI without on-site surgery.

CVA, cerebrovascular accident; PCI, percutaneous coronary intervention. Adapted from Ref. 6.

TABLE IV. Requirements for Off-Site Surgical Backup

1. Interventional cardiologists establish a working relationship with cardiac surgeons at the receiving facility.
2. Cardiac surgeon must have privileges at the referring facility to allow review of treatment options as time allows.
3. Cardiac surgeons and receiving hospital agree to provide cardiac surgical backup for urgent cases at all hours and for elective cases at mutually agreed hours
4. Surgeon and receiving facility assure that patient will be accepted based on medical condition, capacity of surgeons to provide services at the time of request and availability of resources. If this cannot be assured before starting an elective procedure, the case should not be done at that time.
5. Interventional cardiologist must review with the surgeon the immediate needs and status of any patient transferred for urgent surgery.
6. Hospital administrations from both facilities endorse transfer agreement.
7. Transferring and receiving facility establish a rigorous protocol for the rapid transfer of patients, including the proper personnel with appropriate experience.
8. Transport provider is available to begin transport within 20 min of the request and provide vehicle/helicopter with necessary life-sustaining equipment, including IABP and monitoring capability.
9. Transferring physician obtains consent for surgery from patient or appropriate surrogate.
10. Initial informed consent for PCI discloses that procedure is being done without on-site surgical backup and acknowledges possibility of risks related to transfer. The consent process should include the risk of urgent surgery (~0.3%) and state that a written plan for transfer exists.
11. As part of the local continuous quality improvement program, a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of any improvement opportunities.

IABP, intraaortic balloon pump; PCI, percutaneous coronary intervention.

program without on-site surgery to perform only elective procedures or not provide availability to primary PCI 24 hr/day, but such a situation may exist in other countries and be appropriate. New programs should have 2 years to reach the absolute minimum volume, but after that programs failing to reach this volume for 2 consecutive years should not remain open under any circumstance.

Patient and Lesion Selection

Rigorous clinical and angiographic selection criteria are essential for programs performing PCI without on-site surgery. Since the clinical situation and risk-to-benefit ratio are different for primary versus elective PCI, different criteria and standards should apply (Table II). In elective PCI without on-site surgery, it is necessary to assess not only the likelihood of PCI failure, but also the potential patient risk if complications occur since it is possible to have a low-risk lesion in a high-risk patient and vice versa. It is important to consider both the patient and lesion risk when developing criteria for selection of appropriate patients for treatment in facilities without on-site surgery (Table III).

Requirements for Off-Site Surgery

A close alliance and cross-communication with cardiovascular surgeons with formalized agreements and periodically tested protocols for the emergency transfer of patients are essential (Table IV). Interventional cardiologists and cardiac surgeons must be actively involved in the program with attendance at regularly scheduled cardiac catheterization conferences and participation in risk management activities.

In hospitals with on-site surgery, it is no longer standard for a surgical suite to be held open awaiting the completion of a PCI. Because the need for urgent

surgery is so infrequent, there are no current data regarding the actual time required to transport a patient to the operating room and initiate cardiopulmonary bypass should the need arise. Should a patient undergoing PCI at a facility without on-site surgery develop a complication requiring urgent transfer for surgery, it is unclear whether or by how much the facility-to-facility transport would add an additional delay in the current practice environment where operating rooms are not held open at on-site facilities. Minimizing the time to the initiation of cardiopulmonary bypass is the goal in this situation and more likely is feasible with on-site cardiac surgery if that surgery is immediately available. There is no acknowledged goal with supporting data similar to a door-to-balloon time for the initiation of cardiopulmonary bypass in this situation, but this should always be accomplished as rapidly as possible, with the goal of <120 min. Operators at facilities without on-site surgical backup should activate the emergency transport system at the first clear signs of a complication even if they attempt to salvage the situation using percutaneous techniques.

Monitoring of Programs

Providing the highest quality PCI services to patients mandates the collection of outcome data and comparison of these data to established benchmarks. Regardless of the mechanism, all PCI programs, with or without on-site surgical backup, must collect appropriate outcome data and compare their data to state, national or their country's performance standards. Data submitted must be audited by an independent authority periodically to insure integrity of the entire process.

UNRESOLVED ISSUES AND FUTURE DIRECTIONS

PCI without on-site surgery is a polarizing and emotional issue for many individuals both within and external to the interventional community. Although debate has focused on whether facilities that offer PCI without on-site surgery should exist, a more meaningful approach would focus on the goal of providing the best possible care to patients who require PCI, regardless of the setting. Recent publications suggest this goal is not being consistently met. Data indicate that the number of coronary artery bypass operations is declining. This trend is likely to continue, resulting in the closing of smaller surgical programs and the coalescence of cardiac surgical services to more centralized locations. If cardiac surgery programs begin to shrink, it will become more difficult for all PCI facilities to have on-site cardiac surgery.

It is inappropriate to open PCI centers if they are not based on the health needs of the community. Opening a low-volume PCI program within the same geographic area and thereby converting a high-volume program at another facility to a low-volume program is not necessarily in the best interests of patients in the community. There is clearly a potential for unnecessary or inappropriate PCI program development in the same geographic area and this is strongly discouraged. However, the factors that define a geographic area are not consistent throughout the United States or other countries. The level and availability of emergency transport services, response times of emergency medical transport, immediate availability of qualified cath lab personnel, and coverage by interventional cardiologists must be considered.

Desires for personal or institutional financial gain, prestige, market share, or other similar motives should not be part of the decision process in determining the need for a PCI program. These considerations apply equally to those wishing to start a new PCI program without on-site backup and those wishing to protect existing programs with on-site backup. In the final analysis, every PCI procedure, regardless of where it is performed, should be of the highest possible quality. This means the PCI is done for appropriate clinical indications, by a skilled operator with documented satisfactory outcomes in a laboratory with appropriate equipment and personnel that has careful tracking of patient outcomes and corrective mechanisms in place to manage individual operator or laboratory outcome data that fall below national standards. Ensuring that all PCI programs meet appropriate performance metrics is likely to save more lives than requiring all PCI programs have on-site surgery.

RECOMMENDATIONS

1. PCI without on-site surgical backup is being performed with acceptable outcomes and risks in the United States and many other countries. The recommendations outlined in this document are made to ensure patient safety and quality outcomes in such a work environment. This is not an open endorsement of PCI without on-site surgery and we do not support the wide-spread use of PCI without on-site surgery especially in the United States, but acknowledge that this practice may be appropriate in some circumstances.
2. The decision to begin or operate a PCI program without on-site surgical backup should be based on the health needs of a local area, not on desires for personal or institutional financial gain, prestige, market share, or other similar motives. Rural communities may have different health care delivery needs than urban centers and this should be considered.

Catheterization and Cardiovascular Interventions DOI 10.1002/ccd.
Published on behalf of The Society for Cardiovascular Angiography and Interventions (SCAI).

3. It is the goal of SCAI to promote the highest possible program quality. Accordingly, PCI programs both with and without on-site surgical backup must evaluate their outcomes against their countries' benchmark for program performance or other acceptable standard.
4. Operators performing PCI without on-site surgery should perform $\geq$100 total PCIs per year, including $\geq$18 primary PCIs per year. The initial operators at a facility without on-site backup should not begin performing PCI in such facilities until they have a lifetime experience of >500 PCIs as primary operator after completing fellowship. Only operators with complication rates and outcomes equivalent or superior to national benchmarks should perform PCI procedures.
5. Independent program oversight should occur either within the context of a local facility's quality assurance program or through an independent government or external agency. Any program failing to perform adequately should close.
6. Further data collection and analysis should be done to more completely understand the role of PCI without on-site surgical backup as a strategy for the delivery of care.

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APPENDIX

TABLE SCAI Writing Committee for Expert Consensus Document Disclosures

Name	Do you perform elective PCIs in a hospital that has on-site surgical backup?	Do you have an ownership or other financial relationship with a hospital that performs elective PCIs and has on-site surgical backup?	Do you perform elective PCIs in a hospital that does not have on-site surgical backup?	Do you have an ownership or other financial relationship with a hospital that performs elective PCIs and does not have on-site surgical backup?	Comments
Dr. Gregory J. Dehmer	Yes	No	No	No	None
Dr. James Blankenship	Yes	No	No	No	None
Dr. Thomas P. Wharton, Jr.	Yes	No	Yes	No	None
Dr. Ashok Seth	Yes	No	No	No	None
Dr. Douglass A. Morrison	Yes	No	No	No	I perform PCI at one hospital with on-site surgery and primary PCI only at a different hospital without on-site surgery.
Dr. Carlo DiMario	Yes	No	No	No	
Dr. David Muller	Yes	No	No	No	I perform primary PCI at a hospital without on site surgery
Dr. Mirle Kellett	Yes	No	No	No	None
Dr. Barry F. Uretsky	Yes	No	No	No	None

PCI, percutaneous coronary intervention.

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ATTACHMENT VII

Signed Agreements Between Greenwich Hospital and Yale-New Haven Hospital

Yale-New Haven Heart and Vascular Center Cardiac Services at Greenwich Hospital

I. General Description of the Program

The Yale-New Haven Heart and Vascular Center (YNHHVC) has established and supported the development of cardiac services at Greenwich Hospital for the purpose of improving acute cardiac care to the residents of Connecticut and Westchester County, New York. The initial relationship was established with the implementation of the Primary Angioplasty program in 2005. The YNHHVC with Greenwich Hospital is seeking the development of an Elective Angioplasty program at Greenwich Hospital to be part of an expanded cardiac program at Greenwich Hospital to include advanced congestive heart failure and management and treatment of peripheral vascular disease. YNHHVC will provide cardiac specialists at Greenwich Hospital. The frequency of YNHHVC physicians' presence at Greenwich Hospital will be determined by patient demand, but the interventional cardiologists will be onsite to ensure 24-hour coverage, 365 days a year. The services will be operated under the license of Greenwich Hospital. The Elective Angioplasty program will be located on the Greenwich Hospital campus on Perryridge Road.

The YNHHVC will provide medical and clinical direction, education, training and management and oversight to ensure the delivery of the highest quality of care. A Medical Director and HVC Patient Services Director from YNHHVC will oversee the global aspects of the cardiac services at Greenwich Hospital. The Directors will work closely with Vice President of the YNHHVC as well as Greenwich Hospital's Director, Section of Cardiology and the Program Director for Cardiology and Medicine to ensure the smooth operation of all aspects of the Cardiac program including Elective Angioplasty.

Participation in the Elective Angioplasty program will be limited to experienced interventional cardiologists who meet or exceed the minimum volume standards put forth in the ACCF/AHA/SCAI guidelines as well as the more stringent guidelines from the SCAI Expert Consensus Document for Percutaneous Coronary Intervention without On-site Cardiac Surgery. All interventional cardiologists will also be required to fulfill all necessary educational and academic criteria to maintain a full-time appointment on the GH Department of Medicine, Section of Cardiology medical staff. Greenwich Hospital will participate in ACC benchmarking registry and D_2B benchmarking.

Responsibilities

YNHHVC is responsible for providing the clinical oversight to the proposed program and for providing training to GH staff. YNHHVC management is responsible for the overall management of the cardiac services at Greenwich Hospital, including the proposed Elective Angioplasty program. YNHHVC involvement provides integration with the YNHHVC to ensure one standard of care across the Yale New Haven Health System. Greenwich Hospital will retain appropriate authorities and responsibilities that are necessary for Greenwich Hospital to comply with Medicare requirements for provider-based status and state licensure. The expectation is that Greenwich Hospital will adhere to and complete same the Competency Based Orientation.

Patient Selection Guidelines

Elective PCI Patient Selection Criteria

Pre-catheterization:
Be undergoing diagnostic cardiac catheterization for suspected coronary artery disease
Be at least 18 years of age
Must not be pregnant

Post catheterization:
Coronary artery disease judged to be clinically and angiographically significant
Ability to perform PCI with equipment available at the local site
Procedure risk judged to be not high (See below)
No need for coronary artery by-pass surgery

High procedural risk criteria are:
PCI of unprotected left main coronary artery
PCI of left coronary circulation lesion in the presence of critical (greater than 70%) unprotected left main coronary artery lesion
Poor left ventricular function (EF less than 25%) and need to perform PCI in a vessel supplying significant myocardium
PCI of single lesion that jeopardizes greater than 50% of viable myocardium

II. Emergency Transfers/Referrals

Elective angioplasty patients from Greenwich Hospital requiring emergency cardiac surgery can be transferred to the nearest cardiac surgery facility or to Yale-New Haven Hospital or Bridgeport Hospital when travel time does not impose a safety risk for the patient. Y-Access will be utilized to ensure ready access.

VI. Joint Quality Assurance Reviews

The program will be consistent with the clinical standards established through the Yale New Haven Heart and Vascular Center. In addition to strict adherence to the American College of Cardiology/American Heart Association (ACCF/AHA/SCAI) guidelines for PCI the proposed program will strive to meet the more stringent guidelines from the SCAI Expert Consensus Document on PCI without On-site Surgical Backup.

YNHHVC will draw on its collective clinical resources and experience to ensure that all of the necessary standards, protocols, policies, procedures and quality assessments are in place prior to the initiation of the elective angioplasty program and that the program staff and physicians are fully educated on these standards and procedures.

Utilization and outcomes data will be tracked by YNHHVC and the Center for Outcomes Research and Evaluation (CORE) and provided to GH on a regular basis for ongoing quality improvement. Quality improvement plans will be developed. The Greenwich Hospital program will be fully integrated into YNHHVC quality improvement activities including monthly morbidity and mortality (M&M) conferences and quality indicators monitoring. The YNHHS Quality Council will also track the elective angioplasty program outcomes. This includes participation in national and state benchmarking projects. Expect participation D_2B quality review and full case review analysis for outliers.

VII. Joint Training

All technical and nursing staff from Greenwich Hospital's Cardiac Catheterization Laboratory participates in an education program consisting of didactic, "one-on-one" observational and hands-on training. Greenwich Hospital staff rotates through the cardiac catheterization laboratory at YNHH, as well as shadow experiences in ICU and CV floor.

Training includes but is not limited to familiarization with: angioplasty equipment (guide catheters, guide wires, and angioplasty catheters including balloons and stents); commonly used drugs, assessment and monitoring anticoagulation, use of intra-aortic balloon equipment, patient transfer and a number of items related to patient care before, during and after the procedure. Participation in HVC Operations Council with issues relevant to the Elective Angioplasty Program.

VIII. Implementation of Agreement

Implementation of the agreement is subject to the receipt of the CON approval from OHCA and an ongoing evaluation of quality and outcomes measures that have been identified by YNHHVC to the program.

The foregoing is agreed to this 27th day of January, 2012.

GREENWICH HOSPITAL

By:_____
Frank Corvino
President and Chief Executive Officer

YALE-NEW HAVEN HOSPITAL

By:_____
Richard D'Aquila
Chief Operating Officer

VIII. Implementation of Agreement

Implementation of the agreement is subject to the receipt of the CON approval from OHCA and an ongoing evaluation of quality and outcomes measures that have been identified by YNHHVC to the program.

The foregoing is agreed to this 27th day of January, 2012.

YALE-NEW HAVEN HOSPITAL

By: _____
Marna P. Borgstrom
President and Chief Executive Officer

VIII. Implementation of Agreement

Implementation of the agreement is subject to the receipt of the CON approval from OHCA and an ongoing evaluation of quality and outcomes measures that have been identified by YNHHVC to the program.

The foregoing is agreed to this 27th day of January, 2012.

YALE NEW HAVEN HEALTH SYSTEM

By: _____
Gayle Capozzalo
Executive Vice President

ATTACHMENT VIII

Greenwich Hospital's Historical
PAMI Volume by ZIP Code

Angioplasty by ZIP Code

ZIP Code	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012*
06484	1	0	0	0	0
06606	0	0	0	1	0
06759	0	0	0	1	0
06807	3	0	0	0	0
06824	0	1	0	0	0
06825	1	0	0	0	1
06830	9	4	5	8	3
06831	5	8	3	0	2
06850	1	0	1	0	0
06851	0	0	0	1	0
06854	1	0	0	0	0
06870	0	2	1	2	0
06878	0	0	1	2	0
06896	1	0	0	0	0
06902	2	1	2	2	1
06906	0	0	0	1	0
06907	2	0	0	1	0
07921	0	0	0	0	0
10003	0	0	0	1	0
10462	0	1	0	0	0
10528	1	1	1	0	0
10538	0	2	0	0	0
10543	1	3	1	3	1
10550	0	1	0	0	0
10573	7	8	10	5	4
10580	2	5	2	4	0
10591	0	1	0	0	0
10597	0	0	0	1	0
10604	0	0	1	0	0
10605	1	0	1	0	0
10707	1	0	0	0	0
10709	0	0	1	0	0
10801	1	0	0	0	0
10804	0	0	0	1	0
10974	0	0	0	1	0
11372	0	0	1	0	0
12533	0	1	0	0	0
12590	0	1	0	0	0
19810	0	0	0	0	1
22827	0	0	1	0	0
33446	0	0	0	1	0
44113	0	0	0	1	0
78148	0	0	0	0	1
78624	0	0	0	0	1
99998	0	0	0	1	0
Total	**40**	**40**	**32**	**38**	**15**

*Note: Actual Q1 volume; annualized volume would equal 60

Sources: CHIME and Greenwich Hospital Department of Cardiology

ATTACHMENT IX

Articles, Studies, Reports

- Atlantic Cardiovascular Patient Outcomes Research Team CPORT-E Trial Presentation
- American Heart Association/American Stroke Association CPORT-E Trial Summary
- 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention Presentation
- For PCI, No Surgeons Required – Study: Elective PCI No Longer Requires On-Site Surgical Backup, The Advisory Board Company, The Daily Briefing

CPORT-E Trial Presentation

Atlantic Cardiovascular Patient Outcomes Research Team

CPORT- E Trial

Randomized trial comparing medical, economic and quality of life outcomes of non-primary PCI at hospitals with and without on-site cardiac surgery

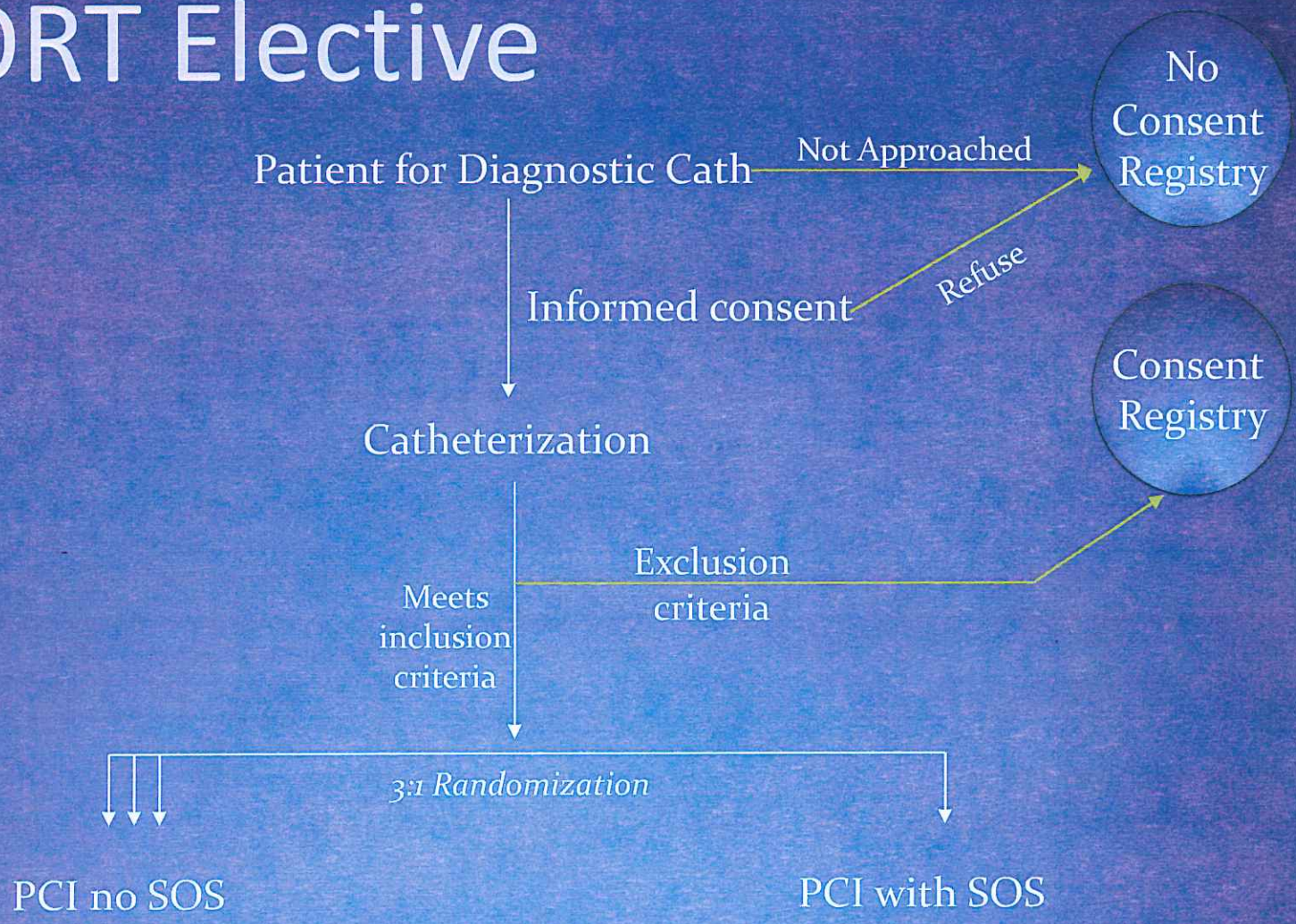
Atlantic C-PORT

Motivation for Trial

- Sustain primary PCI program at no-SOS hospitals
- Improve access to PCI services
- Reduce pressure to create additional cardiac surgery programs
- Need for research to inform healthcare policy decisions by state and national organizations

Atlantic C-PORT

C-PORT Elective



Analysis by intention-to-treat

Atlantic C-PORT

Study Endpoints

- Non-inferiority trial
- Primary Endpoints
  - **All-cause mortality at 6 weeks**
  - MACE at 9 months
    - All-cause mortality
    - Q-wave myocardial infarction
    - Target vessel revascularization
- *Assuming 6 week mortality to be 0.8%, a sample size of **18360** was selected to define a non-inferiority margin of 0.4% with a one-sided test for non-inferiority using α=0.05 and β=0.80 for both primary endpoints.*

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Inclusion and Exclusion Criteria

Patient

Inclusion

- Age ≥ 18 years
- Informed consent
- ≥ 50% stenosis
- All target lesions approachable at no-SOS hospital

Exclusion

- Unprotected LM
- EF < 20%
- MD-judged high risk

Devices

Inclusion

- Balloon, stent
- Distal protection
- Covered stent
- Cutting balloon - in-stent restenosis

Exclusion

- Atherectomy
- Cutting balloon- de novo lesion

Institution

Inclusion

- ≥ 200 PCI/year
- 24/7 Primary PCI
- Complete formal development program
- Interventionalist meets AHA/ACC competency

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Participating Centers

60 Centers

Center Annual PCI Procedure Volume

150 (99,216)

median (25th,75th percentile)

Median Participation Duration

2.2 years

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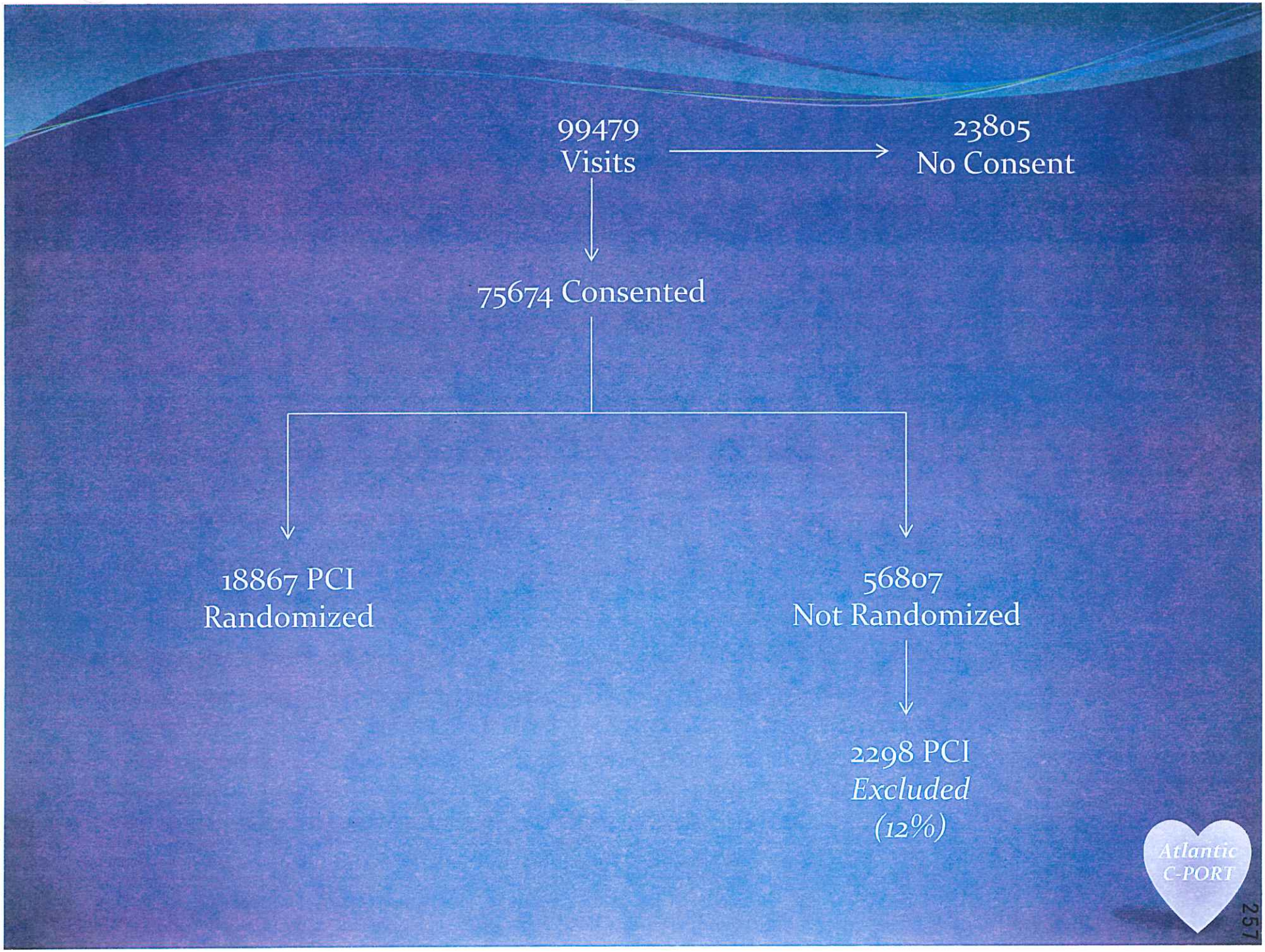
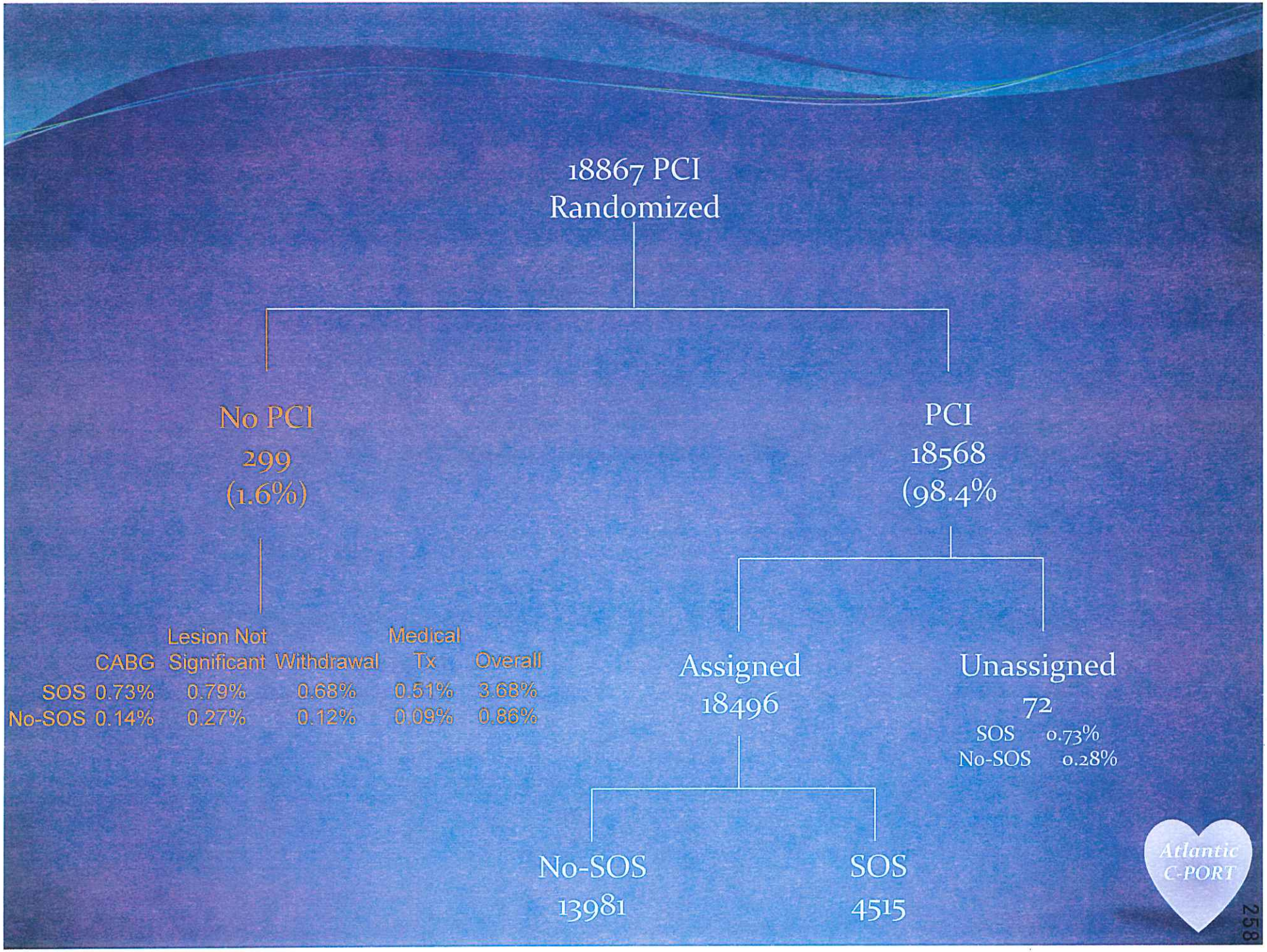

99479
Visits
23805
No Consent
75674 Consented
18867 PCI
Randomized
56807
Not Randomized
2298 PCI
Excluded
(12%)
Atlantic
C-PORT
257


18867 PCI
Randomized
No PCI
299
(1.6%)
PCI
18568
(98.4%
CABG
Lesion Not Significant
Withdrawal
Medical Tx
Overall
SOS 0.73% 0.79% 0.68% 0.51% 3.68%
No-SOS 0.14% 0.27% 0.12% 0.09% 0.86%
Assigned
18496
Unassigned
72
SOS 0.73%
No-SOS 0.28%
No-SOS
13981
SOS
4515
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	No-SOS	SOS	p-value
Age (years) (mean+/-SD)	64+/-12	64+/-12	0.42
Male Gender (%)	64.0	63.2	0.37
Race/Ethnicity (%)			
Caucasian	79.1	80.2	0.33
Africa-American	11.8	11.3	
Hispanic	5.6	5.6	
Asian	2.1	1.9	
Hypertension (%)	84.6	85.3	0.29
Hypercholesterolemia (%)	82.2	82.2	0.95
Smoking (Current & Former) (%)	61.6	62.7	0.20
Diabetes (%)	39.0	39.7	0.41
Family History of CAD (%)	56.7	57.9	0.17
Heart Failure (%)	8.6	8.8	0.64
Prior MI (%)	42.5	43.3	0.35
Prior PCI (%)	31.9	30.4	0.06
Prior CABG (%)	13.1	13.5	0.47
Prior Stroke or PVD (%)	17.3	18.4	0.09
Creatinine (mg/dl)	1.15+/-0.88	1.15+/-0.87	0.63
GFR ml/min/1.73 m^2	76.5+/-34.1	76.3+/-27.1	0.63
BMI kg/m^2	32.7+/-21.9	33.2+/-24.5	0.22

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Presentation

Clinical Characteristics

	No-SOS (%)	SOS (%)
ACS	63.8	64.1
Stable	36.1	36.0

Procedure Status

	No-SOS (%)	SOS (%)
Elective	76.7	79.4
Urgent	22.9	20.1
Emergency	0.36	0.57

* $P < 0.001$

Atlantic C-PORT

Baseline Diagnostic Catheterization

	No-SOS (%)	SOS (%)	p-value
One vessel CAD	36.1	34.7	0.22
Two vessel CAD	35.9	37.2	
Three vessel CAD	28.0	28.0	
Left main disease	3.2	3.7	0.13
Graft disease	9.4	9.7	0.44
LV function (EF)	54.2 +/- 10.6	54.3 +/- 10.7	0.72

Totals add up to >100% because Left Main and Graft disease are in addition to disease in the three major circulations

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Procedure Characteristics

	No-SOS (%)	SOS (%)	P-Value
Staged	25.7	67.7	<0.0001
Lab Visits /Index PCI	1.28	1.73	<0.0001
Single Vessel PCI	79	78	
Multi-Vessel PCI	21	22	

Staged Index PCI
procedure requires one or more catheterization laboratory visit dates in addition to the diagnostic catheterization date

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PCI Success

	No-SOS (%)	SOS (%)
Complete Success	90.8	91.9*
Partial Success	5.7	5.5
Failure	3.4	2.5*

Patient Success
P=0.0096

	No-SOS (%)	SOS (%)
Success	93.4	94.1
Failure	6.6	5.9

Lesion Success
P=0.0474

PCI Success: ≤20% residual stenosis and TIMI 3 flow

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Mortality *6- Weeks*

	No-SOS (%)	SOS (%)	P-value
Death	0.91	0.93	0.94

The difference in 6 week mortality is -0.014% with a 90% confidence interval of -0.26% to 0.28%. The upper bound is <0.4%, so that the hypothesis of inferior 6 week mortality for the no-SOS hospitals is rejected at the one-sided P<0.05 level.

Atlantic C-PORT

Adverse Events - *6-Weeks*

	No-SOS (%)	SOS (%)	P-value
Death	0.91	0.93	0.94
Bleeding	3.41	3.00	0.18
Vascular repair	0.38	0.40	0.86
Stroke	0.27	0.15	0.16
Renal Failure	0.50	0.37	0.28

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Unplanned Procedures

	No-SOS (%)	SOS (%)	P-value
CABG	0.48	0.68	0.10
Emergency CABG	0.10	0.22	0.05
Unplanned Cath	4.41	3.35	0.002
Unplanned PCI	2.11	1.32	0.001

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Summary

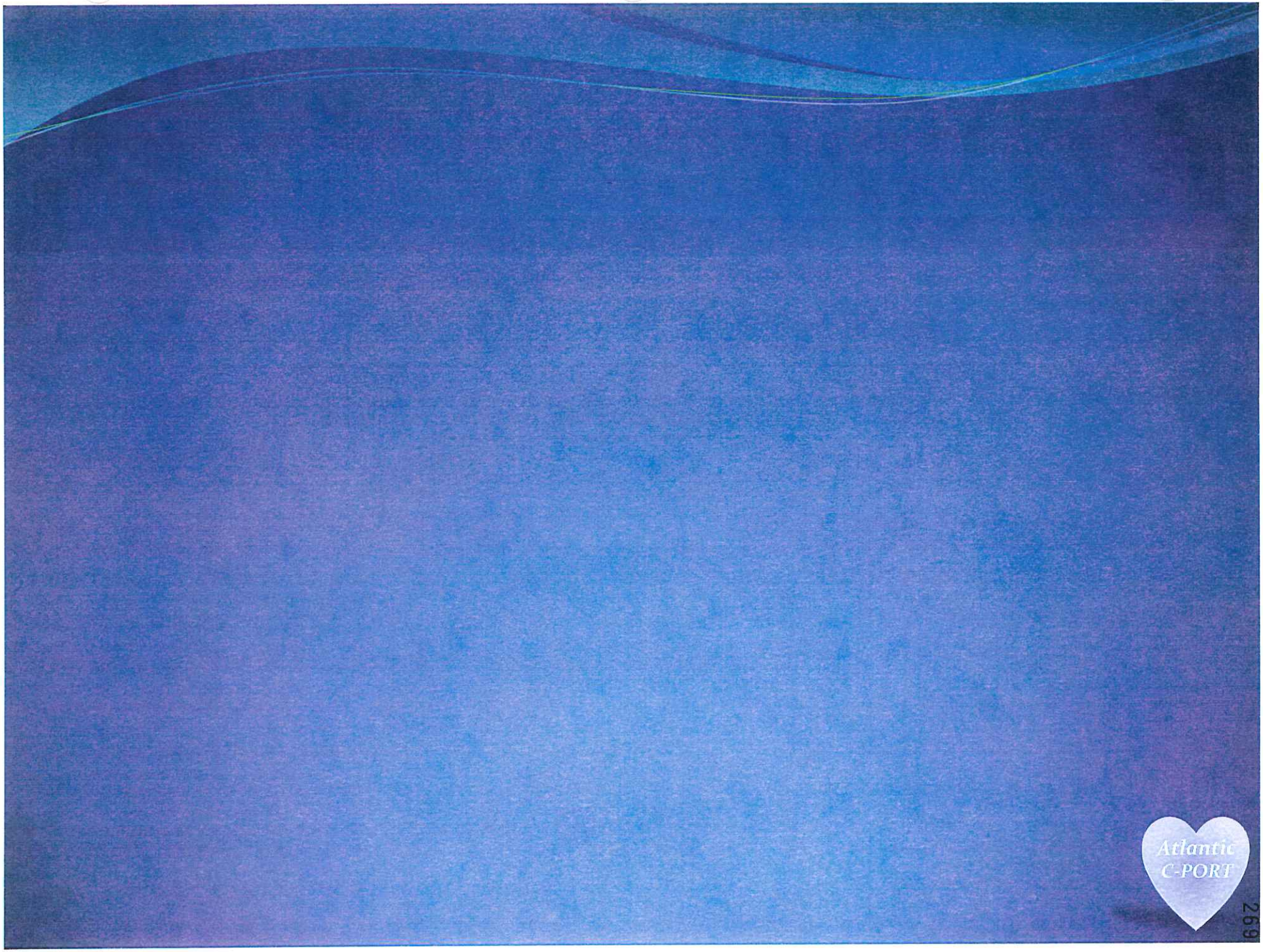
- **PCI success is greater than 90% in both groups but lower in patients randomized to hospitals without surgery on-site**
  (success rate difference of 1.1% on per patient basis; 0.7% on per lesion basis)
- **Number of cath lab visits required to complete the index PCI is greater in patients randomized to hospitals with surgery on-site**
  (1.3 versus 1.7 visits/patient)
- **Unplanned catheterization and PCI procedures are uncommon but occur more frequently in patients randomized to hospitals without surgery on-site**
  (4.4% no-SOS vs 3.4% SOS)
- **Emergency CABG procedures are rare, but occur more frequently in patients randomized to hospitals with surgery on-site**
  (0.1% no-SOS vs 0.2% SOS)
- **Mortality is similar in both groups**
  (0.91% no-SOS vs 0.93% SOS)
- **The incidence of bleeding, vascular repair, stroke and renal failure is similar in both groups**

Atlantic C-PORT

Conclusion

- In hospitals without on-site cardiac surgery that complete a formal PCI development program, adhere to C-PORT participation requirements, and whose outcomes are monitored, non-primary PCI is safe and associated with similar rates of adverse events including mortality.
- Long-term, quality outcome data are currently being collected on these study subjects and will be reported early in 2012.

Atlantic C-PORT


Atlantic
C-PORT

Summary

- **Angiographic Outcomes**
  - PCI Success > 90% in both groups but lower in hospitals without surgery on-site
    (success rate difference of 1.1% on per patient basis; 0.7% on per lesion basis)
  - Number of catheterization laboratory visits required to complete the index PCI is greater in patients randomized to hospitals with surgery on-site
    (1.3 versus 1.7 visits/patient)
- **Unplanned procedure outcomes**
  - Unplanned catheterization and PCI procedures were uncommon but occurred more frequently in patients randomized to hospitals without surgery on-site
    (4.4% no-SOS vs 3.4% SOS)
  - Emergency coronary CABG was rarely required, but was utilized more among patients at hospitals with surgery on-site
    (0.1% no-SOS vs 0.2% SOS)
- **Patient Outcomes**
  - Mortality is similar in both groups
    (0.91% no-SOS vs 0.93% SOS)
  - The incidence of bleeding, vascular repair, stroke and renal failure is similar in both groups

Atlantic C-PORT

Summary

	No SOS (%)	SOS (%)	Relative Difference	Absolute Difference
PCI Success	90.8	91.9	1.2 %	204
Number procedures / index PCI	1.3	1.7	30 %	5570
Unplanned cath or PCI	4.4	3.4	29 %	184
Unplanned emergency CABG	0.10	0.22	50 %	22
Mortality	.91	.93	3.2 %	4
Bleeding	3.4	3	13 %	76

Atlantic C-PORT

Summary - 1

- Historical, angiographic and clinical characteristics of study subjects are similar at hospitals with and without on-site surgery
- Acute coronary syndrome is the most frequent clinical presentation in both groups
- Fewer procedures are classified as "elective" at hospitals without surgery on-site
- PCI success rate differs by less than 1% in the two groups, but is statistically lower at hospitals without on-site surgery
- In patients assigned to hospitals with on-site surgery there are more staged procedures and more catheterization laboratory visits are required to complete the index PCI.

Atlantic C-PORT

Summary - 2

- Six weeks after index PCI
  - Mortality is similar at hospitals with and without SOS
  - Incidence of bleeding, renal failure and stroke are similar at hospitals with and without SOS
  - Unplanned CABG, particularly emergency CABG, are more frequent at hospitals with SOS
  - Unplanned catheterization and PCI procedures are more frequent in patient assigned to no-SOS hospitals

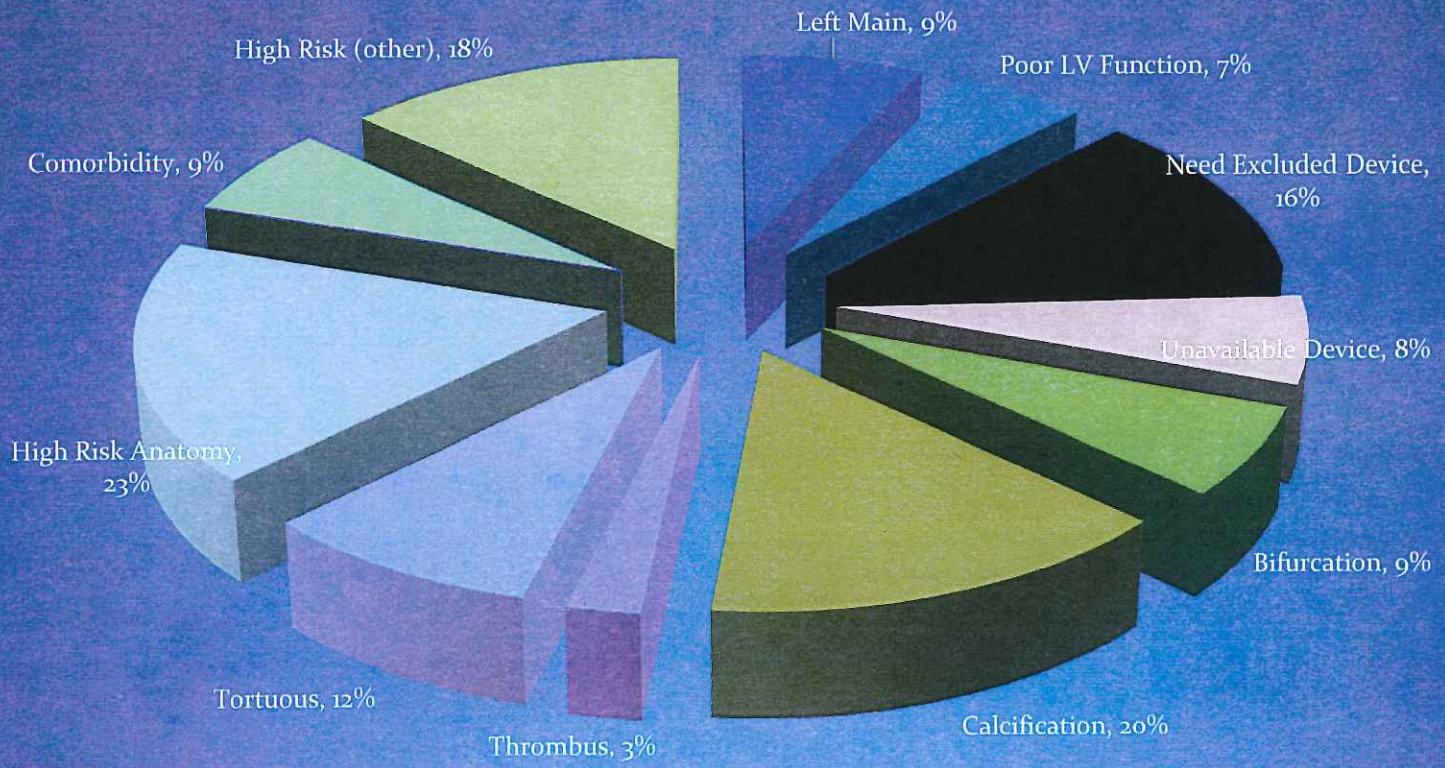
Atlantic C-PORT

Catheterization Laboratory Visits

	No-SOS	SOS
Diagnositic Cath Visits	14023	4545
Visits to Complete Index PCI	17964	7855
Visits/PCI	1.28	1.73
Unplanned Visits	618	152
Total	18302	8007
Visits/PCI	1.31	1.76

Atlantic C-PORT

Reason No PCI – consented, not randomized



Atlantic C-PORT

Consented But Not Randomized

PCI at alternate site

Exclusion Criteria		
Need Excluded Device	368	16%
Left Main	218	9%
Poor LV Function	161	7%
High Risk		
High Risk Anatomy	537	23%
Calcification	452	20%
High Risk (other)	410	18%
Tortuous	270	12%
Co-morbidity	200	9%
Bifurcation	197	9%
Thrombus	70	3%

Total > 100 % because of multiple reasons for some patients

Atlantic C-PORT

PCI Success

	No-SOS (%)	SOS (%)	Off-Site* (%)	On-Site* (%)
Success	94.3	95.2	95	94
Partial Success or Failure	5.7	4.8		

PCI Success: ≤50% residual stenosis and TIMI 3 flow

** Kutcher MA et al. J Am Coll Cardiol, 2009, 54:16-24*

Atlantic C-PORT

	No-SOS	SOS	Off-Site*	On-Site*
Age (years) (mean+/-SD)	64+/-12	64+/-12	64.2	64 ± 12
Male Gender (%)	64.0	63.2	65	66
Race/Ethnicity (%)				
Caucasian	79.1	80.2		
Africa-American	11.8	11.3		
Hispanic	5.6	5.6		
Asian	2.1	1.9		
Hypertension (%)	84.6	85.3	76	77
Hypercholesterolemia (%)	82.2	82.2	71	76
Smoking (Current & Former) (%)	61.6	62.7		
Diabetes (%)	39.0	39.7	32	33
Family History of CAD (%)	56.7	57.9		
Heart Failure (%)	8.6	8.8	11	11
Prior MI (%)	42.5	43.3	29	31
Prior PCI (%)	31.9	30.4	36	37
Prior CABG (%)	13.1	13.5	14	21
Prior Stroke or PVD (%)	17.3	18.4		
Creatinine (mg/dl)	1.15+/-0.88	1.15+/-0.87		
GFR ml/min/1.73 m^2	76.5+/-34.1	76.3+/-27.1		
BMI kg/m^2	32.7+/-21.9	33.2+/-24.5		

** Kutcher MA et al. J Am Coll Cardiol, 2009, 54:16-24*

Atlantic C-PORT

Adverse Events - *6-Weeks*

	No-SOS (%)	SOS (%)	Off-Site* (%)	On-Site* (%)
Death	0.91	0.93	0.8	0.8
Bleeding	3.41	3.00	2.3	2
Vascular repair	0.38	0.40	0.8	1.1
Stroke	0.27	0.15		
Renal Failure	0.50	0.37		

** Kutcher MA et al. J Am Coll Cardiol, 2009, 54:16-24*

Atlantic C-PORT

Unplanned Procedures

	No-SOS (%)	SOS (%)	Off-Site* (%)	On-Site* (%)
CABG	0.48	0.68		
Emergency CABG	0.10	0.22	0.3	0.4
Unplanned Cath	4.41	3.35		
Unplanned PCI	2.11	1.32		

*Kutcher MA et al. J Am Coll Cardiol, 2009, 54:16-24

Atlantic C-PORT

Disclosure

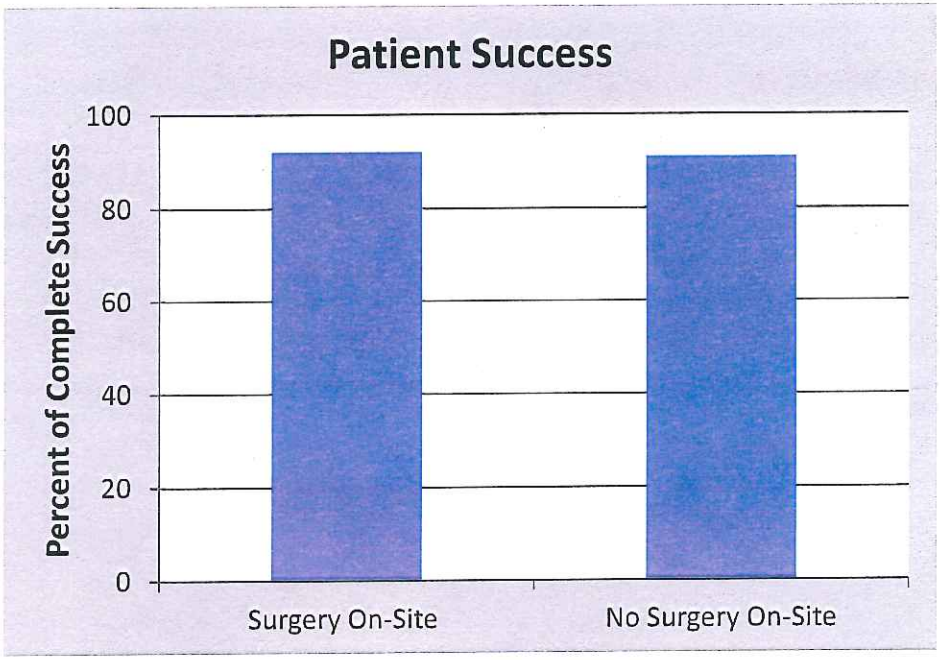
- Participating sites supported study infrastructure and personnel at
  - Johns Hopkins – Clinical Coordinating Center
  - Duke – Economics and Quality of Life
  - Clinical Trials and Survey Corporation – Data Analysis

AHA/ASA CPORT-E Trial Summary

CPORT-E Trial

Background: Comparison of the safety and quality outcomes of PCI performed at hospitals with and without on-site cardiac surgery.

Purpose: To determine whether the safety and benefits of angioplasty are the same at hospitals with or without surgery backup. The study is designed to show that there is no detectable difference between the safety and benefits of the procedure at the two types of hospital. Cost is also compared.



Methods: Interventional , randomized, safety/efficacy study, parallel assignment, open label, non-inferiority, health services research (n=18,867 randomized)

Primary Endpoints: Mortality at 6 weeks and MACE = death + MI + TVR at 9 months

Secondary Endpoints: Include emergency CABG; MI; TVR & subsequent TVR; HF & class; Angina & class; stroke; MACE; angiographic complications & success; please see complete listing at clinicaltrials.gov

Results: Mortality and incidence of bleed, vascular repair, stroke and renal failure was comparable in both groups.

Conclusion: Patients who had non-emergency artery-opening angioplasty or stent implantation at hospitals without cardiac surgery capabilities fared as well as those in hospitals that did. Outcomes at 9 months post procedure will be reported next year.

Presented by: T. Aversano, AHA Scientific Sessions , 2011, Orlando

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2011 ACCF/AHA/SCAI
Guideline Presentation

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions

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Citation

This slide set was adapted from the 2011 ACCF/AHA /SCAI Guideline for Percutaneous Coronary Intervention. Published on November 7th ahead of print, available at: http://circ.ahajournals.org/lookup/doi/10.1161/CIR.0b013e31823ba622

The full-text guidelines are also available on the following Web sites:
ACC (www.cardiosource.org), AHA (my.americanheart.org), and SCAI (www.scai.org)

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Special Thanks To

Slide Set Editor

Glenn N. Levine, MD, FACC, FAHA

The PCI Guideline Writing Committee Members

Glenn N. Levine, MD, FACC, FAHA, *Chair*
Eric R. Bates, MD, FACC, FAHA, *Vice Chair*
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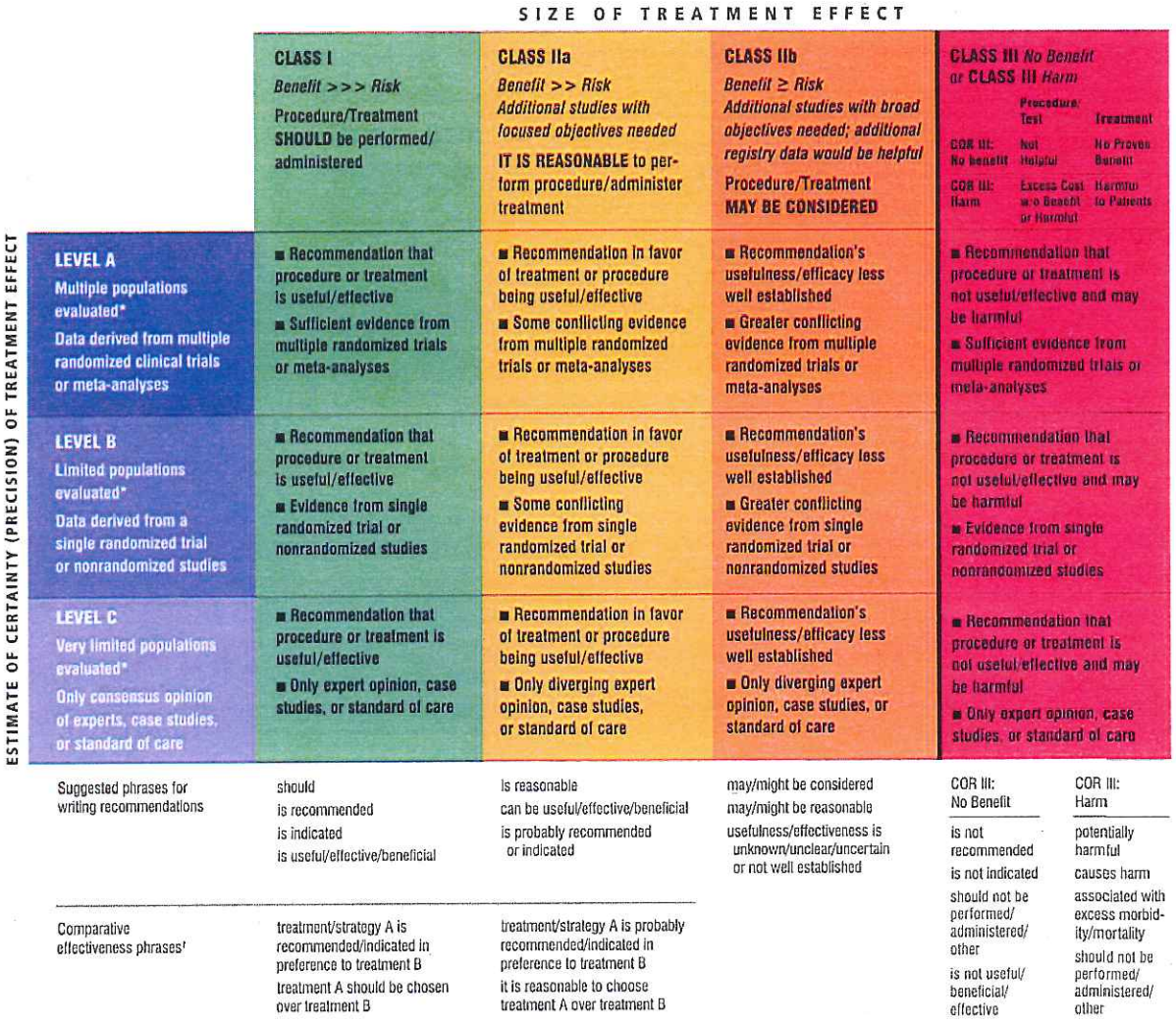
Classification of Recommendations and Levels of Evidence



SIZE OF TREATMENT EFFECT

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT

	CLASS I *Benefit >>> Risk* Procedure/Treatment **SHOULD** be performed/ administered	CLASS IIa *Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	CLASS IIb *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	CLASS III *No Benefit* or CLASS III *Harm* Procedure/ Test / Treatment COR III: No benefit — Not Helpful — No Proven Benefit COR III: Harm — Excess Cost w/o Benefit or Harmful — Harmful to Patients
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care
Suggested phrases for writing recommendations	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR III: No Benefit: is not recommended; is not indicated; should not be performed/ administered/ other; is not useful/ beneficial/ effective COR III: Harm: potentially harmful; causes harm; associated with excess morbidity/mortality; should not be performed/ administered/ other
Comparative effectiveness phrases†	treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B		

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

*Data available from clinical trials or registries about the usefulness/ efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

†For comparative effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

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Introduction

The PCI guideline reflects the growth of knowledge in the field and parallels the many advances and innovations in the field of interventional cardiology, including primary PCI, BMS and DES, IVUS and physiologic assessments of stenosis, and newer antiplatelet and anticoagulant therapies. This guideline addresses ethical aspects of PCI, vascular access considerations, CAD revascularization, including hybrid revascularization, revascularization before noncardiac surgery, optical coherence tomography, advanced hemodynamic support devices, no-reflow therapies, and vascular closure devices.

Most of this document is organized according to "patient flow," consisting of preprocedural considerations, procedural considerations, and postprocedural considerations.

The STEMI, PCI, and CABG guidelines were written concurrently, with additional collaboration with the SIHD guideline writing committee, allowing for greater collaboration on topics such as PCI in STEMI and revascularization strategies in patients with CAD.

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CAD Revascularization

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Heart Team Approach to Revascularization Decisions

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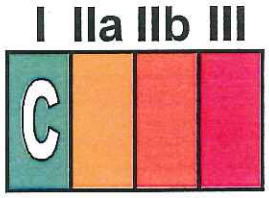
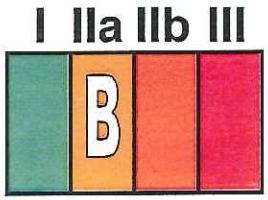
Heart Team Approach to Revascularization Decisions



A Heart Team approach to revascularization is recommended in patients with unprotected left main or complex CAD.



Calculation of the STS and SYNTAX scores is reasonable in patients with unprotected left main and complex CAD.

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Revascularization to Improve Survival

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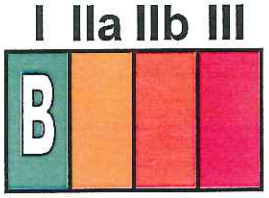
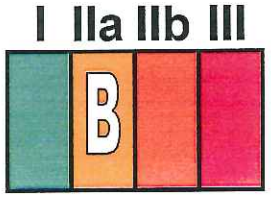
Revascularization to Improve Survival: Left Main CAD Revascularization



CABG to improve survival is recommended for patients with significant (≥50% diameter stenosis) left main CAD.



PCI to improve survival is reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of a good long-term outcome (e.g., a low SYNTAX score [≤22], ostial or trunk left main CAD); and 2) clinical characteristics that predict a significantly increased risk of adverse surgical outcomes (e.g., STS-predicted risk of operative mortality ≥5%).

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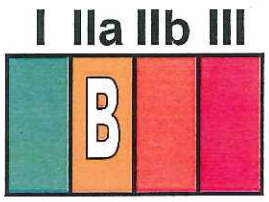
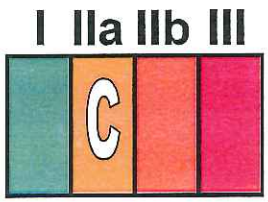
Revascularization to Improve Survival: Left Main CAD Revascularization (cont.)



PCI to improve survival is reasonable in patients with UA/NSTEMI when an unprotected left main coronary artery is the culprit lesion and the patient is not a candidate for CABG.



PCI to improve survival is reasonable in patients with acute STEMI when an unprotected left main coronary artery is the culprit lesion, distal coronary flow is TIMI (Thrombolysis In Myocardial Infarction) grade <3, and PCI can be performed more rapidly and safely than CABG.

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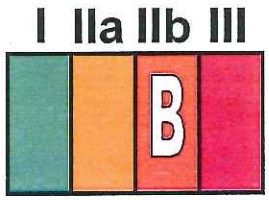
Revascularization to Improve Survival: Left Main CAD Revascularization (cont.)



PCI to improve survival may be reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low to intermediate risk of PCI procedural complications and an intermediate to high likelihood of good long-term outcome (e.g., low-intermediate SYNTAX score of <33, bifurcation left main CAD); and 2) clinical characteristics that predict an increased risk of adverse surgical outcomes (e.g., moderate-severe chronic obstructive pulmonary disease, disability from previous stroke, or previous cardiac surgery; STS-predicted risk of operative mortality >2%).

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Revascularization to Improve Survival: Left Main CAD Revascularization (cont.)



Harm

PCI to improve survival should not be performed in stable patients with significant (≥50% diameter stenosis) unprotected left main CAD who have unfavorable anatomy for PCI and who are good candidates for CABG.

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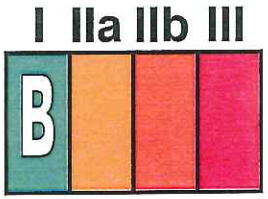
Revascularization to Improve Survival: Non-Left Main CAD Revascularization



CABG to improve survival is beneficial in patients with significant (≥70% diameter) stenoses in 3 major coronary arteries (with or without involvement of the proximal LAD artery) or in the proximal LAD plus 1 other major coronary artery.

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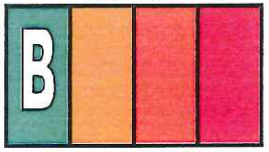
Revascularization to Improve Survival: Non-Left Main CAD Revascularization (cont.)

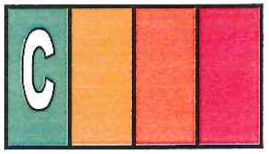
CABG

I IIa IIb III



PCI

I IIa IIb III



CABG or PCI to improve survival is beneficial in survivors of sudden cardiac death with presumed ischemia-mediated ventricular tachycardia caused by a significant (≥70% diameter) stenosis in a major coronary artery.

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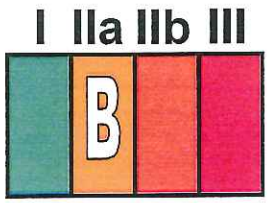
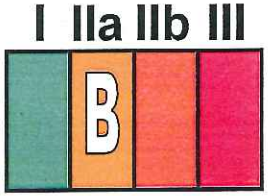
Revascularization to Improve Survival: Non-Left Main CAD Revascularization (cont.)



CABG to improve survival is reasonable in patients with significant (≥70% diameter) stenoses in 2 major coronary arteries with severe or extensive myocardial ischemia (e.g., high-risk criteria on stress testing, abnormal intracoronary hemodynamic evaluation, or >20% perfusion defect by myocardial perfusion stress imaging) or target vessels supplying a large area of viable myocardium.



CABG to improve survival is reasonable in patients with mild-moderate left ventricular systolic dysfunction (ejection fraction 35% to 50%) and significant (≥70% diameter stenosis) multivessel CAD or proximal LAD coronary artery stenosis, when viable myocardium is present in the region of intended revascularization.

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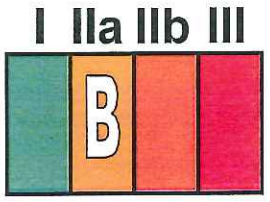
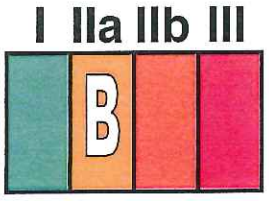
Revascularization to Improve Survival: Non-Left Main CAD Revascularization (cont.)



CABG with a LIMA graft to improve survival is reasonable in patients with a significant (≥70% diameter) stenosis in the proximal LAD artery and evidence of extensive ischemia.



It is reasonable to choose CABG over PCI to improve survival in patients with complex 3-vessel CAD (e.g., SYNTAX score >22) with or without involvement of the proximal LAD artery who are good candidates for CABG.

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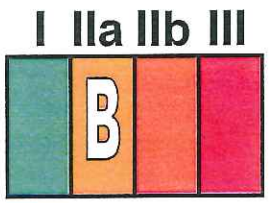
Revascularization to Improve Survival: Non-Left Main CAD Revascularization (cont.)



CABG is probably recommended in preference to PCI to improve survival in patients with multivessel CAD and diabetes mellitus, particularly if a LIMA graft can be anastomosed to the LAD artery.



The usefulness of CABG to improve survival is uncertain in patients with significant (≥70%) stenoses in 2 major coronary arteries not involving the proximal LAD artery and without extensive ischemia.

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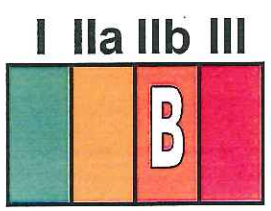
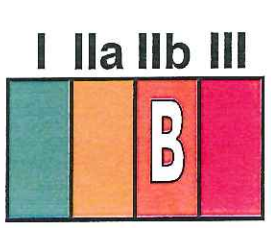
Revascularization to Improve Survival: Non-Left Main CAD Revascularization (cont.)



The usefulness of PCI to improve survival is uncertain in patients with 2- or 3-vessel CAD (with or without involvement of the proximal LAD artery) or 1-vessel proximal LAD disease.



CABG might be considered with the primary or sole intent of improving survival in patients with SIHD with severe LV systolic dysfunction (EF<35%) whether or not viable myocardium is present.



The usefulness of CABG or PCI to improve survival is uncertain in patients with previous CABG and extensive anterior wall ischemia on noninvasive testing.

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Revascularization to Improve Survival: Non-Left Main CAD Revascularization (cont.)



Harm

CABG or PCI should not be performed with the primary or sole intent to improve survival in patients with SIHD with 1 or more coronary stenoses that are not anatomically or functionally significant (e.g., <70% diameter non–left main coronary artery stenosis, fractional flow reserve >0.80, no or only mild ischemia on noninvasive testing), involve only the left circumflex or right coronary artery, or subtend only a small area of viable myocardium.

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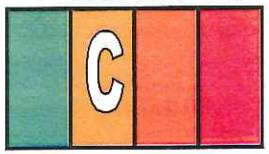
Revascularization to Improve Symptoms



CABG or PCI to improve symptoms is beneficial in patients with 1 or more significant (≥70% diameter) coronary artery stenoses amenable to revascularization and unacceptable angina despite GDMT.



CABG or PCI to improve symptoms is reasonable in patients with 1 or more significant (≥70% diameter) coronary artery stenoses and unacceptable angina for whom GDMT cannot be implemented because of medication contraindications, adverse effects, or patient preferences.

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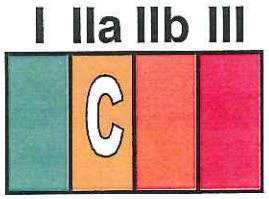
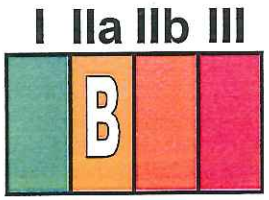
Revascularization to Improve Symptoms (cont.)



PCI to improve symptoms is reasonable in patients with previous CABG, 1 or more significant (≥70% diameter) coronary artery stenoses associated with ischemia, and unacceptable angina despite GDMT.



It is reasonable to choose CABG over PCI to improve symptoms in patients with complex 3-vessel CAD (e.g., SYNTAX score >22), with or without involvement of the proximal LAD artery who are good candidates for CABG.

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Revascularization to Improve Symptoms (cont.)



CABG to improve symptoms might be reasonable for patients with previous CABG, 1 or more significant (≥70% diameter) coronary artery stenoses not amenable to PCI, and unacceptable angina despite GDMT.



Transmyocardial laser revascularization performed as an adjunct to CABG to improve symptoms may be reasonable in patients with viable ischemic myocardium that is perfused by arteries that are not amenable to grafting.

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Revascularization to Improve Symptoms (cont.)



Harm

CABG or PCI to improve symptoms should not be performed in patients who do not meet anatomic (≥50% left main or ≥70% non–left main stenosis) or physiologic (e.g., abnormal fractional flow reserve) criteria for revascularization.

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Dual Antiplatelet Therapy Compliance and Stent Thrombosis

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Dual Antiplatelet Therapy Compliance and Stent Thrombosis



Harm

PCI with coronary stenting (BMS or DES) should not be performed if the patient is not likely to be able to tolerate and comply with DAPT for the appropriate duration of treatment based on the type of stent implanted.

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Hybrid Coronary Revascularization

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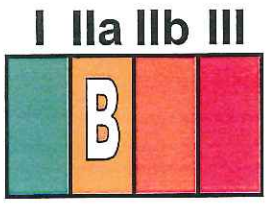
Hybrid Coronary Revascularization



Hybrid coronary revascularization (defined as the planned combination of LIMA-to-LAD artery grafting and PCI of ≥1 non-LAD coronary arteries) is reasonable in patients with 1 or more of the following:

a. Limitations to traditional CABG, such as a heavily calcified proximal aorta or poor target vessels for CABG (but amenable to PCI);

b. Lack of suitable graft conduits;

c. Unfavorable LAD artery for PCI (i.e., excessive vessel tortuosity or chronic total occlusion).

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Hybrid Coronary Revascularization (cont.)



Hybrid coronary revascularization (defined as the planned combination of LIMA-to-LAD artery grafting and PCI of ≥1 non-LAD coronary arteries) may be reasonable as an alternative to multivessel PCI or CABG in an attempt to improve the overall risk-benefit ratio of the procedures.

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Preprocedural Considerations

Radiation Safety

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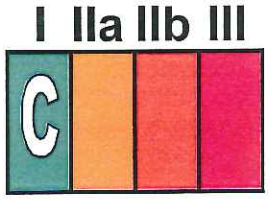
Radiation Safety



Cardiac catheterization laboratories should routinely record relevant available patient procedural radiation dose data (e.g., total air kerma at the international reference point [$K_{a,r}$], air kerma air product [P_{KA}], fluoroscopy time, number of cine images), and should define thresholds with corresponding follow-up protocols for patients who receive a high procedural radiation dose.

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Contrast-Induced Acute Kidney Injury

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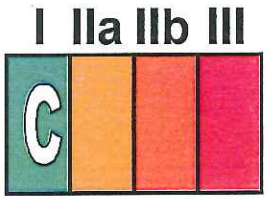
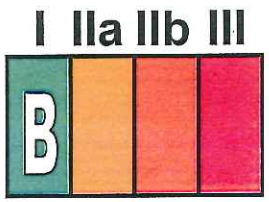
Contrast-Induced Acute Kidney Injury



Patients should be assessed for risk of contrast-induced AKI before PCI.



Patients undergoing cardiac catheterization with contrast media should receive adequate preparatory hydration.



In patients with CKD (Crcl <60 mL/min), the volume of contrast media should be minimized.

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Contrast-Induced Acute Kidney Injury (cont.)



No Benefit

Administration of N-acetyl-L-cysteine is not useful for the prevention of contrast-induced AKI.

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Preprocedural Considerations

Anaphylactoid Reactions

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Anaphylactoid Reactions



Patients with prior evidence of an anaphylactoid reaction to contrast media should receive appropriate steroid and antihistamine prophylaxis before repeat contrast administration.



No Benefit

In patients with a prior history of allergic reactions to shellfish or seafood, anaphylactoid prophylaxis for contrast reaction is not beneficial.

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Preprocedural Considerations

Statin Treatment

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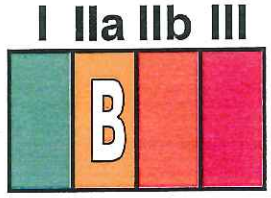
Statin Treatment

Statin-naive patients:



Administration of a high-dose statin is reasonable before PCI to reduce the risk of periprocedural MI.

Patients on chronic statin therapy:



Administration of a high-dose statin is reasonable before PCI to reduce the risk of periprocedural MI.

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Preprocedural Considerations

Bleeding Risk

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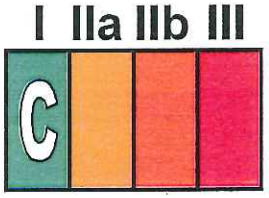
Bleeding Risk



All patients should be evaluated for risk of bleeding before PCI.

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PCI in Hospitals Without On-Site Surgical Backup

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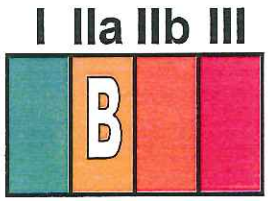
PCI in Hospitals Without On-Site Surgical Backup



Primary PCI is reasonable in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished.



Elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection.

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PCI in Hospitals Without On-Site Surgical Backup (cont.)



Harm

Primary or elective PCI should not be performed in hospitals without on-site cardiac surgery capabilities without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without appropriate hemodynamic support capabilities for transfer.

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Procedural Considerations

Vascular Access

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Vascular Access



The use of radial artery access can be useful to decrease access site complications.

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PCI in Specific Clinical Situations

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PCI in Specific Clinical Situations: UA/NSTEMI



An early invasive strategy (i.e., diagnostic angiography with intent to perform revascularization) is indicated in UA/NSTEMI patients who have refractory angina or hemodynamic or electrical instability (without serious comorbidities or contraindications to such procedures).

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PCI in Specific Clinical Situations: UA/NSTEMI (cont.)



An early invasive strategy (i.e., diagnostic angiography with intent to perform revascularization) is indicated in initially stabilized UA/NSTEMI patients (without serious comorbidities or contraindications to such procedures) who have an elevated risk for clinical events.

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PCI in Specific Clinical Situations: UA/NSTEMI (cont.)



The selection of PCI or CABG as the means of revascularization in the patient with ACS should generally be based on the same considerations as those without ACS.

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PCI in Specific Clinical Situations: UA/NSTEMI (cont.)



No Benefit

An early invasive strategy (i.e., diagnostic angiography with intent to perform revascularization) is not recommended in patients with extensive comorbidities (e.g., liver or pulmonary failure, cancer) in whom

a. The risks of revascularization and comorbid conditions are likely to outweigh the benefits of revascularization,

b. There is a low likelihood of ACS despite acute chest pain, or

c. Consent to revascularization will not be granted regardless of the findings.

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PCI in Specific Clinical Situations: STEMI

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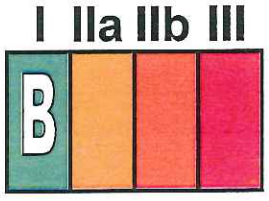
PCI in Specific Clinical Situations: STEMI–Coronary Angiography

Strategies in STEMI



A strategy of immediate coronary angiography with intent to perform PCI (or emergency CABG) in patients with STEMI is recommended for

a. Patients who are candidates for primary PCI.



b. Patients with severe heart failure or cardiogenic shock who are suitable candidates for revascularization.

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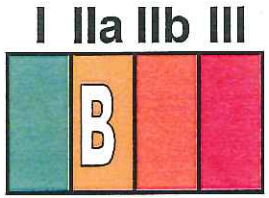
PCI in Specific Clinical Situations: STEMI–Coronary Angiography Strategies in STEMI (cont.)



A strategy of immediate coronary angiography (or transfer for immediate coronary angiography) with intent to perform PCI is reasonable for patients with STEMI, a moderate to large area of myocardium at risk, and evidence of failed fibrinolysis.

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PCI in Specific Clinical Situations: STEMI–
Coronary Angiography Strategies in STEMI (cont.)



A strategy of coronary angiography (or transfer for coronary angiography) 3 to 24 hours after initiating fibrinolytic therapy with intent to perform PCI is reasonable for hemodynamically stable patients with STEMI and evidence for successful fibrinolysis when angiography and revascularization can be performed as soon as logistically feasible in this time frame.

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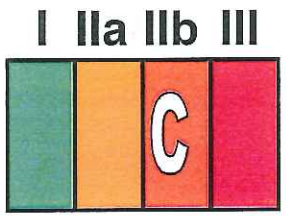
PCI in Specific Clinical Situations: STEMI–Coronary Angiography Strategies in STEMI (cont.)



A strategy of coronary angiography performed before hospital discharge might be reasonable in stable patients with STEMI who did not undergo cardiac catheterization within 24 hours of STEMI onset.

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PCI in Specific Clinical Situations: STEMI–Coronary Angiography Strategies in STEMI (cont.)



No Benefit

A strategy of coronary angiography with intent to perform PCI is not recommended in patients with STEMI in whom the risks of revascularization are likely to outweigh the benefits or when the patient or designee does not want invasive care.

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Procedural Considerations

PCI in Specific Clinical Situations: Primary PCI of the Infarct Artery

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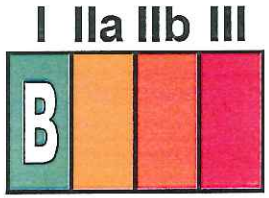
PCI in Specific Clinical Situations: STEMI–Primary PCI of the Infarct Artery



Primary PCI should be performed in patients within 12 hours of onset of STEMI.



Primary PCI should be performed in patients with STEMI presenting to a hospital with PCI capability within 90 minutes of first medical contact as a systems goal.

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PCI in Specific Clinical Situations: STEMI–Primary PCI of the Infarct Artery (cont.)



Primary PCI should be performed in patients with STEMI presenting to a hospital without PCI capability within 120 minutes of first medical contact as a systems goal.



Primary PCI should be performed in patients with STEMI who develop severe heart failure or cardiogenic shock and are suitable candidates for revascularization as soon as possible, irrespective of time delay.

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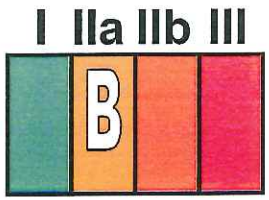
PCI in Specific Clinical Situations: STEMI–Primary PCI of the Infarct Artery (cont.)



Primary PCI should be performed as soon as possible in patients with STEMI and contraindications to fibrinolytic therapy with ischemic symptoms for <12 hours.



Primary PCI is reasonable in patients with STEMI if there is clinical and/or electrocardiographic evidence of ongoing ischemia between 12 and 24 hours after symptom onset.

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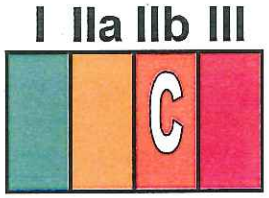
PCI in Specific Clinical Situations: STEMI–Primary PCI of the Infarct Artery (cont.)



Primary PCI might be considered in asymptomatic patients with STEMI and higher risk presenting between 12 and 24 hours after symptom onset.



Harm

PCI should not be performed in a noninfarct artery at the time of primary PCI in patients with STEMI without hemodynamic compromise.

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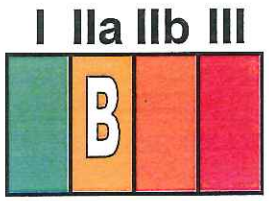
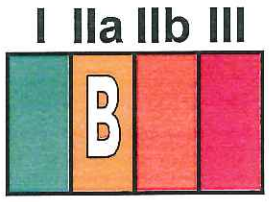
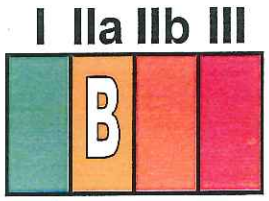
Delayed or Elective PCI in Patients with STEMI



PCI is reasonable in patients with STEMI and clinical evidence for fibrinolytic failure or infarct artery reocclusion.



PCI is reasonable in patients with STEMI and a patent infarct artery 3 to 24 hours after fibrinolytic therapy.



PCI is reasonable in patients with STEMI who demonstrate ischemia on noninvasive testing.

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Delayed or Elective PCI in Patients with STEMI



PCI of a hemodynamically significant stenosis in a patent infarct artery >24 hours after STEMI may be considered as part of an invasive strategy.



PCI of a totally occluded infarct artery >24 hours after STEMI should not be performed in asymptomatic patients with 1- or 2-vessel disease if patients are hemodynamically and electrically stable and do not have evidence of severe ischemia.

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PCI in Specific Clinical Situations: Cardiogenic Shock



PCI is recommended for patients with acute MI who develop cardiogenic shock and are suitable candidates.



A hemodynamic support device is recommended for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacologic therapy.

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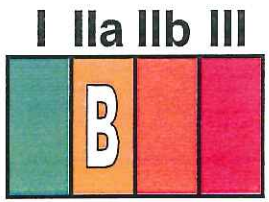
PCI in Specific Clinical Situations: Revascularization Before Noncardiac Surgery



For patients who require PCI and who are scheduled for elective noncardiac surgery in the subsequent 12 months, a strategy of balloon angioplasty, or BMS implantation followed by 4 to 6 weeks of DAPT, is reasonable.

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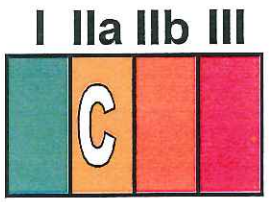
PCI in Specific Clinical Situations: Revascularization Before Noncardiac Surgery



For patients with a DES who must undergo urgent surgical procedures that mandate the discontinuation of DAPT, it is reasonable to continue aspirin if possible and restart the $P2Y_{12}$ inhibitor as soon as possible in the immediate postoperative period.

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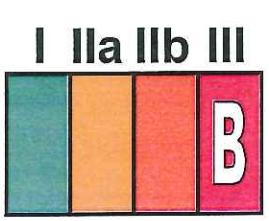
PCI in Specific Clinical Situations: Revascularization Before Noncardiac Surgery



Harm

Routine prophylactic coronary revascularization should not be performed in patients with stable CAD before noncardiac surgery.



Harm

Elective noncardiac surgery should not be performed in the 4 to 6 weeks after balloon angioplasty or BMS implantation or the 12 months after DES implantation in patients in whom the $P2Y_{12}$ inhibitor will need to be discontinued perioperatively.

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Procedural Considerations

Coronary Stents

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Coronary Stents



Before implantation of DES, the interventional cardiologist should discuss with the patient the need for and duration of DAPT and the ability of the patient to comply with and tolerate DAPT.



PCI/STEMI



UA/NSTEMI

DES is useful as an alternative to BMS to reduce the risk of restenosis in cases in which the risk of restenosis is increased and the patient is likely to be able to tolerate and comply with prolonged DAPT.

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Coronary Stents (cont.)



Balloon angioplasty or BMS should be used in patients with high bleeding risk, inability to comply with 12 months of DAPT, or with anticipated invasive or surgical procedures within the next 12 months during which time DAPT may be interrupted.

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Coronary Stents (cont.)



Harm

PCI with coronary stenting should not be performed if the patient is not likely to be able to tolerate and to comply with DAPT.



Harm

DES should not be implanted if the patient is not likely to be able to tolerate and comply with prolonged DAPT, or this cannot be determined prior to stent implantation.

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Adjunctive Diagnostic Devices

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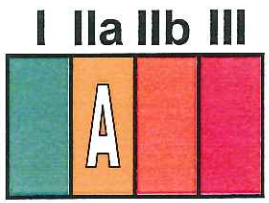
Fractional Flow Reserve



FFR is reasonable to assess angiographic intermediate coronary lesions (50% to 70% diameter stenosis) and can be useful in guiding revascularization decisions in patients with SIHD.

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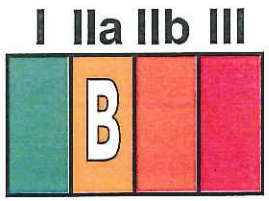
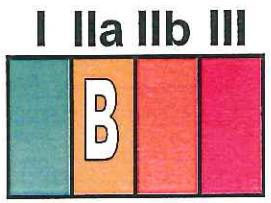
Intravascular Ultrasound



IVUS is reasonable for the assessment of angiographically indeterminate left main CAD.



IVUS and coronary angiography are reasonable 4 to 6 weeks and 1 year after transplantation to exclude donor CAD, to detect rapidly progressive cardiac allograft vasculopathy, and to provide prognostic information.

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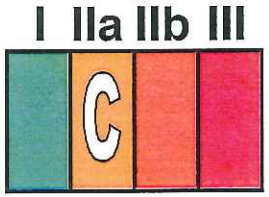
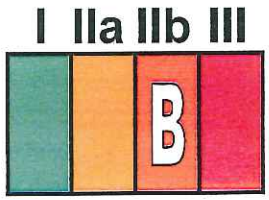
Intravascular Ultrasound (cont.)



IVUS is reasonable to determine the mechanism of stent restenosis.



IVUS may be reasonable for the assessment of non-left main coronary arteries with angiographically intermediate coronary stenoses (50% to 70% diameter stenosis).

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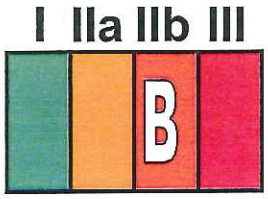
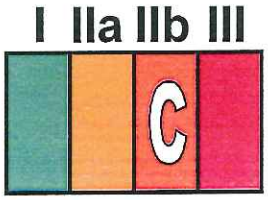
Intravascular Ultrasound (cont.)



IVUS may be considered for guidance of coronary stent implantation, particularly in cases of left main coronary artery stenting.



IVUS may be reasonable to determine the mechanism of stent thrombosis.



No Benefit

IVUS for routine lesion assessment is not recommended when revascularization with PCI or CABG is not being contemplated.

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Procedural Considerations

Adjunctive Therapeutic Devices

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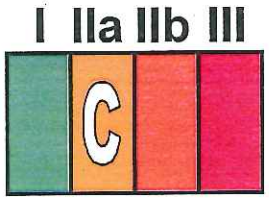
Coronary Atherectomy



Rotational atherectomy is reasonable for fibrotic or heavily calcified lesions that might not be crossed by a balloon catheter or adequately dilated before stent implantation.



No Benefit

Rotational atherectomy should not be performed routinely for de novo or in-stent restenosis.

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Thrombectomy



Aspiration thrombectomy is reasonable for patients undergoing primary PCI.

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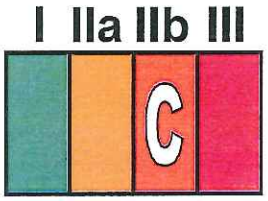
Laser Angioplasty



Laser angioplasty might be considered for fibrotic or moderately calcified lesions that cannot be crossed or dilated with conventional balloon angioplasty.



No Benefit

Laser angioplasty should not be used routinely during PCI.

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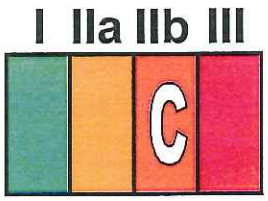
Cutting Balloon Angioplasty



Cutting balloon angioplasty might be considered to avoid slippage-induced coronary artery trauma during PCI for in-stent restenosis or for ostial lesions in side branches.



No Benefit

Cutting balloon angioplasty should not be performed routinely during PCI.

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Embolic Protection Devices



Cutting balloon angioplasty should not be performed routinely during PCI.

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Percutaneous Hemodynamic Support Devices

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Percutaneous Hemodynamic Support Devices



Elective insertion of an appropriate hemodynamic support device as an adjunct to PCI may be reasonable in carefully selected high-risk patients.

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Oral Antiplatelet Therapy



Patients already taking daily aspirin therapy should take 81 to 325 mg prior to PCI.



Patients not on aspirin therapy should be given nonenteric aspirin 325 mg prior to PCI.



After PCI, aspirin should be continued indefinitely.

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Oral Antiplatelet Therapy (cont.)



A loading dose of a $P2Y_{12}$ receptor inhibitor should be given to patients undergoing PCI with stenting. Options include:



a. Clopidogrel 600 mg (ACS and non-ACS patients).

b. Prasugrel 60 mg (ACS patients).

c. Ticagrelor 180 mg (ACS patients).

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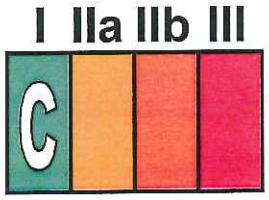
Oral Antiplatelet Therapy (cont.)



The loading dose of clopidogrel for patients undergoing PCI after fibrinolytic therapy should be 300 mg within 24 hours and 600 mg more than 24 hours after receiving fibrinolytic therapy.



Patients should be counseled on the need for and risks of DAPT before placement of intracoronary stents, especially a DES, and alternative therapies should be pursued if they are unwilling or unable to comply with the recommended duration of DAPT.

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Oral Antiplatelet Therapy (cont.)



The duration of $P2Y_{12}$ inhibitor therapy after stent implantation should generally be as follows:

a)In patients receiving a stent (BMS or DES) during PCI for ACS, $P2Y_{12}$ inhibitor therapy should be given for at least 12 months. Options include: clopidogrel 75 mg daily, prasugrel 10 mg daily, and ticagrelor 90 mg twice daily.

b) In patients receiving a DES for a non–ACS indication, clopidogrel 75 mg daily should be given for at least 12 months if patients are not at high risk of bleeding.

c)In patients receiving a BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 month and ideally up to 12 months (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks).

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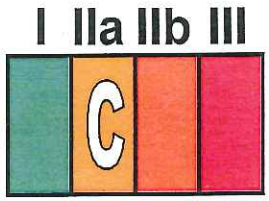
Oral Antiplatelet Therapy (cont.)



After PCI, it is reasonable to use 81 mg per day of aspirin in preference to higher maintenance doses.



If the risk of morbidity from bleeding outweighs the anticipated benefit afforded by a recommended duration of $P2Y_{12}$ inhibitor therapy after stent implantation, earlier discontinuation (e.g., <12 months) of $P2Y_{12}$ inhibitor therapy is reasonable.

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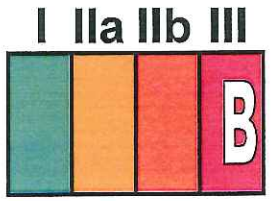
Oral Antiplatelet Therapy (cont.)



Continuation of DAPT beyond 12 months may be considered in patients undergoing DES implantation.



Harm

Prasugrel should not be administered in patients with a prior history of stroke or TIA.

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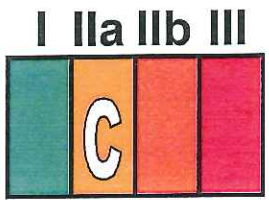
Intravenous Antiplatelet Therapy: STEMI

In patients undergoing primary PCI treated with UFH, it is reasonable to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban), whether or not pretreated with clopidogrel.



For GP IIb/IIIa inhibitor administration in patients not pretreated with clopidogrel.



For GP IIb/IIIa inhibitor administration in patients who are pretreated with clopidogrel.

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Intravenous Antiplatelet Therapy : STEMI (cont.)



In patients undergoing primary PCI with abciximab, it may be reasonable to administer intracoronary abciximab.

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Intravenous Antiplatelet Therapy: STEMI (cont.)



No Benefit

Routine precatheterization laboratory (e.g., ambulance or emergency room) administration of GP IIb/IIIa inhibitors as part of an upstream strategy for patients with STEMI undergoing PCI is not beneficial.

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Intravenous Antiplatelet Therapy : UA/NSTEMI



In UA/NSTEMI patients with high-risk features (e.g., elevated troponin level) not treated with bivalirudin and not adequately pretreated with clopidogrel, it is useful at the time of PCI to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban) in patients treated with UFH.

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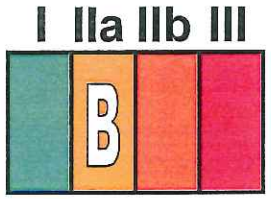
Intravenous Antiplatelet Therapy : UA/NSTEMI (cont.)



In UA/NSTEMI patients with high-risk features (e.g., elevated troponin level) treated with UFH and adequately pretreated with clopidogrel, it is reasonable at the time of PCI to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban).

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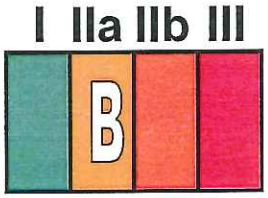
Intravenous Antiplatelet Therapy: SIHD



In patients undergoing elective PCI treated with UFH and not pretreated with clopidogrel, it is reasonable to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban).

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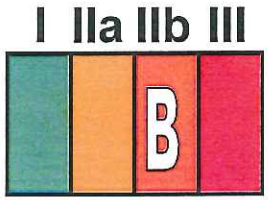
Intravenous Antiplatelet Therapy: SIHD (cont.)



In patients undergoing elective PCI with stent implantation treated with UFH and adequately pretreated with clopidogrel, it might be reasonable to administer a GP IIb/IIIa inhibitor (abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban).

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Antiocoagulant Therapy: Use of Parenteral Anticoagulants During PCI



An anticoagulant should be administered to patients undergoing PCI.

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Antiocoagulant Therapy: UFH



Administration of intravenous UFH is useful in patients undergoing PCI.

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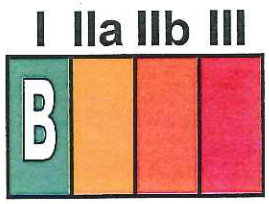
Anticoagulant Therapy: Enoxaparin



An additional dose of 0.3 mg/kg intravenous enoxaparin should be administered at the time of PCI to patients who have received <2 therapeutic subcutaneous doses (e.g., 1 mg/kg) or received the last subcutaneous enoxaparin dose 8 to12 hours prior to PCI.



Performance of PCI with enoxaparin may be reasonable in patients either treated with "upstream" subcutaneous enoxaparin for UA/NSTEMI or who have not received prior antithrombin therapy and are administered intravenous enoxaparin at the time of PCI.



UFH should not be given to patients already receiving therapeutic subcutaneous enoxaparin.

Harm

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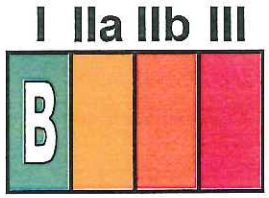
Antiocoagulant Therapy: Bivalirudin and Argatroban



For patients undergoing PCI, bivalirudin is useful as an anticoagulant with or without prior treatment with UFH.



For patients with heparin-induced thrombocytopenia, it is recommended that bivalirudin or argatroban be used to replace UFH.

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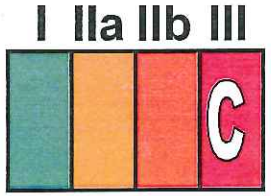
Antiocoagulant Therapy: Fondaparinux



Harm

Fondaparinux should not be used as the sole anticoagulant to support PCI. An additional anticoagulant with anti-IIa activity should be administered because of the risk of catheter thrombosis.

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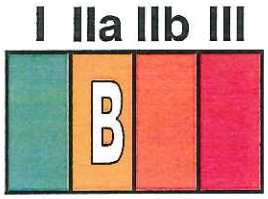
No-Reflow Pharmacologic Therapies



Administration of an intracoronary vasodilator (adenosine, calcium channel blocker, or nitroprusside) is reasonable to treat PCI-related no-reflow that occurs during primary or elective PCI.

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PCI in Specific Anatomic Situations

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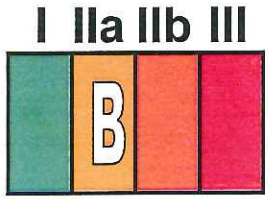
Chronic Total Occlusions



PCI of a CTO in patients with appropriate clinical indications and suitable anatomy is reasonable when performed by operators with appropriate expertise.

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Saphenous Vein Grafts

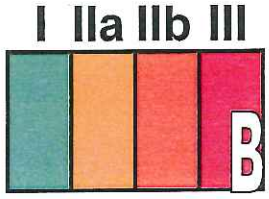


EPDs should be used during SVG PCI when technically feasible.



No Benefit

Platelet GP IIb/IIIa inhibitors are not beneficial as adjunctive therapy during SVG PCI.



Harm

PCI is not recommended for chronic SVG occlusions.

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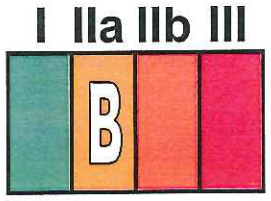
Bifurcation Lesions



Provisional side-branch stenting should be the initial approach in patients with bifurcation lesions when the side branch is not large and has only mild or moderate focal disease at the ostium.



It is reasonable to use elective double stenting in patients with complex bifurcation morphology involving a large side branch where the risk of side-branch occlusion is high and the likelihood of successful side-branch reaccess is low.

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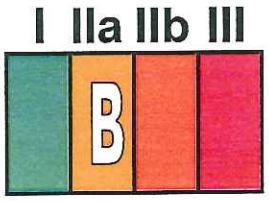
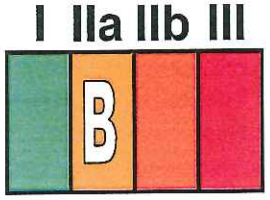
Aorto-Ostial Stenosis



IVUS is reasonable for the assessment of angiographically-indeterminant left main CAD.



Use of DES is reasonable when PCI is indicated in patients with an aorto-ostial stenosis.

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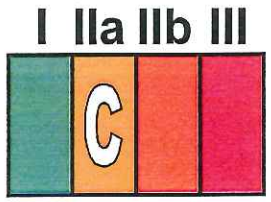
Calcified Lesions



Rotational atherectomy is reasonable for fibrotic or heavily calcified lesions that might not be crossed by a balloon catheter or adequately dilated before stent implantation.

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PCI in Specific Patient Populations

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Chronic Kidney Disease



In patients undergoing PCI, the glomerular filtration rate should be estimated and the dosage of renally-cleared medications should be adjusted.

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Periprocedural Myocardial Infarction Assessment



In patients who have signs or symptoms suggestive of MI during or after PCI, or in asymptomatic patients with significant *persistent* angiographic complications (e.g., large side-branch occlusion, flow limiting dissection, no-reflow phenomenon or coronary thrombosis), creatinine kinase-MB and troponin I or T should be measured.

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Periprocedural Myocardial Infarction Assessment (cont.)



Routine measurement of cardiac biomarkers (creatinine kinase-MB and/or troponin I or T) in all patients post-PCI may be reasonable.

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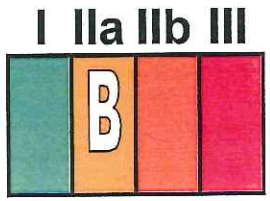
Vascular Closure Devices



Patients considered for vascular closure devices should undergo a femoral angiogram to ensure anatomic suitability for deployment.



The use of vascular closure devices is reasonable for the purposes of achieving faster hemostasis and earlier ambulation compared with the use of manual compression.



No Benefit

The routine use of vascular closure devices is not recommended for the purpose of decreasing vascular complications, including bleeding.

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Postprocedural Antiplatelet Therapy

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Helping Cardiovascular Professionals Learn. Advance. Heal.

American Heart Association.

SCAI The Society for Cardiovascular Angiography and Interventions

Postprocedural Antiplatelet Therapy



After PCI, aspirin should be continued indefinitely.

The duration of $P2Y_{12}$ inhibitor therapy after stent implantation should generally be as follows:

a) In patients receiving a stent (BMS or DES) during PCI for ACS, $P2Y_{12}$ inhibitor therapy should be given for at least 12 months (clopidogrel 75 mg daily); prasugrel 10 mg daily; and ticagrelor 90 mg twice daily.



b) In patients receiving a DES for a non–ACS indication, clopidogrel 75 mg daily should be given for at least 12 months if patients are not at high risk of bleeding.

c) In patients receiving a BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 month and ideally up to 12 months (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks).

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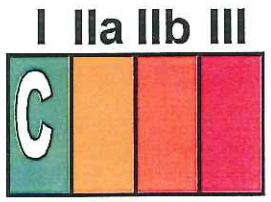
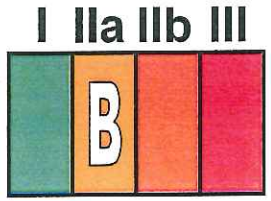
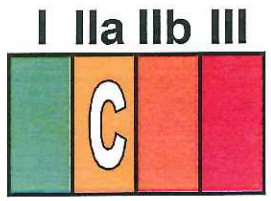
Postprocedural Antiplatelet Therapy (cont.)



Patients should be counseled on the importance of compliance with DAPT, and that therapy should not be discontinued before discussion with the relevant cardiologist.



After PCI, it is reasonable to use 81 mg per day of aspirin in preference to higher maintenance doses.



If the risk of morbidity from bleeding outweighs the anticipated benefit afforded by a recommended duration of $P2Y_{12}$ inhibitor therapy after stent implantation, earlier discontinuation (e.g., >12 months) of $P2Y_{12}$ inhibitor therapy is reasonable.

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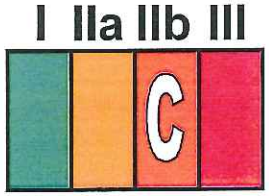
Postprocedural Antiplatelet Therapy (cont.)



Continuation of clopidogrel, prasugrel or ticagrelor beyond 12 months may be considered in patients undergoing DES placement.

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Proton Pump Inhibitors and Antiplatelet Therapy

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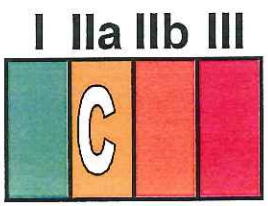
PPIs and Antiplatelet Therapy



PPI should be used in patients with history of prior GI who require DAPT.



PPI use is reasonable in patients with increased risk of gastrointestinal bleeding (advanced age, concomitant use of warfarin, steroids, nonsteroidal anti-inflammatory drugs, H pylori infection, etc.) who require DAPT.



No Benefit

Routine use of a PPI is not recommended for patients at low risk of gastrointestinal bleeding, who have much less potential to benefit from prophylactic therapy.

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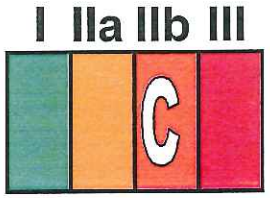
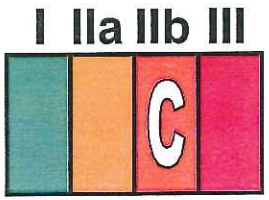
Clopidogrel Genetic Testing



Genetic testing might be considered to identify whether a patient at high risk for poor clinical outcomes is predisposed to inadequate platelet inhibition with clopidogrel.



When a patient predisposed to inadequate platelet inhibition with clopidogrel is identified by genetic testing, treatment with an alternate $P2Y_{12}$ inhibitor (e.g., prasugrel or ticagrelor) might be considered.



No Benefit

The routine clinical use of genetic testing to screen clopidogrel-treated patients undergoing PCI is not recommended.

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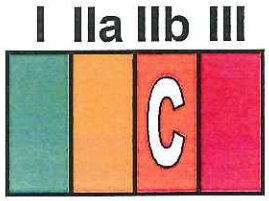
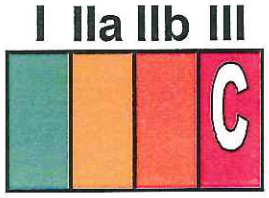
Platelet FunctionTesting



Platelet function testing may be considered in patients at high risk for poor clinical outcomes.



In clopidogrel-treated patients with high platelet reactivity, alternative agents, such as prasugrel or ticagrelor, might be considered.



No Benefit

The routine clinical use of platelet function testing to screen clopidogrel-treated patients undergoing PCI is not recommended.

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Restenosis



Patients who develop clinical restenosis after balloon angioplasty should be treated with BMS or DES if anatomic factors are appropriate and if the patient is able to comply with and tolerate DAPT.



Patients who develop clinical restenosis after BMS should be treated with DES if anatomic factors are appropriate and the patient is able to comply with and tolerate DAPT.

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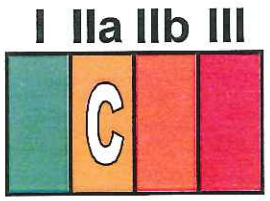
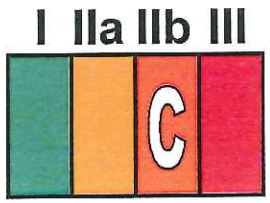
Restenosis (cont.)



IVUS is reasonable to determine the mechanism of stent restenosis.



Patients who develop clinical restenosis after DES may be considered for repeat PCI with balloon angioplasty, BMS, or DES containing the same drug or an alternative antiproliferative drug if anatomic factors are appropriate and patient is able to comply with and tolerate DAPT.

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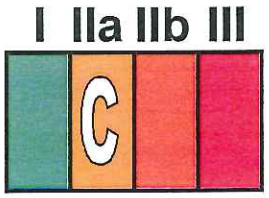
Exercise Testing



In patients entering a formal cardiac rehabilitation program after PCI, treadmill exercise testing is reasonable.



No Benefit

Routine, periodic stress testing of asymptomatic patients after PCI without specific clinical indications should not be performed.

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Cardiac Rehabilitation



Medically-supervised exercise programs (cardiac rehabilitation) should be recommended to patients after PCI, particularly for moderate- to high-risk patients for whom supervised exercise training is warranted.

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Quality and Performance

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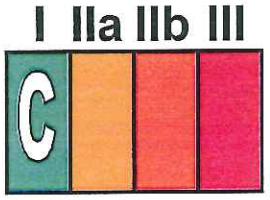
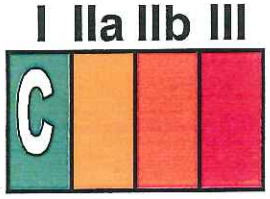
Quality and Performance



Every PCI program should operate a quality improvement program that routinely: a) reviews quality and outcomes of the entire program; b) reviews results of individual operators; c) includes risk adjustment; d) provides peer review of difficult or complicated cases, and; e) performs random case reviews.



Every PCI program should participate in a regional or national PCI registry for the purpose of benchmarking its outcomes against current national norms.

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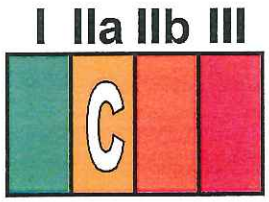
Certification and Maintenance of Certification



It is reasonable for all physicians that perform PCI to participate in the American Board of Internal Medicine interventional cardiology board certification and maintenance of certification program.

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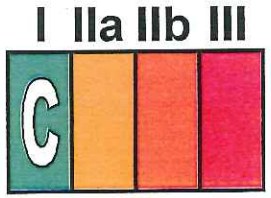
Operator and Institutional Competency and Volume



Elective/urgent PCI should be performed by operators with acceptable annual volume (≥75 procedures) at high-volume centers (>400 procedures) with onsite cardiac surgery.



Elective/urgent PCI should be performed by operators and institutions whose current risk-adjusted outcomes statistics are comparable to those reported in contemporary national data registries.

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Operator and Institutional Competency and Volume (cont.)



Primary PCI for STEMI should be performed by experienced operators who perform more than 75 elective PCI procedures per year and, ideally, at least 11 PCI procedures for STEMI per year. Ideally, these procedures should be performed in institutions that perform more than 400 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year.



It is reasonable that operators with acceptable volume (≥75 PCI procedures per year) perform elective/urgent PCI at low-volume centers (200 to 400 PCI procedures per year) with onsite cardiac surgery.

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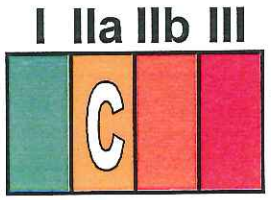
Operator and Institutional Competency and Volume (cont.)



It is reasonable that low-volume operators (<75 PCI procedures per year) perform elective/urgent PCI at high-volume centers (>400 PCI procedures per year) with onsite cardiac surgery. Ideally, operators with an annual procedure volume <75 should only work at institutions with an activity level of more than 600 procedures per year. Operators who perform <75 procedures per year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume of at least 150 procedures per year.

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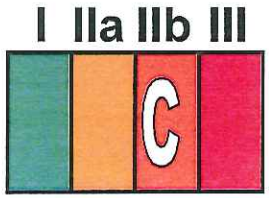
Operator and Institutional Competency and Volume (cont.)



The benefit of primary PCI for STEMI patients eligible for fibrinolysis when performed by an operator who performs <75 procedures per year (<11 PCIs for STEMI per year) is not well established.



No Benefit

It is not recommended that elective/urgent PCI be performed by low-volume operators (<75 procedures per year) at low-volume centers (200 to 400 procedures per year) with or without onsite cardiac surgery. An institution with a volume of <200 procedures per year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer this service.

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Advisory Board Company Daily Briefing

The Daily Briefing

For PCI, no surgeons required

STUDY: ELECTIVE PCI NO LONGER REQUIRES ON-SITE SURGICAL BACKUP

November 16, 2011

Hospitals without on-site cardiac surgery perform elective percutaneous coronary interventions (PCIs) as safely as facilities that have on-site surgical backup, according to a study presented at the **American Heart Association**'s (AHA) annual meeting.

Each year, nearly one million PCIs are performed in the United States, and most of those cases are non-emergency procedures for patients experiencing chest pain. The AHA and the **American College of Cardiologists** currently recommend that PCI be performed only at hospitals that offer coronary artery bypass grafting procedures. Many states also have criteria for which hospitals can offer PCI.

For the first large study to investigate surgical backup for elective PCI procedures, **Johns Hopkins University** researchers assessed data for 4,500 patients who underwent PCI at hospitals with an available cardiovascular surgeon and 14,000 patients who underwent PCI at hospitals without on-site surgical backup. Hospitals performing the procedure with no surgeon on duty were required to complete special PCI training and perform at least 200 PCI procedures annually.

The study found that success, complication, and death rates did not vary between the two patient groups in the six weeks after the procedure. In addition, surgery was only necessary in 30 cases, and patients at hospitals with no on-site surgical backup were transferred to another facility.

The researchers said they hope the findings provide evidence to policymakers that performing elective PCI at smaller community hospitals is safe. However, they warn that not all hospitals should offer the procedure. "Having the ability to perform elective cases, as well as emergency ones, increases quality that comes with more experience," says Thomas Aversano, the study's lead author.

The findings ultimately may prompt regulatory changes that could effectively decouple PCI and open heart surgery, allowing more flexibility for hospitals pursuing a regionalization strategy (Marchione, *AP/Google*, 11/14; *Medical News Today*, 11/15; Phend, *MedPage Today*, 11/14; Phend, *MedPage Today*, 11/15).

November 16, 2011
Daily Briefing

ATTACHMENT X

Curriculum Vitae

FRANK A. CORVINO
408 West Lyon Farm Drive
Greenwich, CT 06831

(203)863-3901 office
(203)344-9612 home

PROFESSIONAL EXPERIENCE

President and Chief Executive Officer	Greenwich Hospital Greenwich, Connecticut	November 1991 - Present
Executive Vice President	Yale New Haven Health System	1998 - Present

Selected Accomplishments:

- Work with Yale New Haven Health System to develop strategic goals and initiatives.
- Facilitated the affiliation with Yale New Haven Health System in 1997.
- Developed a Strategic Plan and Mission Statement in concert with the Board of Trustees, Medical Staff and Community to position Greenwich Hospital for health care delivery in the 21st century.
- Maintained a positive financial position for the institution.
- Aided the Medical Staff in the development of an IPA and developed a hospital-physician partnership.
- Developed integrated approach to health care delivery in the Town of Greenwich.
- Developed and implemented a culture change to the Continuous Quality Improvement philosophy.
- Developed and implemented a communications and community education program.
- Obtained approval from the State of Connecticut for $240 million replacement hospital.
- Developed and opened a free-standing Cancer Center.
- Developed and implemented strategies to increase market share and utilization.
- Led the hospital in its effort to raise $140 million for its Capital Campaign.
- Currently, implementing a plan to effectively downsize and re-engineer the organization to more efficiently deliver higher quality patient care.
- Developed with town government a plan for prevention and wellness.
- Developed a strategic plan with the Board of Directors on affiliations and integration of healthcare.

Chief Operating Officer	Greenwich Hospital	July 1988- November 1991

Selected Accomplishments:

- Responsible for all inpatient and outpatient hospital operations as well as operations of subsidiary corporations of Greenwich Hospital Association Corporation, the Holding Company. These subsidiaries include the following: two walk-in centers, nurse registry, for-profit pharmacy, and real estate company.
- Worked with the President to develop goals and objectives for the hospital and sister corporations in concert with policies set forth by the Board.
- Developed and implemented a marketing and planning department.
- Worked with the Chief Financial Officer in a multi-disciplinary committee structure to reduce accounts receivable by 60 days.
- Developed and implemented a new Quality Assurance, Risk Management Program.
- Worked with the Connecticut Commission on Hospitals and Health Care, the Greenwich Planning and Zoning Commission, and the Building Committee of the Board in preparation for an $117 million renovation and expansion project which includes a free-standing Cancer Center, a 610-car parking garage and modernization of the main hospital.

Chief Operating Officer/Executive Vice President	Our Lady of Mercy Medical Center Bronx, New York	September 1987 - July 1988

Selected Accomplishments:

- Responsible for all inpatient and outpatient hospital operations.
- Worked with the Board of Trustees, Administrative Staff and Medical Staff to develop a strategy for dealing with the nursing shortage.
- Implemented policies and procedures which brought the Medical Center into compliance with new Quality Assurance and Credentialing Regulations.
- Developed a free-standing Department of Emergency Medicine and insured compliance with EMS 911 receiving hospital standards.
- Participated in corporate restructuring plan at Our Lady of Mercy Medical Center in which OLM Holding Company and its subsidiaries were formed.
- Participated in planning and negotiations for acquisition or merger of other health care facilities.

Senior Vice President Professional Services	Our Lady of Mercy Medical Center	July 1986 - September 1987

Selected Accomplishments:

- Worked with Staff to improve clinical departmental operations in order that optimum patient care be delivered in a cost effective efficient way.
- Coordinated application and participated in on-site visit which led to approval of a free-standing residency program in Obstetrics and Gynecology in 1987.
- Developed a program to bring the Institution into compliance with Organ Donation Law.
- Implemented a system of generic screens in the Utilization Review - Quality Assurance departments.
- Developed a working relationship with the Medical Staff in both problem solving an institutional policies and procedures.
- Implemented a guest relations program.

Vice President Medical Support Services	Our Lady of Mercy Medical Center	September 1981 - July 1986

Selected Accomplishments:

- Implemented a computer and case mix management system for Admitting, Medical Records and Utilization Review.
- Designed and implemented a pre-admission testing center.
- Developed a process for effectively dealing with Federal Medicare regulations and Peer Review Organizations.
- Developed policies and strategies which have increased admissions, decreased length of stay and increased efficiency of ancillaries.
- Made numerous educational presentations on all facets of hospital administration at the national, statewide and local level.

Director of Pharmacy and Materials Management	Our Lady of Mercy Medical Center	February 1980 - September 1981

Selected Accomplishments:

- Formulated and implemented a materials management system.
- Coordinated equipment purchase for a $54 million expansion and renovation project.

Director of Pharmacy Services	Our Lady of Mercy Medical Center	February 1979 - February 1980
Asst. Director of Pharmacy Services	Our Lady of Mercy Medical Center	March 1973 - February 1979
Staff Pharmacist	Our Lady of Mercy Medical Center	June 1971 - February 1973

EDUCATION

Fordham University, B.S.	1971
St. John's University, M.S.	1973

FACULTY POSITIONS

New York Medical College - September 1985 - 1990
Clinical Assistant Professor
School of Community and Preventive Medicine

St. John's University - September 1973 - 1988
College of Pharmacy and Allied Health Professions
Affiliated Clinical Professor of Clinical Pharmacy

COMMUNITY AND PROFESSIONAL AFFILIATIONS

- Member - Board of Trustees - Connecticut Hospital Association, 1994 - 2000
- Member - Board of Directors, United Way of Greenwich, 1992 - 1996
- Member - Board of Directors, Boys & Girls Club of Greenwich, 1993 - 1995
- Member - Rotary International, Greenwich Chapter, 1990 - 1994
- Member - American College of Health Care Executives
- Member - Board of Directors, Connecticut Hospital Association Workers' Compensation Trust, 1991 - 1993
- Member of the Board of Pharmacy, Department of Education, State of New York, 1985 – 1988
- Member - Board of Trustees – Norwalk Community College, 2005 to present
- Member – Board of Trustees – Providence Rest Nursing Home, 2003
  Chairman - 2008

EUGENE J. COLUCCI

76 Wilmot Road
Scarsdale, New York 10583
(914) 725-8509

EXPERIENCE

GREENWICH HOSPITAL 1989 to Present
Greenwich, Connecticut

CHIEF FINANCIAL OFFICER

Direct all areas of financial management for a 176-bed acute care facility. These include General Accounting, Budget, Reimbursement, Accounts Receivable, Credit, Collections, Registration, Medical Records, Case Management and Information Systems. Oversee a staff of 225 employees, including the hiring and supervision of management staff. Investigate, plan and monitor areas for new business development. Review investment strategies and develop long and short-term plans to maximize return on assets.

THE MOUNT VERNON HOSPITAL 1985 to 1989
Mount Vernon, New York

CHIEF FINANCIAL OFFICER/CONTROLLER
Direct all aspects of financial management for a 223-bed acute care facility. These include General Accounting, Medical Records, Purchasing, Budget, Reimbursement, Accounts Receivable, Credit, Collections, Admissions and Data Processing Departments. Oversee a staff of 120 employees, including the hiring and supervision of management staff. Investigate, plan and monitor areas for new business development. Review investment strategies and develop long and short-term plans to maximize return on assets.

TOUCHE ROSS & COMPANY 1981 to 1985
New York, New York

AUDIT MANAGER

Supervised financial audits of hospitals. Prepared analyses and reports utilizing various software packages on personal computers. Assisted clients in implemented procedures to ensure collection of detailed financial information.

NEW YORK CITY HEALTH AND HOSPITALS CORP. 1977 to 1981
New York, New York

ASSISTANT DIRECTOR OF REIMBURSEMENT

Coordinated reimbursement reports and third party audits for 18 hospitals and 5 SNFs. Initiated Medicare appeals for cost adjustments.

BLUE CROSS AND BLUE SHIELD 1976 to 1977
New York, New York

AUDITOR

Conducted Blue Cross, Medicaid and Medicare audits on the uniform financial reports.

EDUCATION

ST. JOHN'S UNIVERSITY, Jamaica, New York
M.B.A. - 1979

NIAGARA UNIVERSITY, Niagara Falls, New York
B.B.A. Accounting – 1976

CERTIFICATION

Certified Public Accountant, State of New York – 1984

AFFILIATIONS

American Institute of Certified Public Accountants
New York State Institute of Certified Public Accountants
Healthcare Financial Management Association

REFERENCES

Available upon request.

QUINTON J. FRIESEN
2 Revere Road
Riverside, Connecticut 06878

(203) 863-3903 Office
(203) 698-1722 Home

SUMMARY OF QUALIFICATIONS

Hospital executive with proven track record achieving operational improvements in a highly competitive environment. Career reflects thirty-five years of progressively responsible positions in all aspects of hospital operations, total quality management, budget and financial performance, strategic planning, policy analysis, program planning and implementation.

PROFESSIONAL EXPERIENCE

Executive Vice President - and Chief Operating Officer — **Greenwich Hospital, Greenwich, Connecticut (174 bed, community teaching hospital, $280 million budget, 1600 employees)** — **2003 – Present**

Senior Vice President - and Chief Operating Officer — **Greenwich Hospital** — **1993 - 2003**

Selected Accomplishments:

- **Reorganized hospital around six service lines; recruited and appointed program directors. Wrote program strategic plans, implemented strategic plans.**
- **Directed hospital re-engineering and redesign process designed to streamline major hospital systems and to significantly reduce hospital costs.**
- **Lead facility program planning effort to construct a 400,000 sq. ft. replacement facility valued at $230 million. Coordinated with finance, legal, zoning and planning.**
- **Supervised new hospital construction; directed activation/occupancy process; facilitated training of physicians, staff and volunteers.**
- **Lead and facilitated service excellence, resulting in patient satisfaction greater than or equal to 98% for nine years.**
- **Installed hospital productivity reporting system with benchmark standards in all operating departments; implemented variable staffing system.**
- **Directed efforts to write mission, vision, values, and goal statements in all operating departments; 650 employees participated in writing departmental mission, vision, values, and goal statements.**
- **Lead interventional cardiology program planning and implementation.**

1991-1993

Executive Vice President - and Chief Operating Officer — **Champlain Valley Physicians Hospital Medical Center, Plattsburgh, New York (420 beds, rural referral center, $66 million budget, 1,500 employees)**

Selected Accomplishments:

- **Developed strategic and operational plan to revitalize Human Resources function; introduced organizational development activities; recruited and appointed Vice President/Human Resources to provide organizational leadership; organized policy/ procedure writing process, and coordinated implementation of two first term union contracts.**

- Directed planning and implementation of hospital-wide managerial/supervisory compensation system, pay practices clarified, and compensation policy and procedure written.

- Implemented hospital-wide team building effort involving nearly 140 department managers and supervisors; directed successful effort to write hospital mission, vision, and values statement linked with 45 department mission, vision, and values statements.

- Built total quality management infrastructure; established and currently implementing four quality management teams who are studying their customers' needs and wants, and what can be done to improve customer satisfaction.

- Organized and directed more than 30 departmental total improvement teams.

- Negotiated hospital based physician contracts that resulted in appropriate renewal terms while maintaining positive medical staff/administration relations.

- Established physician/administrative capital budget committee to review and recommend purchase of capital budget items.

1981 - 1991

Vice President - The Valley Hospital, Ridgewood, New Jersey
(421 beds, $118 million budget, 2,200 employees)

1980 - 1981

Assistant Director - The Valley Hospital, Ridgewood, New Jersey

Selected Accomplishments:

- Organized and managed installation of cardiac surgery/angioplasty program that completed nearly 400 cases in its first year of operation. Program implemented in 139 days.

- Directed planning process for new facilities valued in excess of $45 million; facilities occupied and functioning as planned, included OR, Lab, Radiology, and Obstetrics.

- Planned and implemented four hospital joint ventures that opened a free standing magnetic resonance imaging center - $3.6 million capitalization accomplished through a SEC registered offering.

- Created and organized hospital/medical staff (MeSH) organization; recruited and enrolled 145 physicians representing 14 departments; organized MeSH sponsored preferred provider organization which is available to approximately 6,000 employees and dependents; $650,000 claims first year.

- Recruited and trained new managerial leadership; built management skills; developed managerial training programs, resolved chronic medical staff complaints; improved morale, and reduced turnover rates (14%).

- Directed installation of hospital material management program (actual cost of supplies/admission decreased 1986 vs. 1985).

- Extensive experience working with the medical staff; planned and implemented new medical programs; resolved medical staff concerns.

1975 - 1980

Assistant Vice President - Rhode Island Hospital, Providence, Rhode Island
(719 bed university teaching hospital, 4,000 employees, 250 residents, 60 full time M.D. faculty)

Selected Accomplishments:

- Planned construction of $25 million emergency trauma and operating room facility; wrote role and program specifications.

- Reorganized outpatient clinics into decentralized subsidiary corporation group practices and directed implementation of free standing ambulatory surgery program that serves more than 6,000 patients per year.

1970 - 1973

Staffing Coordinator - Methodist Hospital, St. Louis Park, Minnesota
(475 beds, suburban community hospital)

- Introduced a management engineering based patient classification nurse staffing program with documented savings of $220,000 in first year of operation.

EDUCATION

University of Minnesota, Minneapolis, Minnesota, Master of Hospital Administration - 1975
Administrative Residency, Mount Sinai Hospital, Minneapolis, Minnesota

Tabor College, Hillsboro, Kansas; Bachelor of Arts in Business Administration - 1970

PROFESSIONAL AND COMMUNITY AFFILIATIONS

Fellow - American College of Healthcare Executives

Past Board Member - Valley Health Services and MRI of Northern New Jersey

Past Chairman - Private Academy, Hawthorne, New Jersey

TEACHING EXPERIENCE IN HEALTHCARE MANAGEMENT

Adjunct Faculty – St. Peter College, Englewood Cliffs, NJ 1981 - 1990
Adjunct Faculty – Providence College, Providence, RI 1976 - 1980
Guest Lecturer – Columbia University, Yale University
Preceptor in Healthcare Management, Yale University

Marc Kosak PT, MBA, FACHE
59 Brookside Dr. Trumbull, CT 06611 (203) 268-5217
CT License # 007447

Experience

GREENWICH HOSPITAL GREENWICH, CONNECTICUT
Vice President, Administration **Sept. 2008 - Present**

Responsible for the operations of various clinical and non clinical areas of the hospital. Work closely with the Hospital's Chief Operating Officer and Senior Vice President Health Systems Development on hospital wide projects and initiatives.

Administrative Director, Physical Medicine & Occupational Health Services **Jan. 2004 – Sept. 2008**

Direct an interdisciplinary team of 66 employees across multiple physical locations. Responsible for all operations/finances/program planning over 4 separate cost centers. Set mission/vision over these areas. Scored as a Tier 1 department on employee opinion survey. Improved overall Press Ganey mean scores for areas surveyed from 92.1 to 94.1. Increased outpatient Physical Medicine volume 47%. Initiated implementation of electronic medical record. Wrote business plan which gained board approval for new satellite physical medicine site. Successfully planned for and activated the site. Completed Dale Carnegie, Six Sigma, 21st Century Leadership and Lean Training.

BURKE REHABILITATION HOSPITAL WHITE PLAINS, NEW YORK
Administrator, Rehabilitation Services **Mar. 2002 –Jan. 2004**
(Terence Cardinal Cooke Health Care Center, New York New York)

Manage an Interdisciplinary Department of 37 FTE's (Audiology, Occupational, Physical and Speech Therapy), with a 2 million dollar operating budget. Accountable for all rehabilitation services in a 729-bed, multi-diagnostic Skilled Nursing Facility, and Article 16 Developmental Disabilities outpatient clinic. Specialties include Geriatrics, Short Term Rehabilitation, Dialysis, Huntington's Disease, Alzheimer's Disease, End Stage Pulmonary Disorders, Discrete Units for Residents with AIDS, and an OMRDD governed 50-bed Pediatric Hospital. Reduced overtime and salary costs, improved Medicare/Medicaid compliance, instituted productivity standards, improved performance improvement measures and overall efficiency of the department.

Coordinator Network Development **Jan 2001 – March 2002**

Responsible for the coordination and development of a multi-institutional rehabilitation continuum of care. Implement systems of productivity and outcomes measurement. Coordinate staffing for off site departments. Collaborate with department managers to coordinate consistent treatment protocols, and quality of care standards.

Director of Rehabilitation **Jul. 1999 – Dec. 2000**
(The Wartburg, Mount Vernon New York)

Responsible for the interdisciplinary management of the rehabilitation department including, Audiology, Occupational, Physical, and Speech Therapy. Settings include Sub Acute Rehabilitation, Long Term Care, Adult Day Care, Assisted Living and Outpatient Services. Created and completed performance improvement and quality assurance reports relative to the department. Reviewed and revised policies and procedures to comply with JCAHO, CARF, and DOH standards. Acted as a liaison between staff and administration. Participated on the program evaluation, falls risk, and safety committees. Responsible for creating and monitoring department budget. Worked with MDS coordinator and finance department ensuring that rehabilitation documentation and billing were in compliance with Medicare/Medicaid/PPS guidelines.

Physical Therapy Supervisor **Oct. 1996 – Jul. 1999**

Responsible for the day-to-day operations on a dedicated stroke unit. Acted as a liaison between staff physical therapists and other disciplines. Provided supervision, and acted as a mentor, fostering professional growth and education. Responsible for orienting new staff and for writing scheduled performance evaluations. Completed quality management and research studies specific to the stroke population. Served on the cross training committee and professional advisory committee.

Senior Physical Therapist **Jan. 1996 - Oct. 1996**

Assisted supervisor with daily tasks of unit. Co - Treated with new staff. Instructed multiple physical therapy students. Treated caseload appropriate to the stroke unit employing varied techniques learned from continuing education courses. Wrote evaluations on the performance of physical therapy aides. Conducted research in conjunction with supervisor and physician.

Staff Physical Therapist **May. 1994 - Jan. 1996**

Provided physical therapy care to adult inpatients with various cardiac, orthopedic and neurological disorders. Gave patient and family education lectures on stroke, congestive heart failure, and physical conditioning.

MERCY COLLEGE DOBBS FERRY, NEW YORK

Clinical Faculty **Jan. 1997 - Sept 1998**

Responsible for planning lessons and instructing college level students in kinesiology lab exercises. Assisted in creating and grading examinations.

THE THERAPY RESOURCE CENTER MIDDLETOWN, NEW YORK

Physical Therapist **Apr. 1997 - Feb 1998**

Responsible for the evaluation and treatment of residents at the Richmond Children's Center. Evaluated and treated Clients with Profound Cerebral Palsy. Trained nurses and aides.

HOME THERAPISTS ASSOCIATION ARDSLEY, NEW YORK

Home Care Physical Therapist **Aug. 1994 - Feb. 1995**

Provided home care physical therapy to patients with orthopedic, neurologic, pulmonary, and cardiac disorders. Trained home health aides to care for the clients by following through with written home exercise programs.

Presentations

- BRYN MAYR REHABILITATION BRYNMAYR, PENNSYLVANIA
  Body Weight Supported Treadmill Training **Jan. 1997**

- 23rd INTERNATIONAL CONFERENCE ON STROKE AND CEREBRAL CIRCULATION ANAHEIM, CALIFORNIA
  Body Weight Supported Treadmill Training **Feb. 1997**

- BURKE REHABILITATION HOSPITAL WHITE PLAINS, NEW YORK
  Stroke Rehabilitation: Early Mobility **Sept. 1998**

- NORTH AMERICAN STROKE MEETING CANCUN, MEXICO
  Body Weight Supported Treadmill Training **Oct. 1998**

- NORTH AMERICAN STROKE MEETING ASPEN, COLORADO
  Effectiveness of KAFO's in Patients with Stroke **Oct. 1999**

- AMERICAN COLLEGE OF HEALTHCARE EXECUTIVES CHICAGO, ILLINOIS
  Creating and Managing a Multi-Institutional Rehabilitation Continuum of Care **Mar. 2001**

- AMERICAN COLLEGE OF HELATHCARE EXECUTIVES — CHICAGO, ILLINOIS
  Rehabilitation Outcomes in Sub-Acute Care — **Mar. 2003**

Publications

- STROKE; Jan. 1997
  Body Weight Supported Treadmill Training vs. Traditional Physical Therapy
- JOURNAL OF STROKE AND CERBRAL VASCULAR DISEASES; Sept. – Oct. 1998
  Early Aggressive Mobilization is as Effective as Treadmill Training for Ambulation Recovery in Patients with Stroke
- JOURNAL OF STROKE AND CERBRAL VASCULAR DISEASES; Sept. – Oct. 1999
  Effectiveness of Knee-Ankle-Foot-Orthoses in Patients with Stroke
- NEUROREHABILITATION AND NEURAL REPAIR; March 2000
  Comparison of Partial Body Weight Supported Treadmill Gait Training vs. Aggressive Brace Assisted Walking Post Stroke
- AMERICAN COLLEGE OF HEALTHCARE EXECUTIVES, March 2001
  Creating and Managing a Multi-Institutional Rehabilitation Continuum of Care
- AMERICAN COLLEGE OF HEALTHCARE EXECUTIVES, March 2003
  Rehabilitation Outcomes in Sub-Acute Care
- JOURNAL OF REHABILITATION RESEARCH AND DEVELOPMENT, January/February 2005
  Comparison of the 2-, 6-, and 12-Minute Walk Tests in Patients with Stroke

Education and Certifications

DAEMEN COLLEGE — AMHERST, NEW YORK
B.S. in Physical Therapy — **May, 1994**
CUM LAUDE

UNIVERSITY OF PHOENIX
M.B.A with concentration in Healthcare Management — **April, 2006**

CERTIFIED NEURO DEVELOPMENTAL TREATMENT IN ADULTS WITH HEMIPLEGIA — **March, 1998**

DALE CARNEGIE TRAINING — **March, 2005**

SIX SIGMA GREENBELT — **November, 2005**

GREENWICH HOSPITAL MENTOR — **January, 2006**

YNHHS 21st CENTURY LEADERSHIP — **June, 2006**

FELLOW OF THE AMERICAN COLLEGE OF HEALTHCARE EXECUTIVES — **November, 2007**

YNHHS CERTIFIED LEAN PRACTITIONER — **June, 2008**

CURRICULUM VITAE:

Name: Christopher J. Howes, M.D, F.A.C.C, F.A.S.E.

Appointment
Assistant Professor of Medicine, Department of Internal Medicine, Clinician Educator Track

Term: July 1, 2010 to June 30, 2013

School Assignment: Yale University School of Medicine

Born: March 27, 1962

Education: B.A., Brown University 1984
M.D., Albert Einstein College of Medicine, 1989

Career: 1989-1990 Intern, Internal Medicine, Yale-New Haven Hospital, New Haven, CT
1990-1992 Resident, Internal Medicine, Yale New Haven Hospital, CT
1992-1993 Attending Physician, West Haven VAMC, West Haven, CT
1993-1997 Cardiovascular Fellow, Yale University School of Medicine, New Haven, CT
1997-present Assistant Professor, Department of Internal Medicine, Section of Cardiology, YSM, New Haven, CT

Administrative Positions:
1997-2000 Director Outpatient CV services WHVA, West Haven CT.
2000-2005 Medical Director Echo Lab, Branford Cardiology Clinic
2005-present: Medical Director of PAMI program and Cath Lab, Greenwich Hospital

Board Certification:

National Board of Medical Examiners	1990
American Board of Internal Medicine (ABIM)	1992, recertified 2002
ABIM: Cardiovascular Medicine	1997, recertified 2007
ABIM: Interventional Cardiology	1999, recertified 2009
National Board of Echocardiography	2001

Professional Honors or Recognition:

A) 2008, 2009, 2010 Castle Connolly Top Doctors: Interventional Cardiology, NY area
2001 Fellow American Society of Echocardiography
1998 Fellow American College of Cardiology
1989 A.O.A Medical Student Honor Society

B) 2006-7 Housestaff "Teacher of Year" award: Greenwich Hospital
2010-11 Housestaff "Teacher of the Year award: Greenwich Hospital

Grant History for last 12 years:
The Ethel F. Donahue Women's Health Investigator Program at Yale
#1003737.HOWES1.R02524
The effect of antidepressant medication on nitric oxide synthase in platelets and endothelial function in women. P.I. Christopher J. Howes, M.D. 5% total effort, $50,000, 2/01 -2/02, extended -6/03. Expired.

Professional Service

Journal Service

2008-present: Reviewer Southern Medical Journal

Policy Review

2004-present: Anthem BC/BS medical policy & appropriateness criteria.

Yale University Service

2004-2006: YNHH Credentials committee
2005-present: Int. Med. Housestaff Interviews (Greenwich Hospital)
2002-2005: YSM Internal Medicine Housestaff Interviews
1997-present: Cath Lab committee

Public Service

2005-present: Guest Speaker- Heart Awareness Month WGCH (radio) & GCTV
2005-present Guest Speaker: Community Health at Greenwich Hospital

Bibliography:

1. Peer Reviewed

Krumholz HM, **Howes CJ**, Murillo J, Vaccarino V, Radford MJ, Ellerbeck E: Validation of a clinical prediction rule for left ventricular ejection fraction after myocardial infarction in patients greater or equal 65 years old. Am J Card. 7/97, 80 (1): 11-15

Howes CJ, Reid CM, Brandt C, et al: Exercise tolerance and quality of life in elderly patients with chronic atrial fibrillation. J. of Cardiovascular Pharmacology & Therapeutics. 1/01, 6(1): 23-9

Patel PB. Pfau SE. Cleman MW. Brennan JJ. **Howes C**. Remetz M. Cabin HS. Setaro JF. Rinder HM. Comparison of coronary artery specific leukocyte-platelet conjugate formation in unstable versus stable angina pectoris. American Journal of Cardiology. 93(4):410-3, 2004 Feb 15.

Ranjbaran H. Sokol SI. Gallo A. Eid RE. Iakimov AO. D'Alessio A. Kapoor JR. Akhtar S. **Howes CJ**. Aslan M. Pfau S. Pober JS. Tellides G. An inflammatory pathway of IFN-gamma production in coronary atherosclerosis. Journal of Immunology. 178(1):592-604, 2007 Jan 1.

2. Case Reports

Weisman G. Scandrett, RM. **Howes CJ.** Russell RR 3rd: Coronary vasospasm during an adenosine stress test. Journal of Nuclear Cardiology. 11(6): 747-50 2004 Nov-Dec.

3. Reviews

Howes CJ: Percutaneous Angioplasty: Debulking Techniques. Applications in Imaging, Cardiac Interventions. 8/97, 17-25

Howes CJ: Atrial fibrillation in the elderly: Who is at risk. Am J of Geriatric Card. 9/98, 7 (5), 13-23

Howes CJ, Ezekowitz MD: Editorial: Alternate-day dosing of aspirin in atrial fibrillation: a critical evaluation. Am Heart J. 7/99, 138(1): 13

MARNA PARKE BORGSTROM

Home: 458 Three Mile Course
Guilford, Ct. 06437

(203) 453-8782

Business: Yale-New Haven Hospital
20 York Street
New Haven, CT 06510
(203) 688-2608

EDUCATION

1977-1979 Yale University School of Medicine
Department of Epidemiology and Public Health
Program in Hospital Administration, M.P.H.

1972-1976 Stanford University
Bachelor of Arts in Human Biology awarded June, 1976

EXPERIENCE

2005-Present President and Chief Executive Officer: Yale New Haven Health System (YNHHS)

Yale New Haven Health System is a regional, integrated health care delivery system composed of three local health care delivery networks,as well as a physician foundation, Northeast Medical Group. Anchored by Yale-New Haven Hospital, the Yale-New Haven Children's Hospital, and the Yale-New Haven Psychiatric Hospital totaling 1008-beds, the System includes a Bridgeport network led by the 425-bed Bridgeport Hospital and a Greenwich network anchored by 180-bed Greenwich Hospital. Westerly Hospital (Rhode Island) is a network participant.

Feb. 2012 - Present Chief Executive Officer: Yale-New Haven Hospital and Delivery Network (YNHH)

2005- Feb. 2012 President and Chief Executive Officer: Yale-New Haven Hospital and Delivery Network (YNHH)

Yale-New Haven, a private not-for-profit 1008-bed hospital founded in 1826. It serves as the primary teaching hospital for the Yale University School of Medicine and provides tertiary and quaternary patient care for patients referred, as well as general acute care services for the Greater New Haven metropolitan area.

1993-2005 Executive Vice President & Chief Operating Officer: Yale-New Haven Hospital
Executive Vice President and Secretary: Yale-New Haven Health Services Corporation

Responsible for New Haven Delivery Network operations including Yale-New Haven Hospital operations, finance, human resources and planning and marketing; and Yale-New Haven Ambulatory Services Corporation, which operates two independent surgery centers and a large, full-service radiology business in New Haven and Guilford. Served as the senior Hospital interface for Yale School of Medicine operational issues.

Represented the YNHH Delivery Network in all Health System strategic and operational activities.

1992-1993 Senior Vice President, Administration: Yale-New Haven Hospital
Senior Vice President and Secretary: Yale-New Haven Health Services Corporation

Responsible for Hospital strategic planning and marketing, facilities planning and design, risk management and medicolegal affairs, managed care contracting, Service Quality Improvement, Community Relations, Public Affairs and Engineering.

Project Executive for implementation of Yale-New Haven's $156 million Facilities Renewal Project.

1985-1992 Vice President, Administration: Yale-New Haven Hospital

Responsible for Hospital strategic planning and marketing, facilities planning and design, risk management and medicolegal affairs, managed care contracting, Service Quality Improvement, Community Relations, Public Affairs and Engineering. Provided administrative leadership to Yale-New Haven Health Services Corporation corporate affairs and strategic initiatives.

1984-1985 Assistant Vice President: Yale-New Haven Hospital

Directed the development and implementation of annual Hospital business plan format derived from strategic plan. Completed $6 million renovation of Hospital clinical laboratories. Represented Hospital on underwriting and eligibility and finance activities in malpractice insurance captive.

Dec. 1982-1984 Associate Administrator: Yale-New Haven Hospital

Responsible for Hospital planning activities, including Strategic Planning and general facilities planning and related capital budget activities. Also responsible for Clinical Laboratories ($23 million gross revenue and $11 million expense) and Risk Management and Medicolegal Affairs.

Dec. 1980-Nov. 1982 Assistant Administrator: Yale-New Haven Hospital

Responsible for planning and implementing $11 million renovation program done in concert with major facility replacement project, and for planning and overseeing the move of five major departments and three clinical services (including 80 ICU beds) to a new $73 million facility, during the Spring of 1982. Prepared and presented to the Health Systems Agency and Commission on Hospitals and Health Care, three Certificates of Need; all were approved. Also responsible for Hospital space planning and management, and provided general staff support to the Executive Vice President.

Jan. 1980-Dec. 1980 Administrative Associate: Yale-New Haven Hospital

Provided general staff support to Executive Vice President. Major activities included employee fundraising and campaign to support $73 million facility replacement and renovations program (50% of Hospital employees contributed almost $500,000) and preparation of capital and operating budget materials.

Jan. 1979-Dec. 1980 Administrative Resident: Yale-New Haven Hospital

Summer 1978 Administrative Intern: Alexian Brothers Hospital, San Jose, California

PROFESSIONAL AWARDS:

1992 Up and Comers Award - Sponsored by Modern Healthcare and 3M Health Systems
Women In Leadership Award, 1993 - YWCA
Junior Achievement Hall of Fame, 1998
20 Noteworthy Women, New Haven Business Times, 1999
Gateway Community College Hall of Fame, 2002

Hill Health Center Leadership Award, 2006
Connecticut Women in Leadership, 2009 (Women & Families Center Award)
Girl Scouts of Connecticut Women of Achievement Award, 2010
Anti-Defamation League Torch of Liberty Award, 2010
Business New Haven's Business Person of the Year, 2010
American Hospital Association 2010 Grassroots Champion Award
Doctor of Humane Letters, Quinnipiac University, 2011

MAJOR PROFESSIONAL AFFILIATIONS, BOARDS AND ACTIVITIES:

Yale-New Haven Hospital Board of Trustees (1994 – present)
Yale New Haven Health System Board of Directors (2005 - present)
The Connecticut Hospital Association, Chair, Board of Trustees (2008-2010); Vice Chair (2006-2008); Member, Executive Committee (2006-), Secretary and Member, Executive Committee (1999-2001)
VHA, Inc. (Dallas, Texas), Board of Directors (2009 -)
Council of Teaching Hospitals (COTH) Administrative Board (2008 - present); Chair-elect (2010)
Healthcare Executives Study Society (2006-present)
Greater New Haven Regional Leadership Council (2005-present)
The Hole in the Wall Gang Camp Board of Directors (2007 - 2010)
Northwestern Mutual Policyowners' Examining Committee (2009)
Fellow – American College of Healthcare Executives
Association of American Medical Colleges Board of Directors, 2010-present
Coalition to Protect America's Health, 2011-present

University Appointments

Yale University – Lecturer, Department of Epidemiology & Public Health, Health Policy & Administration Division.

PERSONAL:
Married: Eric N. Borgstrom (5/27/78)
Children: Christopher (4/14/85) and Peter (8/4/89)

CURRICULUM VITAE

RICHARD D'AQUILA
282 Boston Post Road
Westbrook, CT 06498
Telephone: (860) 669-0871

PERSONAL DATA:
Married
U.S. Citizen
Birth Date: 6/29/55

BUSINESS ADDRESS:

Yale-New Haven Hospital
20 York Street
New Haven, CT 06510
Telephone: (203)-688-2606

PROFESSIONAL EXPERIENCE:

February, 2012

President and Chief Operating Officer
Yale-New Haven Hospital
Executive Vice President
Yale New Haven Health System

May, 2006 to
February, 2012

Executive Vice President and Chief Operating Officer
Yale-New Haven Hospital/Yale New Haven Health System

Organizational Profile

Yale New Haven Health System (YNHHS) is a 1545-bed delivery network formed in 1995 which consists of Yale-New Haven, Bridgeport and Greenwich Hospitals. YNHHS has revenues in excess of $1.1 billion in FY '05 based on 80,000 discharges and 1.3 million outpatient visits. Yale-New Haven Hospital is a 944-bed tertiary referral medical center that includes the 201-bed Yale New Haven Children's Hospital and the 76-bed Yale New Haven Psychiatric Hospital. Both Yale New Haven Health System and Yale-New Haven Hospital are formally affiliated with Yale University School of Medicine.

Responsibilities

Overall responsibility for all aspects of day to day operations for Yale-New Haven Hospital (YNHH) and the senior network leader at the Yale New Haven Health System representing the YNHH delivery network. Hospital leadership responsibilities include direct accountability for the senior leadership team, strategic planning, organizational performance, quality improvement, labor relations and human resources management, system integrations, external relations and service line development. Senior leadership and implementation responsibility for all aspects of the hospital's annual business (operating) plan. Senior level oversight of the hospital's facility plan including

construction of a 112-bed, $450 million Comprehensive Cancer Pavilion commencing construction in the fall of 2006.

August, 2000 to April, 2006

Senior Vice President/Chief Operating Officer
New York Presbyterian Hospital/
Weill Cornell Medical Center
New York, New York

Organizational Profile
New York Presbyterian Hospital is a 2,369 bed Academic Medical Center created from the merger between the New York Hospital and the Presbyterian Hospital in the City of New York. The Weill Cornell Medical Center consists of an 880 bed acute care facility in Manhattan and the 239 bed Westchester Division campus in White Plains specializing in behavioral health.

Responsibilities
Overall responsibility for all aspects of day to day operations for the Weill Cornell Medical Center and the Westchester Division, a two campus Academic Medical Center of 1120 beds. Direct responsibility for a total operating expense budget in excess of $450,000,000 and revenues of $850,000,000. Senior leadership and implementation for all aspects of the Medical Center's operating plan including quaternary and tertiary service development, medical staff relations and recruitment, employee relations and labor strategy. System level member of the Corporate Management Team with involvement in strategic and facilities planning, service line development, information technology and performance improvement.

May 1992 to June 2000

Executive Vice President/Chief Operating Officer
St. Vincent's Medical Center
Bridgeport, Connecticut

President
Vincentures, Inc.

President
St. Vincent's Development Corporation, Inc.

Chief Operating Officer of 391 bed, university-affiliated acute care hospital and health system. President/CEO of affiliated subsidiaries with management responsibility at

the Medical Center and corporate level. Medical Center responsibilities including day to day operations oversight for patient care services; support services and facilities planning and development. Corporate responsibilities including information systems, ambulatory network development, managed care contracting network oversight and real estate/satellite facility development.

January 1987-April 1992

President/CEO
Health Initiatives Corporation
Providence, Rhode Island

Chief Executive Officer of a consulting practice specializing in strategic planning, business development and project implementation assistance for acute care and specialty hospitals, state planning agencies and private investors. Specific responsibilities included:

- Practice Leadership
- Engagement Planning and Management
- Project Supervision and Control
- Client Interface
- Practice Marketing and Business Development

June 1984-December 1986

Vice President
The Mount Sinai Hospital Corporation
Hartford, Connecticut

June 1981-June 1984

Vice President, Division of Planning and Community Services
The Mount Sinai Hospital
Hartford, Connecticut

June 1979-June 1981

Assistant Executive Director
The Mount Sinai Hospital
Hartford, Connecticut

January 1979-May 1979

Administrative Resident
The Mount Sinai Hospital
Hartford, Connecticut

OTHER APPOINTMENTS:

November 2000
To Present

Member, Board of Directors
Voluntary Hospitals of America/Metro New York
New Rochelle, New York

January 1995- June 2000	**Member, Board of Directors** Goodwill Industries Bridgeport, Connecticut
December 1993- June 2000	**Founding Board Member** Park City Primary Care Center Bridgeport, Connecticut
May, 1992- June 2000	**Member, Board of Directors** St. Vincent's Development Corporation Vincentures, Inc. Omicron, Inc. Connecticut Health Enterprises Bridgeport, Connecticut
January 1992- December 1994	**Member, Board of Directors** Visiting Nurses Association of Fairfield County Bridgeport, Connecticut
January 1989- December 1991	**Member, Board of Directors** Easter Seal Society/Meeting Street Rehabilitation Center, Inc. of Rhode Island Providence, Rhode Island
January 1980- December 1989	**Member, Board of Directors** Combined Hospitals Alcohol Program Hartford, Connecticut
September 1985- December 1986	**President, Board of Directors** Regional Alcohol and Drug Abuse Resources, Inc. Hartford, Connecticut
September 1981- December 1986	**Adjunct Faculty/Lecturer** University of Hartford, Barney School of Business and Public Administration West Hartford, Connecticut
January 2001 - Present	**Adjunct Faculty/Residency Preceptor and Lecturer** Robert F. Wagner Graduate School of Public Service New York University New York, N.Y.
December 2000 - Present	**Adjunct Faculty/Lecturer** Weill Medical College of Cornell University Department of Public Health, New York New York, N.Y.

EDUCATION:

Yale University School of Medicine
Graduate Program in Hospital Administration
Academic Distinctions: Research Excellence Award (1979)
1979 Graduate

Central Connecticut State University
Bachelor of Arts: Economics/Business
Academic Distinctions: Omicron Delta Epsilon
Economics Honor Society
1977 Graduate

PROFESSIONAL AFFILIATIONS:
Fellow, American College of Health Care Executives
Yale Hospital Administration Alumni Association
Connecticut Hospital Association
Habitat of Greater New Haven

CURRICULUM VITAE

NAME: James M. Staten
BIRTHDATE: September 26, 1958
EDUCATION: 1980 – B.S. – Business / Economics / State University College of NY

Yale New Haven Health System (YNHHS) and Yale-New Haven Hospital (YNHH)

October 2000 - Present

Executive Vice President of Finance and Corporate Services, YNHHS
Senior Vice President and CFO, YNHH

Yale New Haven Health system is a regional, integrated health care system composed of three regional health care delivery networks. The New Haven-based delivery system is anchored by Yale-New Haven Hospital, the Yale-New Haven Children's Hospital, and the Yale-New Haven Psychiatric Hospital, which total 944-beds. The system includes a Bridgeport-based delivery system led by the 425-bed Bridgeport Hospital and Greenwich-based delivery system anchored by 160-bed Greenwich Hospital. The System is also affiliated with the Westerly Hospital in Rhode Island. The Yale New Haven Health System has a formal affiliation with the Yale University School of Medicine, as does Yale-New Haven Hospital which serves as the Medical School's primary teaching hospital. System services include acute care hospitals, ambulatory surgery and outpatient diagnostic imaging centers, as well as primary care centers. In total, the System has 1,500 beds, 74,000 admissions, 10,000 employees, assets of $1.6 billion, and annual net revenues of over $1.4 billion.

Responsible for financial and corporate services of YNHHS including managed care, information systems, materials management, admitting/registration, and medical records, as well as all financial responsibilities such as accounting, budgeting, financial and operational reporting, tax, reimbursement, and treasury.

OTHER EMPLOYMENT

New York-Presbyterian Hospital (NYPH) and New York-Presbyterian Healthcare System (NYPHS)

July 1999 – October 2000 Senior Vice President of Finance

Responsible for assuring the financial viability of a $3 billion Health System, including monitoring financial condition of approximately 15 corporately-controlled Sponsored/Member Hospitals and other healthcare related organizations. Report regularly to the NYPHS Board and NYPH Board Executive Committee on financial performance.

January 1997 - June 1999 Vice President of Financial Planning
June 1993 - December 1996 Director of Financial Planning

Responsible for complete integration of financial planning at all Sponsored Hospital Members including NYPH and leading the financial group of approximately 70 professionals in performing budget, reimbursement, managed care contracting, decision support and business plan development functions.

Ernst & Young

January 1991 - June 1993 Senior Manager - Consulting Services

Directed and coordinated Ernst & Young's New York State Reimbursement Consulting Services.

Pannell Kerr Forster

October 1980 – December 1990 Partner

Elected Partner in June 1990 after working 10 years in the firm's large healthcare practice as a certified public accountant. 11th Largest Public Accounting Firm in United States during late 1980s.

PROFESSIONAL MEMBERSHIPS

American Institute of Certified Public Accountants (1982 – 1998)
New York State Society of Certified Public Accountants (1982 – 1996)
- Healthcare Committee (1988 – 1991)
- Chairman of the Hospital Sub-Committee (1990/1991)

Healthcare Financial Management Association (1984 – 1994)
- Chairman of various Committees (1984 – 1994)
- Trustee (1990/1991)
- President Elect (1993/1994)

Greater New York Hospital Association
- Fiscal Policy Committee (1993 – 2000)
- Managed Care Committee (1995 – 2000)

Connecticut Hospital Association
- Finance Committee (2000 – 2004)
- Special Committee on Medicaid Reimbursement (2000 – 2004)

Blue Ribbon Committee on the Future of Healthcare in Connecticut (2000 – 2003)

OTHER PROFESSIONAL ACTIVITIES

Presenter at New Jersey Health Care Financing Authority on Medicare Payment System
Presenter on Hospital Reimbursement Issues for the NYS Society of CPAs
Presenter on Accounts Receivable Issues for the Connecticut Hospital Association
Guest Speaker at NYU's graduate program in Hospital Administration on Healthcare Financing
Guest speaker at Cornell University's Sloan Program in Health Services on Managed Care
Presenter on Mergers and Acquisitions to New York State Hudson Valley HFMA
Guest speaker at Chicago Municipal Bond Analysts Society on New York State Hospital Deregulation
Guest speaker at Yale's School of Epidemiology and Public Management on Health Systems

THOMAS D. LEARY

20 Morgan Point
Noank, Connecticut 06340
(860) 536-2698

EDUCATION

Business Administration, M.B.A.	Boston University	1982
Economics, B.A..	College of the Holy Cross	1975

PROFESSIONAL HISTORY

2000	-	Present	Yale-New Haven Hospital
1994	-	1999	Yale New Haven Health Services Corporation
1992	-	1994	Yale-New Haven Hospital
1991	-	1992	Harbor Health Plans
1988	-	1991	Healthcare Venture Associates
1983	-	1988	VHA (Voluntary Hospitals of America)
1977	-	1983	John Hancock Financial Services
1975	-	1976	General Dynamics, Electric Boat Division

PROFESSIONAL EXPERIENCE

Yale-New Haven Hospital
New Haven, Connecticut

As Vice President, Mr. Leary is responsible for clinical program development and physician recruiting with the Yale School of Medicine. He also serves as the Service Line executive for the operation of the Heart & Vascular Center, Organ Transplantation Center and the Level I Trauma Center. These programs are all leading New England providers of tertiary care services.

As Vice President, Physician Development, Mr. Leary was responsible for medical staff outreach to community based physicians and managed medical staff development programs, including computer networking. He restructured the Hospital's diagnostic service privileging and physician reporting systems. The Hospital MDLink Program expanded to 1600 physicians and ancillary staff users. He also served as the Executive Director of the YNHH-Physician Corporation and the Yale-New Haven Community Medical Group with responsibilities for managed care contracting and clinical integration program development.

Yale New Haven Health Services Corporation
New Haven, Connecticut

As Vice President, Mr. Leary was responsible for the Health System's managed care plans and contracting functions. He also managed the system's physician network development programs in primary care and specialty services. Mr. Leary also organized the Health System's central contracting organization. Mr. Leary was responsible for Yale New Haven Health's acquisition of a 50% interest of a 150,000 member PPO plan. He also developed and managed an HMO serving 25,000 Medicaid beneficiaries in Connecticut, as well as a fifty physician primary care group. Mr. Leary also negotiated the sale of the Hospital's interest in a regional HMO.

Yale-New Haven Hospital
New Haven, Connecticut

As Administrative Director, Mr. Leary was responsible for HMO/PPO contracting and payer relations for Yale-New Haven Hospital. He served as Executive Director of its PHO and Medical Staff IPA. Contract revenue exceeded $300 million.

Harbor Health Plans
Mystic, Connecticut

As President, Mr. Leary had overall responsibility for managed care consulting engagements, PPO and workers compensation health plan product development. Mr. Leary founded the company.

Healthcare Venture Associates
Irving, Texas

As a partner in this consulting firm, Mr. Leary was responsible for managed care and physician service programs. Mr. Leary's consulting engagements included HMO turnaround, market development for a leading physician referral service, and physician networking product development for a major communications company.

VHA Physician Services
Irving, Texas

As Vice President, Mr. Leary was responsible for all computer, practice management, and marketing services delivered to over one thousand physicians in twelve network locations. Mr. Leary also created physician network designs for VHA Physician Services hospital clients.

Partners National Health Plans
Irving, Texas

As Vice President of Marketing for this Aetna/VHA joint venture, Mr. Leary was responsible for marketing the Partners' product line including advertising, product development, and national

account sales. Mr. Leary created a 70,000 member PPO for the Teamsters and Partners' National Advantage, the largest hospital PPO in the country.

As Director of Alternative Delivery Systems Consulting, Mr. Leary provided development consulting services to hospitals, medical groups and large employers to create HMOs, PPOs, and other alternative delivery systems.

John Hancock Financial Services
Boston, Massachusetts

As Director of Cost Containment Marketing, Mr. Leary's responsibilities included market management and product development. Mr. Leary helped the company develop its first PPO plan.

As Senior Sales Representative, Mr. Leary was responsible for the sale of $1,000,000 premium accounts. Mr. Leary earned several Production Leader Awards for his efforts.

General Dynamics
Groton, Connecticut

As a Production Planner, Mr. Leary's responsibilities included scheduling, procurement, and materials management for nuclear submarines at the Electric Boat Division.

Board Positions
New England Organ Bank
Board of Trustees, Executive Committee
Waltham, Massachusetts

Hygeia Foundation and Institute for Perinatal Loss and Bereavement
Hygeia Foundation Board
New Haven, CT

CURRICULUM VITAE

Name: Michael Simons, M.D.

Professor with Tenure, Department of Medicine
Traditional Track

Term: *Primary:* with Tenure beginning September 1, 2008

School: Yale University School of Medicine (and the Graduate School)

Education:
B.S. Massachusetts Institute of Technology, Cambridge, MA, June 1980
M.D. *cum laude* Yale University School of Medicine, New Haven, CT, June 1984

Career/Academic Appointments:

1984-1985	Intern in Internal Medicine, New England Medical Center, Boston, MA
1985-1986	Resident in Internal Medicine, New England Medical Center, Boston, MA
1986-1989	Medical Staff Fellow, NIH, NHLBI, Bethesda, MD
1987-1989	Postdoctoral Fellow, Laboratory of Molecular Cardiology, NIH, NHLBI, Bethesda, MD
1989-1991	Fellow in Cardiology, Beth Israel Hospital, Boston, MA
1990-1993	Associate Scientist, Program for Excellence in Molecular Biology of the Cardiovascular System, MIT, Cambridge, MA
1991 - 1993	Instructor in Medicine, Harvard Medical School, Boston MA
1993 - 1997	Assistant Professor of Medicine, Harvard Medical School, Boston MA
1997 - 2001	Associate Professor of Medicine, Harvard Medical School, Boston MA
2001 – 2008	A.G. Huber Professor of Medicine, Dartmouth Medical School, Lebanon NH
2002 – 2008	Professor of Pharmacology & Toxicology, Dartmouth Medical School, Lebanon NH
2008 - Present	Professor with Tenure, Yale University School of Medicine
2008 - Present	Robert W. Berliner Professor of Medicine, Yale University School of Medicine
2008 - Present	Honorary Professor of Medicine, University College London, London, UK
2009 - Present	Professor of Cell Biology, Yale University School of Medicine

Administrative Positions:

2008 – Present	Chief, Section of Cardiovascular Medicine, Yale University School of Medicine
2006 - 2008	Director, Cardiovascular Center, Dartmouth-Hitchcock Medical Center
2003 - 2006	Associate Chair of Medicine for Research, Dartmouth-Hitchcock Medical Center
2001 - 2008	Chief of Cardiology, Dartmouth-Hitchcock Medical Center
2001 - 2008	Director, Angiogenesis Research Center, Dartmouth Medical School
1996 - 2001	Director, Angiogenesis Research Center, Beth Israel Hospital/BIDMC
1995 - 1999	Director, Morse Coronary Care Unit, Beth Israel Hospital/BIDMC
1993 - 2001	Attending Cardiologist, Beth Israel Hospital/BIDMC
1993 - 2001	Associate in Medicine, Beth Israel Hospital/BIDMC

Board Certification:

National Board of Medical Examiners, 1985
Diplomate, American Board of Internal Medicine, 1987
Diplomate, ABIM, Subspecialty of Cardiovascular Disease, 1991, re-certified 2001
Diplomate, Certification Board of Nuclear Cardiology, 1996

Professional Honors & Recognition

A) International/National/Regional

2010	Chair, Keystone Conference Angiogenesis in Health and Disease
2009	Chair, Gordon Research Conference on Vascular Biology
2005-2006	President, North American Vascular Biology Organization
2005	Excellence in Cardiovascular Science Award, AHA Northeast
2005	Elected member, Association of American Physicians (AAP)
2004	Elected member, Association of University Cardiologists (AUC)
2002	Fellow (elected), CV Section, American Physiological Society
2001	Fellow (elected), Basic Science Council, AHA
1999-2003	Established Investigator, American Heart Association
1999	Honorary Citation, Cardiovascular Society of India
1998	Fellow (elected), ATVB Council, AHA
1998	Elected Member, American Society for Clinical Investigations (ASCI)
1995	Honorary Citation, Japanese Circulation Society
1991-1996	Clinician-Scientist of the American Heart Association
1984	A. Richman Research Award of the American College of Chest Physicians

B) University

2005	Excellence in Teaching Award, Department of Medicine, Dartmouth
1986	Teaching Resident Award, Tufts University School of Medicine
1984	Cum Laude, Yale University School of Medicine

Grant History:
A) Current Grants

Agency	Leducq Foundation
Program:	Transatlantic Network
Title:	ARTEMIS Network
PI:	Michael Simons MD & Peter Carmeliet, Ph.D.
Percent effort:	20%
Direct costs for project period	$5,400,000
Project period	9/1/09-8/31/2014

Agency:	NIH/NHLBI
I.D.#	R01 HL62289
Title:	Syndecan function in endothelial cells
P.I.:	Michael Simons, M.D.
Percent effort:	20%

Direct costs per year (last year): $388,563
Total costs for project period: $1,877,013
Project period: 10/01/2008 – 11/30/2013

Agency: NIH/NHLBI
I.D.# R01 HL53793
Title: Angiogenesis and ischemia
P.I.: Michael Simons, M.D.
Percent effort: 20%
Direct costs per year: $322,382
Total costs for project period: $1,711,524
Project period: 06/16/2008 – 05/30/2013

Agency: NIH/NHLBI
ID#: R01 HL084619
Title: Arteriogenesis and arterial branching
P.I.: Michael Simons, M.D.
Percent effort: 20%
Direct costs per year: $316,875
Total costs for project period: $1,637,287
Project period: 07/01/2007 – 06/30/2011

Agency: NIH/NHLBI
I.D.# P50 HL084945
Title: Molecular determinants of pulmonary arterial hypertension
P.I.: Laura Nofke, MD
Role on the project: Co-PI
Percent effort: 5%
Direct costs per year: $49,270
Total costs for project period: $197,080
Project period: 01/01/2007 – 12/31/2010

Agency: NIH/NHLBI
I.D.# HL069948
Title: Mechanism of PAI-1-induced anti-angiogenesis
P.I.: Mary Jo Mulligan-Kehoe, Ph.D.
Role on the project: Co-PI
Percent effort: 5%
Direct costs per year: $9,300
Total costs for project period: $37,200
Project period: 12/01/2007 – 11/30/2011

B) Past Grants

Agency: NIH/NHLBI
I.D.# R13 HL093922A
Title: NAVBO workshop: biology of signaling in the cardiovascular system
P.I.: Michael Simons MD and Timothy Hla, PhD (dual PI)
Percent effort: 0%

Direct costs per year: $15,000
Total costs for project period: $15,000
Project period: 09/01/2008 – 08/31/2009

Agency: NIH/NHLBI
I.D.# R01 HL53793
Title: Angiogenesis and ischemia
P.I.: Michael Simons, M.D.
Percent effort: 25%
Direct costs per year: $213,341
(Last funding year)
Total costs for project period:
Project period: 08/01/1997 – 08/31/2008

Agency: NIH/NHLBI
I.D.# R01 HL62289
Title: Syndecan function in endothelial cells
P.I.: Michael Simons, M.D.
Percent effort: 25%
Direct costs per year (last year): $225,000
Total costs for project period:
Project period: 05/01/1999 – 06/18/2008

Agency: NIH/NHLBI
I.D.# R01 HL070247
Title: Peptide regulators of angiogenesis
P.I.: Michael Simons, M.D.
Percent effort: 25%
Direct costs per year: $249,915
Total costs for project period: $999,600
Project period: 04/01/2002 – 03/31/2006

Agency: NIH/NHLBI
I.D.# P50 HL63609
Title: Endothelial signaling and cardiac angiogenesis
P.I.: Michael Simons, M.D.
Percent effort: 25%
Total costs for project period: $5,884,895
Project period: 04/01/2000 – 03/31/2005

Agency: NIH/NHLBI
I.D.# P50 HL56993
Title: Stimulation of coronary angiogenesis with bFGF
P.I.: Lewis Cantley, Ph.D
Role on the grant: Project PI
Percent effort: 25%
Total costs for project period:
Project period: 04/01/1997 – 03/31/2002

Agency: Scleroderma Research Foundation
I.D.# Investigator Grant

Title:	Angiogenic defects in scleroderma
P.I.:	Michael Simons, M.D.
Percent effort:	0%
Total costs for project period:	$160,000
Project period:	04/01/2005 – 03/31/2008

Agency:	American Heart Association
I.D.#	Established Investigator Grant
Title:	Inflammation and angiogenesis
P.I.:	Michael Simons, M.D.
Percent effort:	25%
Total costs for project period:	$300,000
Project period:	01/01/1999 – 12/31/2003

Agency:	American Heart Association
I.D.#	Clinician-Scientist Award
Title:	Molecular control of restenosis
P.I.:	Michael Simons, M.D.
Percent effort:	75%
Total costs for project period:	$175,000
Project period:	07/01/1991 – 06/30/1996

Lectures, Courses, Web-based Education:

Courses:

2006-2008	Leader, Vascular biology curriculum, Program in experimental molecular medicine
2005-2008	Receptors Course, Department of Pharmacology, Dartmouth
2005	Vasculata Course, Dartmouth College
2004	Vasculata Course, University of Washington
2001	Dartmouth-Hitchcock Cardiology Course

Grand Rounds/Medical School Lectures:

2009	Cardiology Grand Rounds, MGH, Boston, MA
2009	Cardiovascular Research Center Seminar, MGH, Boston, MA
2009	Cardiology Grand Rounds, NYU, NY, NY
2009	Visiting Professor, CBVR, BIDMC, Boston, MA
2009	Cardiovascular Seminar, University of Connecticut
2009	Molecular Biology & Biochemistry Seminar, Mayo Clinic, Rochester, MN
2009	NIH TARP Vascular Biology Seminar, NIH, Bethesda, MD
2009	Cardiology Grand Rounds, University of Massachusetts
2009	Cardiology Grand Rounds, University of Pennsylvania
2009	Cardiovascular Seminar, University of Pennsylvania
2008	Medicine Grand Rounds, Yale University School of Medicine
2008	Vascular biology seminar, Institute of Ophthalmology, University College, London, UK
2008	Seminar, Institute for Cardiovascular Sciences, UCL, London, UK
2008	Cardiology seminar, University of Hawaii, Honolulu, HI
2007	Vascular biology seminar, Yale University School of Medicine
2006	Plenary lecturer, University of North Carolina Vascular Biology Day
2006	Medicine Grand Rounds, University of Rochester, Rochester, NY
2006	Cardiovascular Research Center Seminar, MGH, Boston, MA

2006	Cardiovascular Center Seminar, University of Rochester, Rochester, NY
2005	Vascular Biology Seminar, Emory University
2005	Seminar, Sol Sherry Thrombosis Center, Temple University School of Medicine
2005	Medicine Grand Rounds, University of Texas, Houston
2005	Cell Biology & Biochemistry seminar, University of Texas, Houston
2005	Cardiology Grand Rounds, University of California San Francisco
2005	Cardiology Grand Rounds, Dartmouth Medical School
2004	Medicine Grand Rounds, Dartmouth Medical School
2004	Lecturer, ECM Society, Okayama University School of Medicine
2004	Cardiology Grand Rounds, Yale University School of Medicine
2004	Barry Zaret Symposium, Yale University School of Medicine
2003	Vascular Biology Seminar, University of Washington
2003	Research Seminar, British Heart Foundation/University College London
2003	CARIM Seminar, University of Maastricht School of Medicine
2003	Cardiology Grand Rounds, The University of Chicago
2003	Cardiology Grand Rounds, New England Medical Center
2002	Surgery Grand Rounds, Dartmouth Medical School
2002	ICVBM Seminar, Indiana University School of Medicine
2001	Medicine Grand Rounds, Dartmouth Medical School
2001	Cardiology lecturer, Chiba University, Chiba, Japan
2000	Hematology seminar, NYU School of Medicine
2000	Cardiology Research Seminar, Albert Einstein College of Medicine
2000	Cardiology Grand Rounds, University of California, Irvine
2000	Cardiology Grand Rounds, NYU School of Medicine
2000	Cardiology Grand Rounds, Massachusetts General Hospital
2000	Cardiology Grand Rounds, Dartmouth Medical School
2000	Cardiology Grand Rounds, College of Physicians & Surgeons, Columbia University
1999	Vascular Biology Seminars, Harvard University
1999	Physiology Research Seminar, University of Wisconsin
1999	Physiology Research Seminar, University of Iowa
1999	Medical Grand Rounds, UC Davis Medical Center
1999	Medical Grand Rounds, BIDMC
1999	Cardiology Research Grand Rounds, New England Medical Center
1998	Vascular Biology Seminars, Harvard University
1998	Cardiovascular Research Seminars, St. Elizabeth Hospital
1998	Cardiovascular Grand Rounds, Brigham and Women's Hospital
1997	Cardiovascular Grand Rounds, Northwestern University School of Medicine
1997	Cardiology Grand Rounds, University of Calgary School of Medicine
1996	TCT Conference, Washington, DC, Invited Speaker
1996	Cardiovascular Grand Rounds, Albert Einstein College of Medicine
1995	Nuclear Medicine Grand Rounds, JPNM, Harvard University
1995	Cardiovascular Research Seminars, St. Elizabeth Hospital
1995	Cardiology Grand Rounds, Yamaguchi University School of Medicine, Japan
1995	Cardiology Grand Rounds, University of Montreal, Notre Dame Hospital
1994	Physiology Research Seminar, Texas A&M University
1994	Cardiology Grand Rounds, New York University
1993	Physiology Research Seminar, University of Vermont
1993	Pathology Research Seminar, Beth Israel Hospital
1993	Department of Physiology, Southwestern University School of Medicine
1993	Cardiology Grand Rounds, University of Montreal, Notre Dame Hospital
1992	Nephrology Research Seminar, Beth Israel Hospital

Regional, National and International Contributions:

2009	Speaker and Session Chair, TCT 2009, San Francisco, CA
2009	Speaker, Vesalius Research Center Symposium, KU Leuven, Belgium
2009	CRT 2009, Washington, DC, Invited Speaker
2008	Kloster Seeon 5th International Angiogenesis conference, Kloster Seeon, Germany. Invited Speaker
2008	Biology of signaling in cardiovascular system. NAVBO workshop. Cape Cod, MA. Chair and organizer
2008	Angiogenesis in cancer and other diseases. University of Helsinki symposium. Invited Speaker, Helsinki, Finland.
2008	EECPS/Leopoldina symposium, Bad Nauheim, Germany, Invited speaker
2008	The US-Japan cooperative cancer research program invitational meeting, Kyoto, Japan
2007	USA-France NIH/INSERM Vascular Biology invitational meeting, Paris, France
2007	European Vascular Biology and Microcirculation Conference, Plenary lecturer, Heidelberg, Germany
2007	European Society of Cardiology meeting, Invited Speaker, Vienna, Austria
2007	ESH Conference on Angiogenesis, Albufiera, Portugal, Invited speaker
2007	5th International Proteoglycans conference, Invited speaker, Rio de Janeiro, Brazil
2006	USA-France NIH/INSERM Vascular Biology invitational meeting, Denver, CO
2006	State-of-the-Art lecture, International Vascular Biology Meeting, Amsterdam, NL
2006	Plenary lecture, ATVB Conference, Denver, CO
2006	Nature Biotechnology Conference, Invited Speaker, Miami, FL
2006	Frontiers in Cardiology, Invited Speaker, Munich, Germany
2006	Detours'Sils '06, Invited Speaker, Sils-Maria, Switzerland
2005	NHLBI Arteriogenesis Panel, Bethesda, MD
2005	International Society for Heart Research, Invited Speaker, New Orleans, LA
2005	Gordon Conference on Vascular Biology, Invited Speaker, Ventura Beach, CA
2005	CRT 2005 Meeting. Associate Course Director, Washington, DC
2005	Association of University Cardiologists, Invited Speaker, Phoenix, AZ
2005	AHA Scientific Sessions. Session Chair and Invited Speaker, Dallas, TX
2005	ACC Annual meeting, Invited Speaker, Orlando, FL
2004	PULSE 2004 University of Crete and Hellenic Cardiovascular Society, Invited Speaker, Crete, Greece
2004	NIH Workshop on Trans-institute Angiogenesis Program, Towson, MD
2004	Molecular Imaging, Invited Speaker, Bethesda, MD
2004	International Society for Differentiation, Invited Speaker, Honolulu, HI
2004	Cardiovascular Revascularization Therapy, Invited Speaker ,Washington, DC
2004	2nd International Gene Therapy Conference, Invited Speaker, Osaka, Japan
2003	XXX Argentine Cardiovascular Society Meeting, Invited Speaker, Buenos Aires
2003	XIII International Atherosclerosis Society Mtg, Invited Speaker, Kyoto, Japan
2003	TCT Symposium, Washington, DC, Plenary lecture
2003	Japanese Circulation Society, Fukuoka, Japan, Invited Speaker
2003	International Society for Heart Research, Invited Speaker, Newport, CT
2003	Heart Failure Society of America, Invited Speaker, Las Vegas, NV
2003	Gordon Conference on Angiogenesis, Invited Speaker, Newport, RI
2003	EB2003, Invited Speaker
2003	ACC Annual Meeting, Chicago, IL, Invited Speaker
2002	TCT Symposium, Washington, DC, Plenary lecture
2002	Society of Vascular Surgery, Boston, Invited Speaker

2002	Society of Vascular Biology & Medicine, Boston, Invited Speaker
2002	Keystone Conference on Angiogenesis, Banff, Canada, Invited Speaker
2002	International Vascular Biology Meeting, Kuruizawa, Japan, Invited Speaker
2002	International Society for Heart Research, Landmark Lecture
2002	European PCR 2002 Meeting, Paris, France. Invited Speaker
2002	ACC Annual meeting, Atlanta, GA, Invited Speaker
2002	6th Invitational meeting of the American Society of Nuclear Cardiology
2002	3rd Annual Conference on Atherosclerosis, Thrombosis and Vascular Biology, Salt Lake City, NV, Invited Speaker
2002	2nd Interdisciplinary Euroconference on Angiogenesis, Cascais, Portugal, Invited Speaker
2001	VII World Congress on Microcirculation, Sydney, Australia, Invited Speaker
2001	TCT Symposium, Washington, DC, Invited Speaker
2001	Keystone Conference, Angiogenesis and Chronic Disease, Keystone, CO, Invited speaker
2001	Japanese Cardiovascular Society Annual Meeting, Kyoto, Japan, Invited Speaker
2001	Indian Interventional Society Meeting, Bombay, India, Plenary lecture
2001	Cardiology Frontiers Conference, Tokyo, Japan, Invited Speaker
2001	Angiogenesis & DMR, Washington, DC, Invited Speaker
2001	ACC Annual meeting, Orlando, FL, Invited Speaker
2000	Research Seminar, Proctor & Gamble, Inc.
2000	Research Seminar, Genentech, Inc.
2000	Research Seminar, Biogen, Inc.
2000	Research Initiatives Conference in Vascular Disease, Invited Speaker
2000	Plenary lecturer, XXI Congresso Da Sociedade de Cardiologia Do Estado DeSao Paolo, Campos do Jordao
2000	NIH/NSF Technology Assessment Panel, member
2000	International Society for Vascular Biology, Geneva, Invited Speaker
2000	Guidant Angiogenesis & DMR Workshop, Invited Speaker
2000	European Cardiovascular Society, Amsterdam, Session Chair & Invited Speaker
2000	EB2000, Plenary lecture
2000	EB2000, Featured research symposium, Invited Speaker
2000	Angiogenesis experts panel/Expert forum in bio-interventional cardiology
2000	Angiogenesis & DMR Symposium, Invited Speaker
2000	AHA Symposium and Angiogenesis and DMR, Meeting Co-Chair
2000	ACC Mini-symposium, Invited Speaker
2000	1st R. Ross Memorial Conference, Ulm University, Germany, Invited Speaker
1999	TCT Conference, Invited Speaker
1999	Plenary lecture, Cardiac Society of India, New Delhi, India
1999	Medical University of Beijing, Beijing, China, Invited Speaker
1999	International Society for Heart Research, Invited Speaker
1999	Guest lecturer, Madras and Bombay, India
1999	EPIC Course, Emory University, Invited Speaker
1999	ACCIS Symposium, Plenary Speaker
1999	ACC Minicourse, Invited Speaker
1999	3rd International Seminar on Cardiovascular Biology and Medicine, Pamplona, Spain, Invited Speaker
1999	2nd Annual meeting, International Institute for Research, Co-Chair
1999	2nd Angiogenesis & DMR Symposium, Invited Speaker
1998	Update in Cardiology, University of Toronto, Invited Speaker
1998	TCT Conference, Invited Speaker

1998	Schering Workshop on Angiogenesis, Invited Speaker
1998	Merck Research Labs, Invited Speaker
1998	Gordon Research Conference on Proteoglycans, Invited Speaker
1998	Cleveland Clinic Foundation Mini-Symposium on Angiogenesis, Invited Speaker
1998	4th Local Drug Delivery Conference, Geneva, Switzerland, Invited Speaker
1997	Philip T. Goldenberg Lecture St. Francis Hospital, University of Connecticut
1997	NIH Workshop on Antisense Therapeutics, Invited Speaker
1997	Bristol Myers Squibb Symposium on Promotion of Angiogenesis as Therapy for Cardiovascular Disease, Invited Speaker
1996	NHLBI Workshop on Current Directions in Ischemic Heart Disease, Invited Speaker
1996	Fireside seminar, ACC Annual Meeting, Invited Speaker
1996	2nd International Symposium on Local Cardiovascular Drug Delivery, Invited Speaker
1995	Plenary lecture, Japanese Circulation Society Annual Meeting, Nagoya, Japan
1995	Joint Program in Nuclear Medicine, Harvard University, Invited Speaker
1995	First International Symposium on Local Cardiovascular Drug Delivery, Invited Speaker
1995	Boston Biomedical Research Institute, Invited Speaker
1995	AFCR Featured Research Symposium, Invited Speaker
1994	Program of Excellence in Molecular Biology Meeting, Santa Barbara,
1994	Merck Research Labs, Invited Speaker
1994	Hewlett-Packard Medical Advisory Board Meeting, Invited Speaker
1994	Eighth International Workshop on Future Directions in Interventional Cardiology, Santa Barbara, CA, Invited Speaker
1994	Cell cycle workshop, NHLBI, NIH, Invited Speaker
1993	Society of Experimental Pathology, Invited Speaker
1993	Seventh International Workshop on Future Directions in Interventional Cardiology, Santa Barbara, CA, Invited Speaker
1993	Restenosis Summit, Cleveland Clinic, Invited Speaker
1993	New York Cardiovascular Society, Invited Speaker

PROFESSIONAL SERVICE

Peer Review Groups/Grant Study Sections

2009	Chair, Special Emphasis panel ZRG CVS-F02, NIH
2008	Member, Special emphasis panel ZRG1 CVS D02, NIH
2003-2007	Member, Vascular Cell Molecular Biology Study Section, NIH
1998-2003	Ad hoc member, PPG and SCOR Study section, NIH
1995-2000	National referee, VA Merits Grants Program
1997-1999	Panel Member, US Civilian Research and Development Foundation

Journal Service

2008- Present	Editorial Board, *Circulation Genetics*
2006- Present	Editorial Board, *Circulation*
2005- Present	Editorial Board, *American Journal of Physiology: Heart & Circulatory Physiology*
2004- Present	Editorial Board, *Circulation Research*
1999 - 2003	Editorial Board, *American Journal of Physiology: Heart & Circulatory Physiology*
1998-2007	Editorial Board, Vascular Pharmacology
1993-Present	Reviewer for *American Journal of Pathology; Atherosclerosis; Arteriosclerosis, Thrombosis and Vascular Biology; Circulation; Circulation Research; Developmental Cell, FASEB Journal; Journal of Biological*

Chemistry; Journal of Cell Biology; Journal of Cell Science; Journal of Clinical Investigations; Journal of Leukocyte Biology; Journal of Molecular and Cellular Cardiology; Journal of Nuclear Medicine; Journal of Pathology; Microcirculation; Nature; Nature Medicine; Nature Biotechnology; Nature Cell Biology; New England Journal of Medicine; PNAS; Science

Professional Organizations

North American Vascular Biology Organization (NAVBO)

2003- 2007	Member, NAVBO Council
2003- 2004	Secretary-Treasurer
2005- 2006	President

Meeting Planning/Participation

2010	Chair & Organizer, Keystone conference on angiogenesis
2009	Chair & Organizer, Gordon Research Conference on Vascular Biology
2008	Chair & Organizer, NAVBO workshop on Cardiovascular Signaling
2007	Vice-Chair, Gordon Research Conference on Vascular Biology
2007	Program Committee Chair, Vascular Biology '07 national meeting
2005	Chair and organizer, Vasculata annual conference
2004	Chair and organizer, Angiogenesis: basic science to clinical reality, Dartmouth Science Day conference
2001	Co-chair and organizer, AHA conference on angiogenesis
2001-present	Transcatheter Therapeutics Conference (TCT), Abstract selection committee
1997-present	American College of Cardiology, Abstract Selection Committee
1996-present	American Heart Association, Abstract selection committee

Yale University School of Medicine

2008-Present	Steering Committee, Vascular Biology & Therapeutics Program

Main Medical Center Research Institute

2006- Present	Chair, External Advisory Board

Dartmouth College/Dartmouth Medical School

2002-2008	Dartmouth Advanced Imaging Center Steering committee
2004-2008	Dartmouth-Philips Research Steering committee
2006-2008	Dean's Advisory Board
2006-2008	Clinical chairs committee
2004-2008	Executive Committee, Program in Experimental Molecular Medicine
2002-2006	Dean's committee on translational research

Dartmouth-Hitchcock Medical Center

2006 - 2008	Board of Governors
2006 - 2008	Senior Leadership Committee
2004 - 2008	Web Oversight Committee

Beth Israel Hospital/Beth Israel-Deaconess Medical Center

1998 - 2001	Technology Transfer Committee
1997 - 1999	Clinical Practice Assessment Committee
1996 - 1999	Chair, Institutional Animal Care and Utilization Committee
1995 - 1999	Critical Care Committee

1995 - 1999	Quality Assurance Committee
1995 - 1999	Cardiovascular Practice Guidelines
1995 - 1999	Patient Care Committee

Public Service

2004-2008	Data Safety Monitoring Board, NHLBI, NIH
2004-2006	Advisory Board, FDA

BIBLIOGRAPHY:

Peer-Reviewed Manuscripts

1. **Simons M**, Cabin HS, Jaffe CC. Lipomatous hypertrophy of the atrial septum: diagnosis by combined echocardiography and computerized tomography. *Am J Cardiol* 1984;54:465-466
2. Leppo JA, **Simons M**, Hood WB Jr. Effect of adenosine on transmural flow gradients in normal canine myocardium. *J Cardiovasc Pharmacol* 1984; 6:1115-1119.
3. **Simons M**, Downing SE. Coronary vasoconstriction and catecholamine cardiomyopathy. *Am Heart J* 1985;109:297-304
4. **Simons M**, Isner JM, Pandian NG, Konstam MA, McAdam KPWJ, McInerney KP, Caldeira ME. Noninvasive evaluation of cardiac amyloidosis. *Echocardiography* 1985;2:401-408
5. **Simons M**, Pandian NG, Isner JM, McInerney KP, Caldeira M. Calcific aortic stenosis. *Echocardiography* 1985;2:481-490
6. **Simons M**, Cohn A, Miller KM. Plasma cell leukemia with meningial involvement. *NY State J Med* 1986;86:539-540
7. Martins LR, **Simons M**, Kolodny GM, Parker JA, Warren SE. Aortic root dimension measurement by first-pass radionuclide angiography. *Am J Cardiovasc Imaging* 1991;6:116-120
8. **Simons M**, Wang M, McBride OW, Kawamoto S, Yamakawa K, Gdula D, Adelstein RS, Weir L. Human nonmuscle myosin heavy chains are encoded by two genes located on different chromosomes. *Circ Res* 1991;69:530-539
9. Leclerc G, Isner JM, Kearney M, **Simons M**, Safian RD, Baim DS, Weir L. Evidence implicating nonmuscle myosin in restenosis: use of in situ hybridization to analyze human vascular lesions obtained by directional atherectomy. *Circulation* 1992;85:543-553
10. **Simons M**, Isner JM. Assessment of relative sensitivities of non-invasive tests for cardiac amyloidosis in documented cardiac amyloidosis. *Am J Cardiol* 1992;69:425-427
11. Peng CK, Buldyrev SV, Goldberger AL, Havlin S, Sciortino F, **Simons M**, Stanley HE. Long-range correlations in nucleotide sequences. *Nature* 1992;356:168-170
12. **Simons M**, Rosenberg RD. Antisense nonmuscle myosin and c-myb oligonucleotides suppress smooth muscle cell proliferation in vitro. *Circ Res* 1992;70:835-843
13. **Simons M**, Edelman ER, DeKeyser J-L, Langer RS, Rosenberg RD. Antisense *c-myb* oligonucleotides suppress smooth muscle cell accumulation *in vivo*. *Nature* 1992; 359:67-70.
14. **Simons M**, Morgan KG, Parker C, Collin E, Rosenberg RD. Proto-oncogene c-myb mediates an intracellular calcium rise during the late G_1 phase of the cell cycle. *J Biol Chem* 1993;268:627-632
15. **Simons M**, Leclerc G, Safian RD, Isner JM, Weir L, Baim DS. Activated smooth muscle cells in coronary lesions. *N Engl J Med* 1993;328:608-613
16. Peng CK, Buldyrev SV, Goldberger AL, Havlin S, **Simons M**, Stanley HE. Finite-size effects on long range correlations: implications for analyzing DNA sequences. *Phys Rev E* 1993;47:3730-3733
17. Buldyrev SV, Goldberger AL, Havlin S, Peng CK, **Simons M**, Stanley HE. Generalized Levy walk model for DNA sequences. *Phys Rev E* 1993;47:4514-4523
18. Buldyrev SV, Goldberger AL, Havlin S, Sciortino F, **Simons M**, Stanley HE. Long-range power law correlations in DNA. *Phys Rev Letters* 1993;71:1176
19. Buldyrev SV, Goldberger AL, Havlin S, Peng CK, Stanley HE, **Simons M**. Fractal landscapes and molecular evolution. *Biophys J* 1993;65:2675-2681

20. **Simons M**, Edelman ER, Rosenberg RD. Antisense PCNA oligonucleotides prevent neointimal formation in a rat injury model. *J Clin Invest* 1994;93:2351-2356
21. Peng CK, Buldyrev SV, Havlin S, **Simons M**, Stanley HE, Goldberger AL. Mosaic organization of DNA nucleotides. *Phys Rev E* 1994;49:1685-89
22. **Simons M**, Parker JA, Udelson JE, Donohoe K, Gervino E. The role of clinical history in interpretation of thallium scintigrams. *J Nuc Card* 1994;1:365-71
23. Ossadnik M, Buldyrev SV, Goldberger AL, Havlin S, Peng CK, **Simons M**, Stanley HE. Correlation approach to identify coding regions in DNA sequences. *Biophys J* 1994;67:64-70
24. Harada K, Grossman W, Friedman M, Edelman ER, Prasad P, Kehilly CS, Manning WE, Sellke FW, **Simons M**. Basic fibroblast growth factors improves myocardial function in chronically ischemic porcine hearts. *J Clin Invest* 1994;94:623-630
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27. Edelman ER, **Simons M**, Sirois MG, Rosenberg RD. c-Myc in vasculoproliferative disease. *Circ Res*, 1995;76: 176-182
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29. Buldyrev SV, Goldberger AL, Havlin S, Mantegna RN, Matsa M, Peng CK, **Simons M**, Stanley HE. Long-range correlation properties of coding and non-coding DNA sequences: Analysis of GenBank data set. *Phys Rev E*, 1995;51:5084-5091.
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A. National

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Papers in Press

CURRICULUM VITAE

HENRY S. CABIN, M.D., F.A.C.C.

Address: Home: 154 Peck Hill Rd.
Woodbridge, CT 06525

Office: Yale University School of Medicine
Section of Cardiovascular Medicine
333 Cedar Street, P.O. Box 208017, Rm 307-FMP
New Haven, CT 06520-8017

Birth Date: April 18, 1950, New York City, New York

Education:

June 1967 -	Graduated from Public High School
June 1971 -	B.A. Cum Laude, University of Pennsylvania, Philadelphia, PA
June 1975 -	M.D. Cum Laude, Yale University School of Medicine, New Haven, CT

Board Certification:

1978 -	Diplomate of the American Board of Internal Medicine
1983 -	Diplomate of the American Board of Internal Medicine, Subspecialty of Cardiovascular Disease
2000 -	Diplomate of the American Board of Internal Medicine, Subspecialty of Interventional Cardiology

Career:

1975-1976	Internship in Internal Medicine, Yale-New Haven Hospital, New Haven, CT
1976-1978	Residency in Internal Medicine, Yale-New Haven Hospital, New Haven, CT'
1978-1981	Clinical Associate, National Heart, Lung and Blood Institute, National Institutes of Health, Bethesda, MD
1981-1982	Clinical Fellow in Cardiology, Yale-New Haven Hospital, New Haven, CT
1982-1987	Assistant Professor of Medicine and Pathology, Yale University, University Director of the Coronary Care Unit, Yale-New Haven Hospital, New Haven, CT Director of the Yale Cardiovascular Pathology Study Unit
1987-1992	Associate Professor of Medicine and Pathology, Yale University, University Director of the Coronary Care Unit, Yale-New Haven Hospital, New Haven, CT Director of the Yale Cardiovascular Pathology Study Unit Associate Director of the Cardiac Catheterization Laboratory, Yale-New Haven Hospital, New Haven, CT

1992-present	Professor of Medicine and Pathology, Yale University, University Director of the Coronary Care Unit, Yale-New Haven Hospital, New Haven, CT Associate Director of the Cardiac Catheterization Laboratory, Yale-New Haven Hospital, New Haven, CT
1994-present	Associate Section Chief of Cardiovascular Medicine Chief of Clinical Cardiology Services, Yale-New Haven Hospital
1999-2005	Associate Director Yale-New Haven Heart Center
2005-present	Associate Chief, Yale-New Haven Heart and Vascular Center Clinical Chief, Section of Cardiovascular Medicine Yale University School of Medicine
2004–2009	Associate Chairman of Medicine for Clinical Affairs, Department of Internal Medicine, Yale University School of Medicine

Medical Licensure: Connecticut, 1977-present

Military Service: U.S. Public Health Service, July 1, 1978 - October 31, 1981

Honors: Phi Beta Kappa - Elected in 1975
Samuel Kushlan Award - 1977

Department of Internal Medicine
Yale University School of Medicine
Housestaff Teacher of the Year Award 1984-1985

New York's Best Doctors, June 2007
New York's Best Doctors, June 2008

Professional Societies: Fellow - American College of Cardiology
Member, American Medical Association

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Francine LoRusso, RN, MHA, CCRN, NE-BC
171 Curve Hill Road
Cheshire, Connecticut 06410
203-271-0214
E-mail: lorusso@ynhh.org

Summary of Qualifications

- Over 29 years as a critical care nurse with 9 years as direct caregiver ICU nurse, 15 years spent as a Patient Services Manager and 6 years as Director of Patient Services
- Experienced executive leader responsible for over 15 diverse cost centers.
- Accomplished leader responsible for over 500 FTEs with annual budgets over $60 million.

Professional Experience

Director Patient Services, Heart and Vascular Center
Yale New Haven Hospital, New Haven Conn.
June 2008- Present

- Responsible for executive leadership and clinical and financial oversight of 15 diverse cost centers. Areas include two ICUs, cardiac and cardiothoracic; two stepdown units, cardiac medicine and cardio-vascular; one cardiac telemetry unit; one 26 bed observation unit; five cardiac cath labs and three electrophysiology labs; six vascular and neuro interventional labs; nuclear cardiology areas; cardiac exercise lab; ECHO labs; HVC recovery area ,PICC service; HVC procedural nursing and Yale Cardiology practice at Shoreline and Branford.

- Accountable for attaining high performance in all elements of four business pillars: Quality/ safety, Provider of Choice; Employer of Choice; Financial

Director Patient Services, Medicine
Yale New Haven Hospital, New Haven Conn.
September 2006- June 2008

- Responsible for executive leadership and clinical and financial oversight of 13 cost centers. Areas include one cardiac ICU, two medical ICUs, one cardiac telemetry floor, one cardiac stepdown floor, one pulmonary stepdown floor, 5 general medicine floors, PICC Service, ICU resource unit and diagnostic radiology / cardiac nursing.
- Accountable for attaining high performance in all elements of four business pillars: Quality/ safety, Provider of Choice; Employer of Choice; Financial

Patient Services Manager of PICC Service
Yale New Haven Hospital, New Haven Conn.

June 1999- September 2006

- Created bedside PICC insertion service. Service developed to meet both adult and pediatric patient population needs. Coverage provided 7 days; operating 12 hour days Monday-Friday, and 4 hours on-call weekends and holidays.
- Responsible for consulting on approximately 2400 cases a year.

Patient Services Manager of DI Recovery Area
Yale New Haven Hospital, New Haven, Conn.
December 1998-September 2006

- Oversaw site location and creation of 13 bed outpatient recovery area for Diagnostic Imaging and Heart Center procedural patients.
- Patient population includes cardiac cath, EPS, and cardiac biopsy patients.
- Interventional radiology population includes oncology, renal, and vascular.
- Neuro interventional patients are also cared for in this setting.

Patient Services Manager of Diagnostic Imaging
Yale New Haven Hospital, New Haven, Conn.
May 1995-September 2006

- 24 hour accountability for nursing practice and nursing staff in Diagnostic Imaging
- Patient populations include inpatients and outpatients of varying acuity levels and with multiple diagnoses.
- General nursing oversight of 10 principal interventional labs, including 4 cardiac cath labs, 5 peripheral vascular/ neuro interventional labs, 1 electrophysiology lab.
- Primary nursing coverage for 5 MRI scanners with flexible staffing provided for CT biopsies, bronchoscopies, ultrasound, and x-ray.
- Accountable for personnel management, staffing, scheduling, clinical practice, fiscal planning, quality improvement, environmental management, education, orientation, and patient satisfaction.

Patient Services Manager Cardiac ICU
Yale New Haven Hospital, New Haven, Conn.
July 1991-September 2006

- 24 hour responsibility for the clinical, fiscal, and environmental management of a 14 bed cardiac intensive care unit.
- Patient population includes patients with medical diagnosis of cardiogenic shock; end stage cardiomyopathy; acute coronary syndrome; as well as patients with unstable cardiac arrhythmias.
- Accountable for interviewing, selecting, and professional development of approximately 90 staff.

Staff Nurse Cardiac ICU
Yale New Haven Hospital, New Haven, Conn.
July 1982-1991

- Primary nurse responsible for coordinating and implementing care of critically ill patients.
- Preceptor Coordinator
- One of first Clinical Nurse IV recognitions and advancements.

Recent Committee Memberships

- EPIC ancillary committee : Cardiovascular Work group
- Administrative liaison PCA steering committee
- Co-chair BSI steering committee
- Chest Pain Center Steering committee
- HVC Quality / Safety Committee
- D2B steering committee
- Hospital Patient Safety Committee (PSQC)
- SCM steering committee
- Co-Chair Patient Hourly Rounding Steering Committee
- Chair HVC newsletter committee
- Westerly Hospital Cardiac oversight committee
- Women's Heart Program steering committee
- Administrative liaison Cardiac Cluster
- ICU Leadership Group
- Magnet steering Committee
- Nursing Operations Group
- Nursing Cabinet

Recent Special Projects

- Opened 14 bed Observation Unit 5/2011
- Successful Oversight of Chest Pain Center accreditation process
- Successful Oversight of TJC VAD Destination Therapy Accreditation
- Project lead on Telemetry project
- One of several authors on ST-Map ECG software research poster/ article
- CON process, design and opening of 5th Cardiac Cath Lab and 3rd EP Lab
- Replacement and implementation of new EKG Tracemaster View System
- Co-lead development and implementation PCA career ladder
- Opened 9 bed Cardiac / Medicine Step Down Unit 1/2008

- CON process, design and opening of second EPS lab
- Cardiac Nuclear design , construction and relocationto 2EP .
- CON process, design, and opening of two Interventional labs
- CON process design, opening of Neuro Interventional lab
- Design and replacement of Cardiac Swing Lab
- Design and creation of third EPS lab
- Provided operations support for shared services model of Guilford / Branford programs

Professional Organizations/ Certifications

- 1987-present Critical Care Nurse (CCRN)
- 2004-present Certified Nurse Executive (NE-BC)
- 1985- present American Association of Critical Care Nurses (AACN)
- 1992- present American Association of Critical Care Nurses/ South Central Connecticut Chapter (AACN / SCCC)
- American Heart Association – Council of Cardiovascular Nursing
- 2006 –present American Organization Nurse Executives (AONE)
- 2006-present Organization of Nurse Executives, Conn. Chapter (ONE-CT)

Education

- 2002 Quinnipiac University, Hamden, Conn.
  Masters in Health Administration with Distinction
- 1997 Quinnipiac University, Hamden, Conn.
  Bachelors of Science in Nursing, Magna cum Laude
- 1982 Quinnipiac University, Hamden, Conn.
  Associate Degree in Nursing, Cum Laude

ATTACHMENT XI

NCDR™ CathPCI Registry®
Greenwich Hospital's Institutional
Outcomes Report 2011Q2

NCDR™
National Cardiovascular Data Registry
CathPCI Registry®
Version 4.4

Institutional Outcomes Report
2011Q2

Greenwich Hospital
187346

Aggregation Date: Sep 30, 2011 11:59:59 PM

Publish Date: Oct 19, 2011

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National Cardiovascular Data Registry
CathPCI Registry®
800-257-4737
www.ncdr.com •ncdr@acc.org
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Inclusion Summary

Quarters included in this report:

Timeframe	Benchmark Inclusion Status	Submission Type	Included in Executive Summary
2010Q3	G	All Patients	Yes
2010Q4	G	All Patients	Yes
2011Q1	Y	All Patients	No
2011Q2	G	All Patients	Yes

Comparison group included in this report:

Volume Groups	Number of PCI Procedures per R4Q	Number of Hospitals per Volume Group	Your Hospital's Volume Group	Your Annualized PCI Procedure Volume	Your Declared Procedure Volume
1	0-10	51			
2	11-200	274	X	38	40
3	201-400	299			
4	401-600	233			
5	601-1000	255			
6	1001-2000	139			
7	2001+	23			

Release Notes:

CathPCI Outcomes Registry® Report Release notes for 2011Q2

Report Modifications:

1. This is the first release of the Version 4.4 Outcomes Report.
2. In the Executive Summary Footnote there is a change in the text in regard to bleeding. It now reads, 'To qualify, the event must be associated with a hemoglobin drop of >= 3g/dl...' Where the '>=' symbol is the change.
3. We have now added indicators so that a site can see what lines Leapfrog is looking for in our report. Please see the 'Frequently used terminology' section that follows for information about those changes. We did not specify line numbers as those can change, so we put the acronym '(LFHS)' in the report line description to identify those lines that the Leapfrog Hospital Survey wishes for the sites to report to them.

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Frequently used terminology:

R4Q (Rolling Four Quarters)	The four (4) consecutive quarters included in this report. (Example: The 2011Q1 report includes 2010Q2, 2010Q3, 2010Q4 and 2011Q1. The "Q" in 'R4Q" indicates the last quarter of the rolling four quarters).
Benchmark Inclusion Status	Indicates whether a submission will be included in the R4Q aggregated data (benchmark) and comparison group statistics. "Green," "Yellow" and "Red" stoplights denote the status. A "Green" status indicates the submission (one quarter/timeframe) is included in the benchmark and comparison group statistics. The data has successfully passed all data assessment and completeness checks. A "Yellow" status indicates the submission (one quarter/timeframe) is not included in the benchmark and comparison group statistics. Data is displayed in the quarterly column, but is not included in the "My Hospital R4Q" summary. The data has not passed the overall completeness assessment checks. A "Red" status indicates the submission (one quarter/timeframe) is not included in the benchmark or comparison group statistics. Data is not displayed in the quarterly column. A null or blank status indicates no submission has been received for that quarter/timeframe. Data is not displayed in the quarterly column.
Submission Type	Indicates the Submission Type based on the percentage of procedures performed in the submission file. A file with fewer than 50% of the procedures performed indicated as Diagnostic Catheterizations are designated as "PCI Only" submissions.
My Hospital R4Q	The values for a metric/measure (over R4Q) of data submitted by your facility with a Benchmark Inclusion Status of "Green".
All Hospital 50th Pctl	The median (or midpoint or 50th percentile) of all participant aggregated data for the metric or measure. Half of all participants will be above the median, and half will be below. This value will correspond to the midpoint of the box/whisker plot.
All Hospital 90th Pctl	The 90th percentile of all participant aggregated data for the metric or measure. 10% of all participants will be above the 90th percentile value, and 90% will be below. This value will correspond to the right-most endpoint of the box/whisker plot.
Annualized Volume	Annualized Volume is the total number of PCI procedures submitted over the R4Q period, adjusted for the number of quarters in which valid submissions were received during the R4Q period.
Volume Group Pts R4Q	The aggregated value for the metric/measure across all patients in the specified comparison group (over R4Q). Comparison Groups are based on annualized procedure volume. See the Comparison Group chart on the Inclusion Summary page of this report. To be included, data must have a Benchmark Inclusion Status of "Green".
All Registry Pts R4Q	The aggregated value for the measure/metric across all patients (over R4Q). To be included, data must have a Benchmark Inclusion Status of "Green". Only facilities in the United States and outlying territories are included.
Declared Procedure Volume	Indicates the estimated annual procedure volume as reported by the facility on the NCDR website Site Profile.
LFHS	This stands for Leapfrog Hospital Survey. This is to help identify the lines that are used for Leapfrog reporting for our participants. Please note that in the detail lines you will see "(LFHS)" to denote the lines that are to be used for Actual and Risk Adjusted Mortality Rate calculations.
Actual Mortality Rate (LFHS)	Enter your hospital's (actual) observed mortality rate (OMR) as a percentage. Using data from the My Hospital R4Q "Num" column in the current NCDR CathPCI Registry Institutional Outcomes Reports, OMR must be calculated by dividing the number for "Observed Mortality (among eligible) (LFHS)" by the number for "Eligible pts (LFHS)" to obtain the % rate for the most recent rolling four quarters where 12 consecutive months of data was submitted [i.e., Observed Mortality (among eligible) (LFHS)/Eligible pts (LFHS)].
Expected Mortality Rate (LFHS)	Enter your hospital's expected mortality rate (EMR) as a percentage. Using data from the Hospital R4Q "Num" column in the current NCDR CathPCI Registry Institutional Outcomes Reports, EMR must be calculated by dividing the number for "Expected Mortality (among eligible) (LFHS)" by the number for "Eligible pts (LFHS)" to obtain the % rate for the most recent rolling four quarters where 12 consecutive months of data was submitted [i.e., Expected Mortality (among eligible) (LFHS)/Eligible pts (LFHS)].

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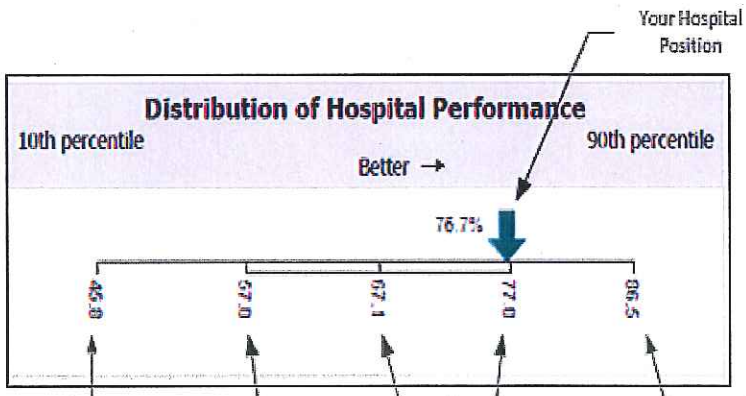
Box and Whisker Plots

Interpreting Box and Whisker Plots



10th percentile
If your hospital scores below the 10th percentile, the arrow will be on the left of this number.

25th Percentile

Median

75th Percentile

90th Percentile
If your hospital scores above the 90th percentile, the arrow will be on the right of this number.

10th Percentile
90% of the hospitals achieved "better" scores than the 10th percentile.

25th Percentile or 1st Quartile
75% of the hospitals achieved "better" scores than the 25th percentile.

50th Percentile or 2nd Quartile
Middle of the distribution: Half of the hospitals data is above and half are below the median.

75th Percentile or 3rd Quartile
25% of the hospitals achieved "better" scores than the 75th percentile.

90th Percentile
10% of the hospitals achieved "better" scores than the 90th percentile.

Your Hospital Position
Your 'Hospital Position' in relation to all other hospitals' data.

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Executive Summary

CathPCI Registry®

Greenwich Hospital(187346) compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2011Q2

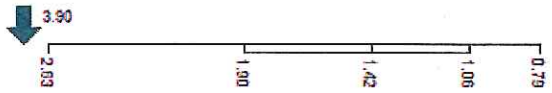
Section I: PCI Performance Measures

Endorsed by the National Quality Forum and appropriate for public reporting

PCI Performance Measures	Distribution of Hospital Performance (10th percentile — 90th percentile; Better →)
1 **PCI in-hospital risk adjusted mortality (all patients)**	

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
3.90	1.42	0.79

Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1997]



Note

In-hospital risk adjusted mortality for PCI is the only performance measure in the CathPCI Registry® that has been endorsed by the National Quality Forum. Such performance measures meeting the requirement for approval are intended not only for clinical quality improvement, but also may be considered for purposes of public reporting.

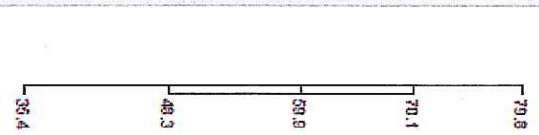
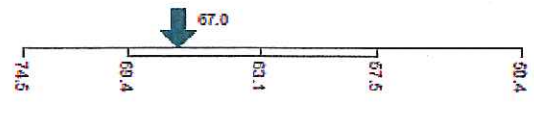
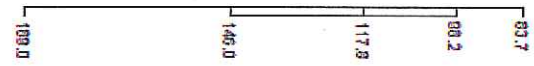
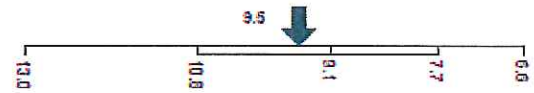
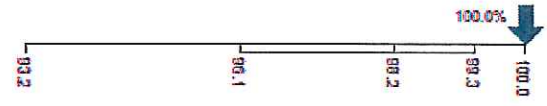
The "Registry Metrics" on the subsequent pages of this report are those measures that have been developed to support self assessment and quality improvement at the provider, hospital, and/or health care system level. While these metrics have not been formally developed by the American College of Cardiology/American Heart Association Task Force for Performance Measures Task Force, they may be identified as evolving measures worthy of consideration for further development into performance measures.

Executive Summary

CathPCI Registry®

Greenwich Hospital(187346) compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2011Q2

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

	PCI Process Metrics	Distribution of Hospital Performance (10th percentile — 90th percentile; Better →)
2	**Proportion of elective PCIs with prior positive stress or imaging study** My Hospital: — | All Hospitals 50th Pctl: 59.9% | All Hospitals 90th Pctl: 79.8% Proportion of elective PCI procedures (excluding patients with ACS) with an antecedent stress or imaging study with a positive result (suggestive of ischemia) or with a fractional flow reserve value of <=0.8 during the PCI procedure [Detail Line:1511]	
3	**Median time to immediate PCI for STEMI patients (in minutes)** My Hospital: 67.0 | All Hospitals 50th Pctl: 63.1 | All Hospitals 90th Pctl: 50.4 Your hospital's median time from hospital arrival to immediate PCI for STEMI patients in minutes. Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1500]	
4	**Proportion of STEMI patients receiving immediate PCI w/in 90"** My Hospital: 100.0% | All Hospitals 50th Pctl: 91.4% | All Hospitals 90th Pctl: 100.0% Proportion of STEMI patients with a time from your hospital arrival (or subsequent ECG if ST elevation first noted on subsequent ECG) to immediate PCI <=90". Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1501]	
5	**Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.** My Hospital: — | All Hospitals 50th Pctl: 85.5 | All Hospitals 90th Pctl: 57.8 Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1503]	
6	**Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)** My Hospital: — | All Hospitals 50th Pctl: 117.8 | All Hospitals 90th Pctl: 83.7 Your hospital's median time from arrival at referring facility to immediate PCI at STEMI receiving facility among transferred patients. Exclusions: Reasons for delay does not equal none. [Detail Line:1504]	
7	**Median fluoro time (in minutes)** My Hospital: 9.5 | All Hospitals 50th Pctl: 9.1 | All Hospitals 90th Pctl: 6.6 Inclusion criteria: PCI of one vessel/lesion. Exclusion criteria: Prior CABG, or "other" procedure during the same lab visit; PCI of >1 vessel/lesion. [Detail Line:1629]	
8	**Proportion of patients with aspirin prescribed at discharge** My Hospital: — | All Hospitals 50th Pctl: 98.2% | All Hospitals 90th Pctl: 100.0% Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1959]	
9	**Proportion of patients with thienopyridine prescribed at discharge** My Hospital: — | All Hospitals 50th Pctl: 99.1% | All Hospitals 90th Pctl: 100.0% Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine prescribed at discharge. [Detail Line: 1968]	

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Executive Summary

CathPCI Registry®

Greenwich Hospital(187346) compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2011Q2

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

10 **Statins prescribed at discharge**

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
100.0%	91.5%	97.3%

Proportion of patients (without a documented contraindication) prescribed a statin at discharge. [Detail Line:1964]



PCI Outcome Metrics

Distribution of Hospital Performance

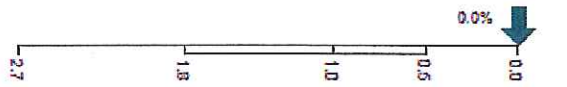
10th percentile — 90th percentile

Better →

11 **Proportion of PCI procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
0.0%	1.0%	0.0%

Your hospital's proportion of patients (excluding CABG or other surgery during same admission) with major access site related injury requiring treatment or major bleeding. [Detail Line:1836]



12 **Proportion of PCI patients with emergency CABG**

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
0.0%	0.1%	0.0%

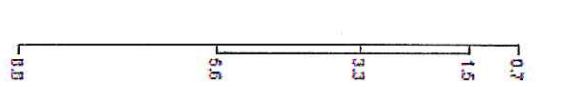
Your hospital's proportion of patients having emergency CABG (at your facility or transferred to another facility). [Detail Line:1941]



13 **Proportion of PCI procedures with a post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
	3.3%	0.7%

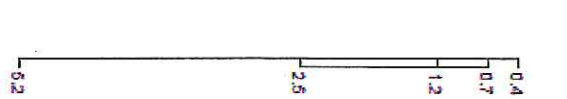
Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with >= 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1799]



14 **Proportion of PCI procedures with post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
	1.2%	0.4%

Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with < 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1800]



15 **Proportion of PCI procedures with acute kidney injury*****

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
	2.2%	1.0%

Your hospital's proportion of patients who had a rise of serum creatinine of > 50% over the pre-procedure baseline (excluding patients on dialysis pre-procedure). Inclusions: >= 90% of patients with a pre and post creatinine coded; LOS >=1 day. [Detail Line:1933]



16 **Proportion of PCI procedures with post procedure stroke**

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
0.0%	0.0%	0.0%

Your hospital's proportion of patients with stroke post procedure. [Detail Line:1807]



17 **Composite: Proportion of PCI patients with death, emergency CABG, stroke or repeat target vessel revascularization.**

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
6.9%	2.3%	0.9%

Your hospital's proportion of patients with death, emergency CABG, stroke or repeat target vessel revascularization post procedure up to hospital discharge. Excludes patients with stroke and an elective, urgent or salvage CABG during same admission. [Detail Line:1797]



Executive Summary

CathPCI Registry®

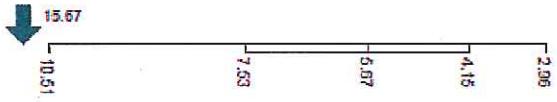
Greenwich Hospital(187346) compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2011Q2

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

18 **PCI in-hospital risk adjusted mortality (patients with STEMI)**

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
15.67	5.67	2.96

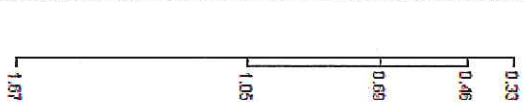
Your hospital's PCI in-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:2006]



19 **PCI in-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
	0.69	0.33

Your hospital's PCI in-hospital risk adjusted mortality rate for patients with other diagnoses (not STEMI) using the NCDR® risk adjustment model. [Detail Line:2015]



Diagnostic Cath Process Metrics

Distribution of Hospital Performance

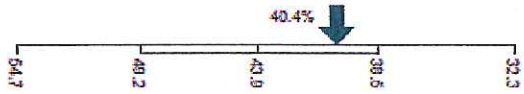
10th percentile — 90th percentile

Better →

20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
40.4%	43.9%	32.3%

Patients with an elective diagnostic cath and coronary angiography with all native coronary territories <50% Exclusions: Patients with prior CABG, cardiac transplant evaluation; pre-op evaluation for non-cardiac surgery and diagnostic cath treatment recommendation of "other cardiac therapy without CABG or PCI". [Detail Line:1252]



Diagnostic Cath Outcomes Metrics

Distribution of Hospital Performance

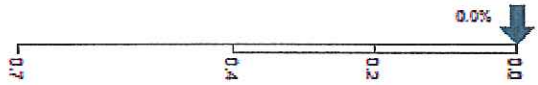
10th percentile — 90th percentile

Better →

21 **Proportion of Diagnostic Catheterization procedures with vascular access site injury requiring treatment or major bleeding***

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
0.0%	0.2%	0.0%

Your hospital's proportion of patients with major access site related injury requiring treatment or major bleeding. [Detail Line:1301]



Utilization Metrics

Distribution of Hospital Performance

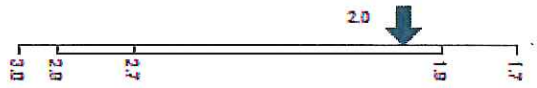
10th percentile — 90th percentile

Better →

22 **Median post-procedure length of stay (in days) for PCI patients with STEMI**

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
2.0	2.7	1.7

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2071]



Data Quality Metrics

Distribution of Hospital Performance

10th percentile — 90th percentile

Better →

24 **Proportion of PCI procedures with creatinine assessed pre and post PCI**

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
79.3%	86.0%	96.1%

Proportion of PCI patients with creatinine assessed pre and post procedure. Inclusions: LOS >=1 day. [Detail Line:1932]



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Executive Summary

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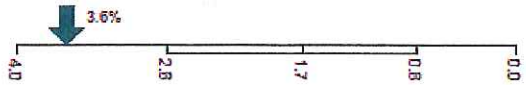
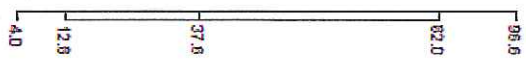
Greenwich Hospital(187346) compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2011Q2

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

Test Metrics		Distribution of Hospital Performance
		10th percentile — 90th percentile; Better →
25	**Test Metric: Proportion of PCI procedures with transfusion of whole blood or RBCs** My Hospital: 3.6% | All Hospitals 50th Pctl: 1.7% | All Hospitals 90th Pctl: 0.0% Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Exclusions: Patients having CABG or other major surgery during the same admission. [Detail Line:1838]	
26	**Test Data Quality Metric: Proportion of PCI procedures with biomarkers assessed post-PCI for elective inpatients** My Hospital: | All Hospitals 50th Pctl: 37.6% | All Hospitals 90th Pctl: 96.6% Proportion of elective procedures with biomarkers assessed post PCI. Inclusion criteria: LOS >= 1 day and hospital status is "not outpatient". [Detail Line:1930]	

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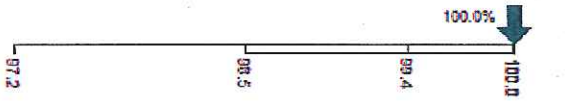
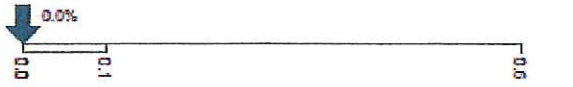
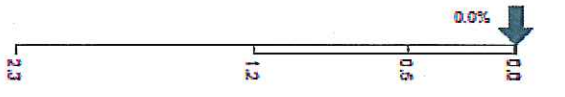
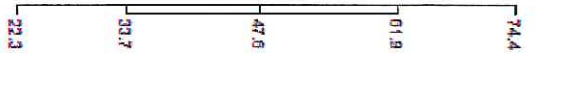
Greenwich Hospital(187346) compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2011Q2

Section III: PCI Appropriate Use Criteria (AUC) Test Metrics – These data are based upon the 2009 Appropriateness Criteria for Coronary Revascularization (J Am Coll Cardiol 2009;53:530-53) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These test metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level. Test metrics are not appropriate for public/external reporting.

Test Metrics: PCI Appropriate Use Criteria (AUC)	Distribution of Hospital Performance (10th percentile – 90th percentile; Better →)
30 **Test Metric: Proportion of PCI procedures not classifiable for AUC reporting** My Hospital: 0.0% | All Hospitals 50th Pctl: 11.9% | All Hospitals 90th Pctl: 2.7% Proportion of PCI procedures that were not classifiable/evaluated for PCI AUC reporting due to incomplete or missing data. [Detail Line:1587]	
31 **Patients WITH Acute Coronary Syndrome (Test Metric): Proportion of evaluated PCI procedures that were appropriate** My Hospital: 100.0% | All Hospitals 50th Pctl: 99.4% | All Hospitals 90th Pctl: 100.0% Proportion of PCI procedures that were evaluated as "Appropriate", among patients with ACS, meaning coronary revascularization is generally acceptable and is a reasonable approach for the indication and is likely to improve the patients' health outcomes or survival. [Detail Line:1579]	
32 **Patients WITH Acute Coronary Syndrome (Test Metric): Proportion of evaluated PCI procedures that were of uncertain appropriateness** My Hospital: 0.0% | All Hospitals 50th Pctl: 0.0% | All Hospitals 90th Pctl: 0.6% Proportion of PCI procedures that were evaluated as "Uncertain", among patients with ACS, meaning coronary revascularization may be acceptable and may be a reasonable approach for the indication. However, some degree of uncertainty exists, implying that more research and/or patient information is needed to determine whether the procedure would improve patients' health outcomes or survival. [Detail Line:1580]	
33 **Patients WITH Acute Coronary Syndrome (Test Metric): Proportion of evaluated PCI procedures that were inappropriate** My Hospital: 0.0% | All Hospitals 50th Pctl: 0.5% | All Hospitals 90th Pctl: 0.0% Proportion of PCI procedures that were evaluated as "Inappropriate", among patients with ACS, meaning coronary revascularization is not generally acceptable and is not a reasonable approach for the indication and is unlikely to improve the patients' health outcomes or survival. [Detail Line:1581]	
34 **Patients WITHOUT Acute Coronary Syndrome (Test Metric): Proportion of evaluated PCI procedures that were appropriate** My Hospital: | All Hospitals 50th Pctl: 47.6% | All Hospitals 90th Pctl: 74.4% Proportion of PCI procedures that were evaluated as "Appropriate", among patients without ACS, meaning coronary revascularization is generally acceptable and is a reasonable approach for the indication and is likely to improve the patients' health outcomes or survival. [Detail Line:1583]	
35 **Patients WITHOUT Acute Coronary Syndrome (Test Metric): Proportion of evaluated PCI procedures that were of uncertain appropriateness** My Hospital: | All Hospitals 50th Pctl: 39.1% | All Hospitals 90th Pctl: 61.5% Proportion of PCI procedures that were evaluated as "Uncertain", among patients without ACS, meaning coronary revascularization may be acceptable and may be a reasonable approach for the indication. However, some degree of uncertainty exists, implying that more research and/or patient information is needed to determine whether the procedure would improve patients' health outcomes or survival. [Detail Line:1584]	

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Section III: PCI Appropriate Use Criteria (AUC) Test Metrics – These data are based upon the 2009 Appropriateness Criteria for Coronary Revascularization (J Am Coll Cardiol 2009;53:530-53) document developed by the ACC, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Heart Association, and other national societies. These test metrics are designed to provide sites feedback on the appropriateness of percutaneous coronary intervention procedures at the hospital level. Test metrics are not appropriate for public/external reporting.

36 **Patients WITHOUT Acute Coronary Syndrome (Test Metric): Proportion of evaluated PCI procedures that were inappropriate**

My Hospital	All Hospitals 50th Pctl	All Hospitals 90th Pctl
	9.5%	0.0%

Proportion of PCI procedures that were evaluated as "Inappropriate", among patients without ACS, meaning coronary revascularization is not generally acceptable and is not a reasonable approach for the indication and is unlikely to improve the patients' health outcomes or survival. [Detail Line:1585]



Executive Summary Footnotes

*Vascular access site injury requiring treatment or major bleeding is defined as:

1.Bleeding at access site, hematoma at access site, or retroperitoneal bleed that occur within 72 hours of the procedure. To qualify, the event must be associated with a hemoglobin drop of >= 3 g/dL; transfusion of whole or packed red blood cells, or a procedural intervention/surgery at the bleeding site to reverse/stop or correct the bleeding. This excludes "GI", "GU" and "Other" bleeds.

2.Major access site related injury requiring treatment includes access site occlusion, peripheral embolization, dissection, pseudoaneurysm, AV fistula requiring treatment anytime from the procedure until discharge.

**Your rate of post procedure MI cannot be reported if you only collected cardiac biomarkers on <90% of your patients who were in the hospital >=1 day.

***Your rate of acute kidney injury cannot be reported if you only collected creatinine pre and post procedure on <90% of your patients who were in the hospital >=1 day.

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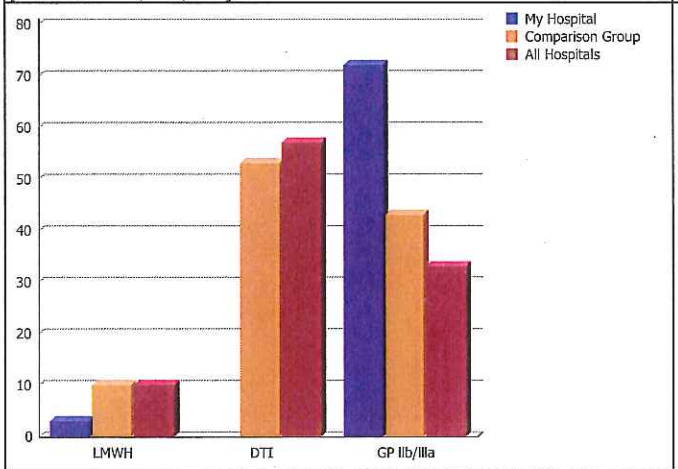
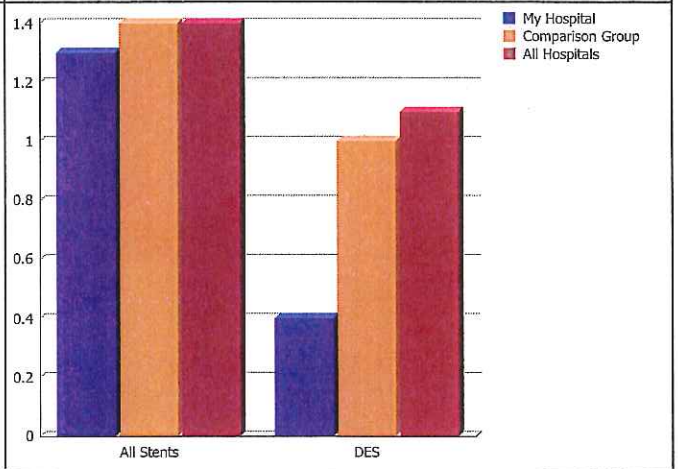
Section IV: PCI Process Comparison Metrics

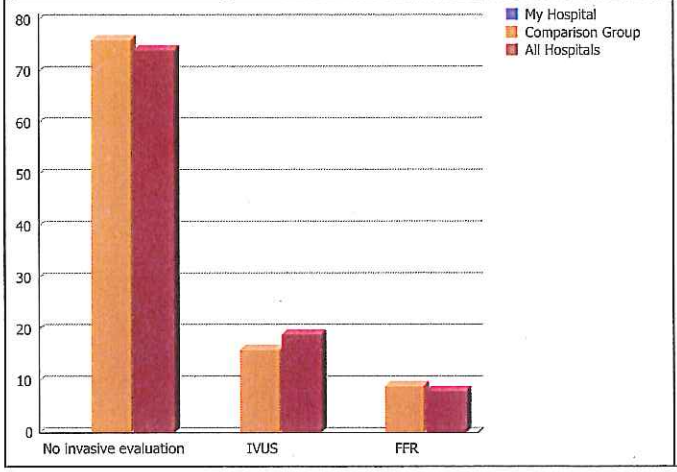
Anticoagulant Use: Low molecular weight heparin, direct thrombin inhibitors, GP IIb/IIIa inhibitor(pts with acute coronary syndrome).
[Detail Line:1596,1598,1603]



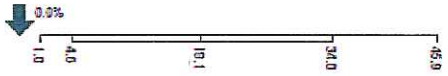
Stent Use: Average # of stents per PCI admission.
[Detail Line:1789,1790]



Intermediate stenosis lesions(40-70%): Further invasive evaluation performed (IVUS or FFR).
[Detail Line:1728,1729,1730]



Outpatients: Proportion of PCI patient admissions whose hospital status was coded as "outpatient".
[Detail Line:1388]



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Detail Section Line Reference

Population	Section	First Line #	Last Line #
All Diagnostic Cath and PCI Patients	Volume Summary	1000	1014
	Demographics and Payors	1015	1049
Diagnostic Cath with/without PCI	Demographics and Payors	1050	1084
	History and Risk Factors (on arrival)	1085	1102
	Clinical Evaluation Leading to the Procedure	1103	1139
	Stress and Imaging Studies	1140	1201
	Procedure Information	1202	1246
	Procedure Findings	1247	1273
	Discharge Information	1302	1323
Diagnostic Cath (No PCI)	Adverse Events	1274	1301
	Length of Stay	1324	1360
PCI	Demographics and Payors	1361	1399
	History and Risk Factors (on arrival)	1400	1431
	Clinical Evaluation Leading to the Procedure	1432	1472
	Procedure Indications	1473	1505
	Stress and Imaging Studies	1506	1569
	Appropriate Use Criteria	1570	1590
	Medications	1591	1608
	Procedure Information	1609	1673
	Procedure Findings	1674	1705
	PCI Lesion Information	1706	1793
	Lab Results	1929	1935
	Discharge Information	1936	2018
PCI (all patients)	Adverse Events	1794	1840
	Length of Stay	2019	2057
PCI (patients with STEMI)	Adverse Events	1841	1882
	Length of Stay	2058	2096
PCI (patients without STEMI)	Adverse Events	1883	1928
	Length of Stay	2097	2135

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All Diagnostic Cath and PCI Patients
Volume Summary
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1000	Summary																			
1001	**Number of Patients treated at this facility**	**53**			**67**			**71**			**71**			**191**			**79,997**		**1,343,820**	
1002	Dx cath	53	53	100.0	67	67	100.0	71	71	100.0	71	71	100.0	191	191	100.0	78,284	97.9	1,273,505	94.8
1003	PCI	5	53	9.4	14	67	20.9	8	71	11.3	10	71	14.1	29	191	15.2	27,644	34.6	619,579	46.1
1004	Other procedure in conjunction w/ a dx cath or PCI	0	53	0.0	1	67	1.5	0	71	0.0	27	71	38.0	28	191	14.7	7,031	8.8	153,348	11.4
1005	Pts w/ dx cath and PCI in the same lab visit	5	53	9.4	14	67	20.9	8	71	11.3	10	71	14.1	29	191	15.2	25,382	31.7	533,939	39.7
1006	Pts w/ dx cath then a PCI in a subsequent lab visit	0	53	0.0	0	67	0.0	0	71	0.0	0	71	0.0	0	191	0.0	545	0.7	15,254	1.1
1007	PCI procedures per PCI admission	5	5	100.0	14	14	100.0	8	8	100.0	10	10	100.0	29	29	100.0	28,171	101.9	636,415	102.7
1008	Pts w/ >1 PCI on the same coronary segment/lesion	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	111	0.4	3,293	0.5
1009	Procedures																			
1010	Dx cath procedures	53	53	100.0	68	68	100.0	71	71	100.0	71	71	100.0	192	192	100.0	78,943	96.9	1,287,327	93.0
1011	Dx coronary angiography	52	53	98.1	67	68	98.5	71	71	100.0	70	71	98.6	189	192	98.4	76,956	97.5	1,259,255	97.8
1012	Left heart cath	52	53	98.1	68	68	100.0	68	71	95.8	71	71	100.0	191	192	99.5	69,309	87.8	1,155,748	89.8
1013	PCI procedures	5	53	9.4	14	68	20.6	8	71	11.3	10	71	14.1	29	192	15.1	28,171	34.6	636,415	46.0
1014	Dx cath and PCI during same lab visit	5	53	9.4	14	68	20.6	8	71	11.3	10	71	14.1	29	192	15.1	25,657	31.5	540,061	39.0

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All Diagnostic Cath and PCI Patients
Demographics and Payors
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1015	Demographics																			
1016	**Sex**																			
1017	Male	32	53	60.4	45	67	67.2	47	71	66.2	52	71	73.2	129	191	67.5	47,651	59.6	822,078	61.2
1018	Female	21	53	39.6	22	67	32.8	24	71	33.8	19	71	26.8	62	191	32.5	32,346	40.4	521,742	38.8
1019	**Age at admission**																			
1020	Mean age	67			65			67			68			67			63		64	
1021	Median age	71			64			64			70			68			63		64	
1022	18-44	2	53	3.8	7	67	10.5	5	71	7.0	3	71	4.2	12	191	6.3	5,500	6.9	82,367	6.1
1023	45-54	6	53	11.3	10	67	14.9	14	71	19.7	10	71	14.1	26	191	13.6	15,012	18.8	232,307	17.3
1024	55-64	12	53	22.6	17	67	25.4	17	71	23.9	16	71	22.5	45	191	23.6	22,114	27.6	366,992	27.3
1025	65-69	6	53	11.3	4	67	6.0	3	71	4.2	6	71	8.5	16	191	8.4	11,071	13.8	197,967	14.7
1026	70-74	10	53	18.9	6	67	9.0	6	71	8.5	13	71	18.3	29	191	15.2	9,381	11.7	169,598	12.6
1027	75-79	7	53	13.2	10	67	14.9	5	71	7.0	7	71	9.9	24	191	12.6	8,082	10.1	141,955	10.6
1028	>= 80	10	53	18.9	13	67	19.4	21	71	29.6	16	71	22.5	39	191	20.4	8,837	11.1	152,624	11.4
1029	Medicare age (>= 65)	33	53	62.3	33	67	49.3	35	71	49.3	42	71	59.2	108	191	56.5	37,371	46.7	662,150	49.3
1030	**Race**																			
1031	White	48	53	90.6	62	67	92.5	66	71	93.0	69	71	97.2	179	191	93.7	66,220	82.8	1,164,171	86.6
1032	Black/African American	2	53	3.8	1	67	1.5	4	71	5.6	2	71	2.8	5	191	2.6	10,785	13.5	134,609	10.0
1033	Asian	2	53	3.8	4	67	6.0	0	71	0.0	0	71	0.0	6	191	3.1	1,550	1.9	26,433	2.0
1034	American Indian/Alaskan	1	53	1.9	0	67	0.0	0	71	0.0	0	71	0.0	1	191	0.5	647	0.8	7,468	0.6
1035	Hawaiian/Pacific Islander	0	53	0.0	0	67	0.0	1	71	1.4	0	71	0.0	0	191	0.0	212	0.3	2,446	0.2
1036	**Hispanic or Latino ethnicity**	**8**	**53**	**15.1**	**8**	**66**	**12.1**	**8**	**71**	**11.3**	**4**	**71**	**5.6**	**20**	**190**	**10.5**	**5,466**	**6.9**	**67,661**	**5.1**
1037	**Insurance payors**																			
1038	Private	23	53	43.4	39	67	58.2	57	71	80.3	61	71	85.9	123	191	64.4	45,601	57.0	848,672	63.2
1039	Medicare	31	53	58.5	31	67	46.3	36	71	50.7	39	71	54.9	101	191	52.9	37,136	46.4	676,557	50.4
1040	Medicaid	1	53	1.9	2	67	3.0	5	71	7.0	2	71	2.8	5	191	2.6	8,126	10.2	140,630	10.5
1041	Military	0	53	0.0	0	67	0.0	0	71	0.0	0	71	0.0	0	191	0.0	1,672	2.1	36,545	2.7
1042	State-specific (non-medicaid)	1	53	1.9	1	67	1.5	2	71	2.8	0	71	0.0	2	191	1.1	1,917	2.4	21,900	1.6
1043	Indian Health Service	0	53	0.0	0	67	0.0	0	71	0.0	0	71	0.0	0	191	0.0	211	0.3	2,336	0.2
1044	Non-U.S. insurance	0	53	0.0	0	67	0.0	0	71	0.0	0	71	0.0	0	191	0.0	41	0.1	857	0.1
1045	None	2	53	3.8	7	67	10.5	2	71	2.8	4	71	5.6	13	191	6.8	5,721	7.2	79,535	5.9
1046	**CABG during episode of care**	**5**	**53**	**9.4**	**2**	**67**	**3.0**	**6**	**71**	**8.5**	**2**	**71**	**2.8**	**9**	**191**	**4.7**	**4,065**	**5.1**	**62,992**	**4.7**
1047	**Discharge status**																			
1048	Alive	50	53	94.3	67	67	100.0	69	71	97.2	69	71	97.2	186	191	97.4	79,106	98.9	1,328,747	98.9
1049	Expired (excluding transplants)	3	53	5.7	0	67	0.0	2	71	2.8	2	71	2.8	5	191	2.6	823	1.1	14,282	1.1

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Diagnostic Cath with/without PCI
Demographics and Payors
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1050	Demographics																			
1051	**Sex**																			
1052	Male	32	53	60.4	45	67	67.2	47	71	66.2	52	71	73.2	129	191	67.5	46,504	59.4	775,181	60.9
1053	Female	21	53	39.6	22	67	32.8	24	71	33.8	19	71	26.8	62	191	32.5	31,780	40.6	498,324	39.1
1054	**Age at admission**																			
1055	Mean age	67			65			67			68			67			63		64	
1056	Median age	71			64			64			70			68			63		64	
1057	18-44	2	53	3.8	7	67	10.5	5	71	7.0	3	71	4.2	12	191	6.3	5,429	6.9	80,029	6.3
1058	45-54	6	53	11.3	10	67	14.9	14	71	19.7	10	71	14.1	26	191	13.6	14,753	18.9	222,938	17.5
1059	55-64	12	53	22.6	17	67	25.4	17	71	23.9	16	71	22.5	45	191	23.6	21,660	27.7	348,350	27.4
1060	65-69	6	53	11.3	4	67	6.0	3	71	4.2	6	71	8.5	16	191	8.4	10,809	13.8	186,267	14.6
1061	70-74	10	53	18.9	6	67	9.0	6	71	8.5	13	71	18.3	29	191	15.2	9,169	11.7	159,403	12.5
1062	75-79	7	53	13.2	10	67	14.9	5	71	7.0	7	71	9.9	24	191	12.6	7,871	10.1	133,230	10.5
1063	>= 80	10	53	18.9	13	67	19.4	21	71	29.6	16	71	22.5	39	191	20.4	8,593	11.0	143,279	11.3
1064	Medicare age (>= 65)	33	53	62.3	33	67	49.3	35	71	49.3	42	71	59.2	108	191	56.5	36,442	46.6	622,185	48.9
1065	**Race**																			
1066	White	48	53	90.6	62	67	92.5	66	71	93.0	69	71	97.2	179	191	93.7	64,695	82.6	1,102,556	86.6
1067	Black/African American	2	53	3.8	1	67	1.5	4	71	5.6	2	71	2.8	5	191	2.6	10,651	13.6	128,396	10.1
1068	Asian	2	53	3.8	4	67	6.0	0	71	0.0	0	71	0.0	6	191	3.1	1,524	2.0	25,078	2.0
1069	American Indian/Alaskan	1	53	1.9	0	67	0.0	0	71	0.0	0	71	0.0	1	191	0.5	643	0.8	7,193	0.6
1070	Hawaiian/Pacific Islander	0	53	0.0	0	67	0.0	1	71	1.4	0	71	0.0	0	191	0.0	211	0.3	2,344	0.2
1071	**Hispanic or Latino ethnicity**	**8**	**53**	**15.1**	**8**	**66**	**12.1**	**8**	**71**	**11.3**	**4**	**71**	**5.6**	**20**	**190**	**10.5**	**5,367**	**6.9**	**64,721**	**5.1**
1072	**Hospital status**																			
1073	Outpt	19	53	35.9	18	67	26.9	21	71	29.6	19	71	26.8	56	191	29.3	28,367	36.3	516,866	40.6
1074	Outpt converted to inpt	2	53	3.8	3	67	4.5	2	71	2.8	3	71	4.2	8	191	4.2	8,283	10.6	147,039	11.6
1075	Inpt	32	53	60.4	46	67	68.7	48	71	67.6	49	71	69.0	127	191	66.5	41,584	53.2	609,230	47.9
1076	**Insurance payors**																			
1077	Private	23	53	43.4	39	67	58.2	57	71	80.3	61	71	85.9	123	191	64.4	44,707	57.1	804,256	63.2
1078	Medicare	31	53	58.5	31	67	46.3	36	71	50.7	39	71	54.9	101	191	52.9	36,249	46.3	636,096	50.0
1079	Medicaid	1	53	1.9	2	67	3.0	5	71	7.0	2	71	2.8	5	191	2.6	8,014	10.2	133,764	10.5
1080	Military	0	53	0.0	0	67	0.0	0	71	0.0	0	71	0.0	0	191	0.0	1,655	2.1	34,566	2.7
1081	State-specific (non-medicaid)	1	53	1.9	1	67	1.5	2	71	2.8	0	71	0.0	2	191	1.1	1,872	2.4	21,044	1.7
1082	Indian Health Service	0	53	0.0	0	67	0.0	0	71	0.0	0	71	0.0	0	191	0.0	207	0.3	2,246	0.2
1083	Non-U.S. insurance	0	53	0.0	0	67	0.0	0	71	0.0	0	71	0.0	0	191	0.0	39	0.1	832	0.1
1084	None	2	53	3.8	7	67	10.5	2	71	2.8	4	71	5.6	13	191	6.8	5,614	7.2	76,508	6.0

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Diagnostic Cath with/without PCI
History and Risk Factors (on arrival)
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1085	Cardiac history and risk factors																			
1086	**Body mass index**																			
1087	Overweight (BMI>=25)	39	53	73.6	45	67	67.2	55	71	77.5	51	71	71.8	135	191	70.7	61,911	79.4	1,014,502	79.8
1088	Obese (BMI>=30)	18	53	34.0	16	67	23.9	24	71	33.8	22	71	31.0	56	191	29.3	35,859	46.0	582,700	45.8
1089	Morbidly obese (BMI>=40)	1	53	1.9	3	67	4.5	0	71	0.0	1	71	1.4	5	191	2.6	7,487	9.6	113,885	9.0
1090	**Family history of premature CAD**	**15**	**53**	**28.3**	**18**	**67**	**26.9**	**21**	**71**	**29.6**	**19**	**71**	**26.8**	**52**	**191**	**27.2**	**23,210**	**29.7**	**321,681**	**25.3**
1091	**Prior MI (>7 days)**	**12**	**53**	**22.6**	**13**	**67**	**19.4**	**22**	**71**	**31.0**	**26**	**71**	**36.6**	**51**	**191**	**26.7**	**16,616**	**21.2**	**310,833**	**24.4**
1092	**Prior PCI**	**7**	**53**	**13.2**	**9**	**67**	**13.4**	**6**	**71**	**8.5**	**17**	**71**	**23.9**	**33**	**191**	**17.3**	**18,943**	**24.2**	**396,406**	**31.1**
1093	Previous PCI timeframe																			
1094	<=1 year	0	1	0.0							0	2	0.0	0	3	0.0	2,411	30.5	67,449	31.4
1095	>1 year	1	1	100.0							2	2	100.0	3	3	100.0	5,483	69.5	147,415	68.6
1096	**Prior CABG**	**3**	**53**	**5.7**	**6**	**67**	**9.0**	**3**	**70**	**4.3**	**7**	**71**	**9.9**	**16**	**191**	**8.4**	**8,813**	**11.3**	**197,026**	**15.5**
1097	Timeframe of prior CABG																			
1098	<=5 years																723	24.4	24,276	24.8
1099	> 5 years																2,242	75.6	73,754	75.2
1100	Other history																			
1101	**Currently on dialysis**	**0**	**53**	**0.0**	**0**	**67**	**0.0**	**0**	**71**	**0.0**	**1**	**71**	**1.4**	**1**	**191**	**0.5**	**2,128**	**2.7**	**30,893**	**2.4**
1102	**Diabetes mellitus**	**13**	**53**	**24.5**	**12**	**67**	**17.9**	**15**	**71**	**21.1**	**17**	**71**	**23.9**	**42**	**191**	**22.0**	**26,563**	**34.0**	**443,170**	**34.8**

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Diagnostic Cath with/without PCI
Clinical Evaluation Leading to the Procedure
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1103	Clinical evaluation leading to the Dx cath																			
1104	**CAD presentation**																			
1105	No symptoms,no angina	18	53	34.0	8	68	11.8	5	71	7.0	4	71	5.6	30	192	15.6	10,636	13.5	166,969	13.0
1106	Symptoms unlikely to be ischemic	17	53	32.1	13	68	19.1	18	71	25.4	17	71	23.9	47	192	24.5	9,743	12.4	142,687	11.1
1107	Stable angina	1	53	1.9	7	68	10.3	5	71	7.0	5	71	7.0	13	192	6.8	15,183	19.2	240,649	18.7
1108	Unstable angina	9	53	17.0	18	68	26.5	15	71	21.1	23	71	32.4	50	192	26.0	24,013	30.4	448,653	34.9
1109	Non-STEMI	2	53	3.8	8	68	11.8	19	71	26.8	11	71	15.5	21	192	10.9	10,378	13.2	176,400	13.7
1110	STEMI	6	53	11.3	14	68	20.6	9	71	12.7	11	71	15.5	31	192	16.2	8,957	11.4	111,628	8.7
1111	**Timeframe from sx onset to arrival (for acute MI)**																			
1112	<=6 hrs	3	8	37.5	8	22	36.4	13	28	46.4	8	22	36.4	19	52	36.5	9,498	49.1	124,420	43.2
1113	>6 hrs	1	8	12.5	4	22	18.2	4	28	14.3	4	22	18.2	9	52	17.3	3,212	16.6	63,278	22.0
1114	Timeframe not available	4	8	50.0	9	21	42.9	10	27	37.0	8	22	36.4	21	51	41.2	5,099	26.8	84,307	29.5
1115	**STEMI pts receiving lytics**	**0**			**0**			**0**			**0**			**0**			**306**		**7,888**	
1116	**Anginal/CCS classification w/in past 2 wks**																			
1117	No symptoms	46	53	86.8	23	68	33.8	27	71	38.0	23	71	32.4	92	192	47.9	19,363	24.7	241,906	18.9
1118	CCS Class I	0	53	0.0	8	68	11.8	18	71	25.4	18	71	25.4	26	192	13.5	9,888	12.6	124,203	9.7
1119	CCS Class II	0	53	0.0	15	68	22.1	17	71	23.9	15	71	21.1	30	192	15.6	19,469	24.9	294,873	23.0
1120	CCS Class III	1	53	1.9	7	68	10.3	1	71	1.4	6	71	8.5	14	192	7.3	16,315	20.8	359,636	28.0
1121	CCS Class IV	6	53	11.3	15	68	22.1	8	71	11.3	9	71	12.7	30	192	15.6	13,315	17.0	262,372	20.5
1122	**Anti-anginal meds w/in past 2 wks**																			
1123	Anti-anginal meds w/in past 2 wks (pts w/ ACS)	9	17	52.9	19	40	47.5	31	43	72.1	29	45	64.4	57	102	55.9	24,182	55.9	493,789	67.1
1124	Anti-anginal meds w/in past 2 wks (pts w/out ACS)	20	36	55.6	14	28	50.0	18	28	64.3	15	26	57.7	49	90	54.4	17,598	49.6	328,606	59.8
1125	**Heart failure w/in past 2 wks**	**5**	**53**	**9.4**	**11**	**68**	**16.2**	**11**	**71**	**15.5**	**12**	**71**	**16.9**	**28**	**192**	**14.6**	**9,238**	**11.7**	**154,713**	**12.0**
1126	**NYHA classification w/in past 2 wks**																			
1127	NYHA Class I	0	5	0.0	0	11	0.0	0	11	0.0	1	12	8.3	1	28	3.6	986	10.8	16,882	11.0
1128	NYHA Class II	2	5	40.0	2	11	18.2	8	11	72.7	2	12	16.7	6	28	21.4	2,814	30.7	46,427	30.1
1129	NYHA Class III	2	5	40.0	3	11	27.3	1	11	9.1	6	12	50.0	11	28	39.3	3,494	38.2	56,873	36.9
1130	NYHA Class IV	1	5	20.0	6	11	54.6	2	11	18.2	3	12	25.0	10	28	35.7	1,863	20.4	33,868	22.0
1131	**Cardiogenic shock w/in the past 24 hrs**	**1**	**53**	**1.9**	**3**	**68**	**4.4**	**2**	**71**	**2.8**	**2**	**71**	**2.8**	**6**	**192**	**3.1**	**1,194**	**1.5**	**17,485**	**1.4**
1132	**Cardiac arrest w/in the past 24 hrs**	**2**	**53**	**3.8**	**0**	**68**	**0.0**	**0**	**71**	**0.0**	**0**	**71**	**0.0**	**2**	**192**	**1.0**	**1,404**	**1.8**	**17,660**	**1.4**

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Diagnostic Cath with/without PCI
Clinical Evaluation Leading to the Procedure
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1133	**Cardiomyopathy or left ventricular systolic dysfunction**	**8**	**53**	**15.1**	**8**	**68**	**11.8**	**11**	**71**	**15.5**	**16**	**71**	**22.5**	**32**	**192**	**16.7**	**9,205**	**11.7**	**160,003**	**12.4**
1134	**Pre-operative evaluation before non-cardiac surgery**	**2**	**53**	**3.8**	**1**	**68**	**1.5**	**1**	**71**	**1.4**	**1**	**71**	**1.4**	**4**	**192**	**2.1**	**3,075**	**3.9**	**46,706**	**3.6**
1135	**Cardiac transplant evaluation**	**0**	**53**	**0.0**	**0**	**68**	**0.0**	**0**	**71**	**0.0**	**0**	**71**	**0.0**	**0**	**192**	**0.0**	**297**	**0.4**	**3,582**	**0.3**
1136	Transplant evaluation type																			
1137	Donor for cardiac transplant																37	12.5	437	12.2
1138	Candidate to receive a cardiac transplant																65	21.9	571	16.0
1139	Post cardiac transplant follow-up																195	65.7	2,564	71.8

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Diagnostic Cath with/without PCI
Stress and Imaging Studies
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1140	Stress or imaging study																			
1141	Stress or imaging study performed	11	53	20.8	21	67	31.3	15	71	21.1	17	71	23.9	49	191	25.7	31,160	39.9	510,222	40.1
1142	Positive stress or imaging study	9	53	17.0	16	67	23.9	10	71	14.1	6	71	8.5	31	191	16.2	23,232	29.7	402,312	31.6
1143	Positive stress or imaging study w/ intermediate risk of ischemia	4	53	7.6	10	67	14.9	3	71	4.2	2	71	2.8	16	191	8.4	7,430	9.5	120,021	9.4
1144	Positive stress or imaging study w/ high risk of ischemia	1	53	1.9	5	67	7.5	5	71	7.0	3	71	4.2	9	191	4.7	3,009	3.9	55,386	4.4
1145	**Standard exercise stress test performed**	**1**	**11**	**9.1**	**2**	**21**	**9.5**	**0**	**10**	**0.0**	**1**	**17**	**5.9**	**4**	**49**	**8.2**	**2,837**	**9.2**	**40,398**	**7.9**
1146	Result																			
1147	Negative	0	1	0.0	0	2	0.0				0	1	0.0	0	4	0.0	507	17.9	5,446	13.5
1148	Positive	1	1	100.0	2	2	100.0				0	1	0.0	3	4	75.0	1,956	69.0	30,456	75.4
1149	Indeterminant	0	1	0.0	0	2	0.0				1	1	100.0	1	4	25.0	242	8.5	3,072	7.6
1150	Unavailable	0	1	0.0	0	2	0.0				0	1	0.0	0	4	0.0	127	4.5	1,404	3.5
1151	Risk or extent of ischemia for positive stress tests																			
1152	Low	0	1	0.0	0	2	0.0							0	3	0.0	208	10.6	2,534	8.3
1153	Intermediate	1	1	100.0	1	2	50.0							2	3	66.7	610	31.2	7,121	23.4
1154	High	0	1	0.0	1	2	50.0							1	3	33.3	308	15.8	4,050	13.3
1155	Unavailable	0	1	0.0	0	2	0.0							0	3	0.0	825	42.2	16,666	54.7
1156	**Stress echocardiogram**	**4**	**11**	**36.4**	**11**	**21**	**52.4**	**8**	**14**	**57.1**	**11**	**17**	**64.7**	**26**	**49**	**53.1**	**4,680**	**15.2**	**53,595**	**10.5**
1157	Result																			
1158	Negative	0	4	0.0	2	11	18.2	1	8	12.5	2	11	18.2	4	26	15.4	861	18.4	7,965	14.9
1159	Positive	4	4	100.0	8	11	72.7	6	8	75.0	5	11	45.5	17	26	65.4	3,273	69.9	40,140	74.9
1160	Indeterminant	0	4	0.0	1	11	9.1	1	8	12.5	4	11	36.4	5	26	19.2	429	9.2	4,429	8.3
1161	Unavailable	0	4	0.0	0	11	0.0	0	8	0.0	0	11	0.0	0	26	0.0	110	2.4	1,021	1.9
1162	Risk or extent of ischemia for positive stress echocardiograms																			
1163	Low	0	4	0.0	1	8	12.5	1	6	16.7	0	5	0.0	1	17	5.9	437	13.4	5,333	13.3
1164	Intermediate	3	4	75.0	5	8	62.5	2	6	33.3	1	5	20.0	9	17	52.9	1,002	30.6	13,580	33.8
1165	High	0	4	0.0	2	8	25.0	3	6	50.0	3	5	60.0	5	17	29.4	566	17.3	6,795	16.9
1166	Unavailable	1	4	25.0	0	8	0.0	0	6	0.0	1	5	20.0	2	17	11.8	1,262	38.6	14,380	35.8
1167	**Stress testing w/ SPECT MPI**	**6**	**11**	**54.6**	**8**	**21**	**38.1**	**7**	**10**	**70.0**	**6**	**17**	**35.3**	**20**	**49**	**40.8**	**22,350**	**71.9**	**402,118**	**78.6**
1168	Result																			
1169	Negative	1	6	16.7	1	8	12.5	1	7	14.3	2	6	33.3	4	20	20.0	2,746	12.3	46,541	11.6
1170	Positive	4	6	66.7	6	8	75.0	4	7	57.1	1	6	16.7	11	20	55.0	18,039	80.7	332,930	82.8

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Diagnostic Cath with/without PCI
Stress and Imaging Studies
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1171	Indeterminant	1	6	16.7	0	8	0.0	2	7	28.6	3	6	50.0	4	20	20.0	1,108	5.0	16,831	4.2
1172	Unavailable	0	6	0.0	1	8	12.5	0	7	0.0	0	6	0.0	1	20	5.0	381	1.7	5,481	1.4
1173	Risk or extent of ischemia for positive SPECT MPI tests																			
1174	Low	0	4	0.0	0	6	0.0	1	4	25.0	0	1	0.0	0	11	0.0	3,082	17.1	57,851	17.4
1175	Intermediate	0	4	0.0	4	6	66.7	1	4	25.0	1	1	100.0	5	11	45.5	5,817	32.3	99,529	29.9
1176	High	1	4	25.0	2	6	33.3	2	4	50.0	0	1	0.0	3	11	27.3	2,139	11.9	44,463	13.4
1177	Unavailable	3	4	75.0	0	6	0.0	0	4	0.0	0	1	0.0	3	11	27.3	6,961	38.6	130,694	39.3
1178	**Stress testing w/ CMR**	**0**	**11**	**0.0**	**0**	**21**	**0.0**	**0**	**9**	**0.0**	**0**	**17**	**0.0**	**0**	**49**	**0.0**	**301**	**1.0**	**3,687**	**0.7**
1179	Result																			
1180	Negative																31	10.3	370	10.0
1181	Positive																240	79.7	3,069	83.2
1182	Indeterminant																16	5.3	155	4.2
1183	Unavailable																12	4.0	82	2.2
1184	Risk or extent of ischemia for positive CMR tests																			
1185	Low																29	12.1	645	21.0
1186	Intermediate																78	32.5	898	29.3
1187	High																38	15.8	622	20.3
1188	Unavailable																95	39.6	898	29.3
1189	**CTA**	**0**	**11**	**0.0**	**0**	**21**	**0.0**	**0**	**9**	**0.0**	**0**	**17**	**0.0**	**0**	**49**	**0.0**	**382**	**1.2**	**10,822**	**2.1**
1190	Result of CTA																			
1191	No disease																43	11.3	615	5.7
1192	One vessel disease																101	26.4	3,781	34.9
1193	Two vessel disease																70	18.3	2,428	22.4
1194	Three vessel disease																94	24.6	2,132	19.7
1195	Indeterminant																25	6.5	608	5.6
1196	Unavailable																48	12.6	1,243	11.5
1197	**Coronary calcium score**	**0**	**11**	**0.0**	**0**	**21**	**0.0**	**0**	**9**	**0.0**	**0**	**17**	**0.0**	**0**	**49**	**0.0**	**290**	**1.0**	**7,014**	**1.4**
1198	Calcium scores																			
1199	<= 100 (none to mild)																28	9.7	954	13.6
1200	101-400 (moderate)																70	24.1	1,720	24.5
1201	>400 (extensive)																181	62.4	3,958	56.4

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Procedure Information
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		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1202	Dx cath procedure information																			
1203	Dx cath procedures	53	53	100.0	68	68	100.0	71	71	100.0	71	71	100.0	192	192	100.0	78,943	100.0	1,287,327	100.0
1204	Dx coronary angiography	52	53	98.1	67	68	98.5	71	71	100.0	70	71	98.6	189	192	98.4	76,956	97.5	1,259,255	97.8
1205	Left heart caths	52	53	98.1	68	68	100.0	68	71	95.8	71	71	100.0	191	192	99.5	69,309	87.8	1,155,748	89.8
1206	Dx cath and PCI during same lab visit	5	53	9.4	14	68	20.6	8	71	11.3	10	71	14.1	29	192	15.1	25,657	32.5	540,061	42.0
1207	**Status of dx cath procedure**																			
1208	Elective	24	53	45.3	22	68	32.4	26	71	36.6	22	71	31.0	68	192	35.4	43,102	54.6	717,382	55.8
1209	Urgent	23	53	43.4	29	68	42.7	34	71	47.9	34	71	47.9	86	192	44.8	25,253	32.0	435,525	33.9
1210	Emergent	6	53	11.3	17	68	25.0	11	71	15.5	15	71	21.1	38	192	19.8	10,404	13.2	131,529	10.2
1211	Salvage	0	53	0.0	0	68	0.0	0	71	0.0	0	71	0.0	0	192	0.0	140	0.2	2,200	0.2
1212	**Fluoro time in minutes**																			
1213	Procedure using fluoro time	53	53	100.0	67	67	100.0	71	71	100.0	44	44	100.0	164	164	100.0	70,749	98.9	1,120,452	98.8
1214	Mean	5.4			6.3			6.0			7.5			6.4			7.7		8.4	
1215	Median	3.1			5.0			4.2			4.6			4.2			4.8		5.4	
1216	Median fluoro time for pts w/ prev CABG	5.7			10.0			9.9			8.8			7.5			9.6		9.8	
1217	Median fluoro time for pts w/out prev CABG	2.9			4.3			4.1			2.8			3.3			4.3		4.7	
1218	**Fluoro dose in milligrays**	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1219	Procedure using fluoro dose	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1220	Mean	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1221	Median	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1222	Median fluoro dose for pts w/ prev CABG	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1223	Median fluoro dose for pts w/out prev CABG	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1224	**Contrast volume (in ml)**																			
1225	Procedures w/ contrast volume coded	53	53	100.0	67	67	100.0	71	71	100.0	44	44	100.0	164	164	100.0	71,815	99.6	1,140,674	99.7
1226	Mean	96.7			99.7			94.1			100.7			99.0			133.8		139.2	
1227	Median	90.0			80.0			86.0			82.5			86.0			115.0		120.0	
1228	Median contrast volume for pts w/ prev CABG	95.0			117.5			100.0			90.0			100.0			150.0		150.0	
1229	Median contrast volume for pts w/out prev CABG	90.0			80.0			86.0			82.5			85.0			110.0		110.0	
1230	**Arterial access site**																			
1231	Femoral	51	53	96.2	68	68	100.0	69	71	97.2	68	71	95.8	187	192	97.4	72,895	92.4	1,165,007	90.5
1232	Brachial	0	53	0.0	0	68	0.0	0	71	0.0	0	71	0.0	0	192	0.0	302	0.4	4,992	0.4
1233	Radial	2	53	3.8	0	68	0.0	2	71	2.8	3	71	4.2	5	192	2.6	5,675	7.2	116,396	9.1

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Diagnostic Cath with/without PCI
Procedure Information
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1234	Other	0	53	0.0	0	68	0.0	0	71	0.0	0	71	0.0	0	192	0.0	18	0.0	365	0.0
1235	**Methods of closure of arterial access site**																			
1236	Manual compression	9	46	19.6	12	52	23.1	11	57	19.3	11	56	19.6	32	154	20.8	27,496	35.5	514,671	38.5
1237	Mechanical compression	0	46	0.0	1	52	1.9	0	57	0.0	2	56	3.6	3	154	2.0	6,606	8.5	161,793	12.1
1238	Suture	0	46	0.0	0	52	0.0	0	57	0.0	0	56	0.0	0	154	0.0	3,323	4.3	85,060	6.4
1239	Staple	0	46	0.0	0	52	0.0	0	57	0.0	0	56	0.0	0	154	0.0	30	0.0	80	0.0
1240	Sealant	37	46	80.4	39	52	75.0	46	57	80.7	43	56	76.8	119	154	77.3	30,595	39.5	392,242	29.4
1241	Patch	0	46	0.0	0	52	0.0	0	57	0.0	0	56	0.0	0	154	0.0	6,270	8.1	117,345	8.8
1242	Other, unspecified device	0	46	0.0	0	52	0.0	0	57	0.0	0	56	0.0	0	154	0.0	3,105	4.0	64,365	4.8
1243	**Mechanical ventricular support**																			
1244	Any mechanical ventricular support (IABP, LVAD or other support)	1	53	1.9	3	68	4.4	2	71	2.8	2	71	2.8	6	192	3.1	1,912	2.4	25,130	2.0
1245	Intra-aortic balloon pump	1	53	1.9	3	68	4.4	2	71	2.8	1	71	1.4	5	192	2.6	1,709	2.2	22,943	1.8
1246	Other mechanical ventricular support (LVAD, etc)	0	53	0.0	0	68	0.0	0	71	0.0	1	71	1.4	1	192	0.5	333	0.4	3,217	0.3

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Diagnostic Cath with/without PCI
Procedure Findings
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1247	**Coronary dominance**																			
1248	Left	5	53	9.4	6	68	8.8	12	71	16.9	10	71	14.1	21	192	10.9	9,197	12.0	128,559	10.3
1249	Right	45	53	84.9	60	68	88.2	48	71	67.6	58	71	81.7	163	192	84.9	60,658	79.0	1,018,437	81.7
1250	Mixed	3	53	5.7	2	68	2.9	11	71	15.5	3	71	4.2	8	192	4.2	6,897	9.0	99,234	8.0
1251	Diagnostic cath procedure findings																			
1252	Non-obstructive CAD - all vessels <50%	4	17	23.5	8	16	50.0	7	22	31.8	7	14	50.0	19	47	40.4	14,171	46.0	205,587	44.2
1253	Pt with positive stress or imaging study	0	6	0.0	4	11	36.4	1	6	16.7	0	1	0.0	4	18	22.2	6,163	40.4	94,560	37.5
1254	Pt with No CAD (all native vessels <=10% stenosis) (w/o CABG)	19	45	42.2	10	60	16.7	26	61	42.6	13	62	21.0	42	167	25.2	16,831	27.3	226,724	24.4
1255	**Diseased vessels (including LM disease)**																			
1256	LM disease (>=50%)	3	53	5.7	3	68	4.4	7	71	9.9	5	71	7.0	11	192	5.7	5,421	6.9	95,269	7.4
1257	LM and RCA disease (triple vessel)	2	53	3.8	3	68	4.4	4	71	5.6	4	71	5.6	9	192	4.7	3,038	3.9	52,483	4.1
1258	LM w/out RCA disease (double vessel)	1	53	1.9	0	68	0.0	3	71	4.2	1	71	1.4	2	192	1.0	2,383	3.0	42,786	3.3
1259	**Diseased vessel w/or w/o LM**																			
1260	Single vessel disease	15	53	28.3	19	68	27.9	18	71	25.4	20	71	28.2	54	192	28.1	23,013	29.2	396,632	30.8
1261	Double vessel disease	5	53	9.4	13	68	19.1	12	71	16.9	14	71	19.7	32	192	16.7	14,463	18.3	262,667	20.4
1262	Triple vessel disease	4	53	7.6	9	68	13.2	7	71	9.9	7	71	9.9	20	192	10.4	9,095	11.5	155,950	12.1
1263	**Treatment recommendation after Dx cath**																			
1264	None	0	53	0.0	0	68	0.0	0	71	0.0	0	71	0.0	0	192	0.0	4,524	5.7	65,949	5.1
1265	Medical therapy and/or counseling	33	53	62.3	29	68	42.7	33	71	46.5	37	71	52.1	99	192	51.6	35,090	44.5	515,152	40.1
1266	PCI w/out planned CABG	11	53	20.8	31	68	45.6	25	71	35.2	20	71	28.2	62	192	32.3	28,835	36.6	553,730	43.1
1267	CABG (including hybrid CABG/PCI procedures)	5	53	9.4	2	68	2.9	8	71	11.3	3	71	4.2	10	192	5.2	7,234	9.2	102,973	8.0
1268	Other cardiac therapy w/out CABG or PCI	4	53	7.6	6	68	8.8	5	71	7.0	11	71	15.5	21	192	10.9	3,159	4.0	48,459	3.8
1269	**EF (closest to discharge)**																			
1270	Normal (EF >=50%)	27	53	50.9	39	67	58.2	46	71	64.8	39	71	54.9	105	191	55.0	47,195	60.3	789,000	62.0
1271	Mildly reduced (EF 40-49%)	6	53	11.3	13	67	19.4	11	71	15.5	6	71	8.5	25	191	13.1	7,994	10.2	135,363	10.6
1272	Moderately reduced (EF 25-39%)	7	53	13.2	3	67	4.5	4	71	5.6	10	71	14.1	20	191	10.5	6,442	8.2	105,907	8.3
1273	Severely reduced (EF <25%)	4	53	7.6	5	67	7.5	4	71	5.6	7	71	9.9	16	191	8.4	2,508	3.2	40,300	3.2

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Diagnostic Cath (No PCI)
Adverse Events
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1274	Post-procedure events																			
1275	**Any adverse event**	**0**	**48**	**0.0**	**0**	**53**	**0.0**	**0**	**63**	**0.0**	**2**	**61**	**3.3**	**2**	**162**	**1.2**	**751**	**1.4**	**10,541**	**1.5**
1276	Pts w/out CABG during admission	0	46	0.0	0	50	0.0	0	61	0.0	2	56	3.6	2	152	1.3	521	1.0	5,016	0.8
1277	**Cardiogenic shock**	**0**	**48**	**0.0**	**0**	**53**	**0.0**	**0**	**63**	**0.0**	**0**	**61**	**0.0**	**0**	**162**	**0.0**	**130**	**0.3**	**2,292**	**0.3**
1278	Pts w/out CABG during admission	0	46	0.0	0	50	0.0	0	61	0.0	0	56	0.0	0	152	0.0	107	0.2	1,094	0.2
1279	**Heart failure**	**0**	**48**	**0.0**	**0**	**53**	**0.0**	**0**	**63**	**0.0**	**0**	**61**	**0.0**	**0**	**162**	**0.0**	**255**	**0.5**	**3,046**	**0.4**
1280	Pts w/out CABG during admission	0	46	0.0	0	50	0.0	0	61	0.0	0	56	0.0	0	152	0.0	221	0.4	1,628	0.3
1281	**CVA/Stroke**	**0**	**48**	**0.0**	**0**	**53**	**0.0**	**0**	**63**	**0.0**	**2**	**61**	**3.3**	**2**	**162**	**1.2**	**65**	**0.1**	**1,243**	**0.2**
1282	Pts w/out CABG during admission	0	46	0.0	0	50	0.0	0	61	0.0	2	56	3.6	2	152	1.3	49	0.1	660	0.1
1283	**Hemorrhagic stroke**										**1**	**2**	**50.0**	**1**	**2**	**50.0**	**7**	**11.1**	**119**	**9.6**
1284	Pts w/out CABG during admission										1	2	50.0	1	2	50.0	6	12.5	76	11.6
1285	**Cardiac tamponade**	**0**	**48**	**0.0**	**0**	**53**	**0.0**	**0**	**63**	**0.0**	**0**	**61**	**0.0**	**0**	**162**	**0.0**	**16**	**0.0**	**235**	**0.0**
1286	Pts w/out CABG during admission	0	46	0.0	0	50	0.0	0	61	0.0	0	56	0.0	0	152	0.0	8	0.0	57	0.0
1287	**New requirement for dialysis**	**0**	**48**	**0.0**	**0**	**53**	**0.0**	**0**	**63**	**0.0**	**0**	**61**	**0.0**	**0**	**162**	**0.0**	**48**	**0.1**	**1,073**	**0.2**
1288	Pts w/out CABG during admission	0	46	0.0	0	50	0.0	0	61	0.0	0	56	0.0	0	152	0.0	29	0.1	396	0.1
1289	Post-procedure bleeding																			
1290	**Bleeding event w/in 72 hrs of the procedure**	**0**	**48**	**0.0**	**0**	**53**	**0.0**	**0**	**63**	**0.0**	**0**	**61**	**0.0**	**0**	**162**	**0.0**	**271**	**0.5**	**3,528**	**0.5**
1291	Pts w/out CABG during admission	0	46	0.0	0	50	0.0	0	61	0.0	0	56	0.0	0	152	0.0	163	0.3	1,778	0.3
1292	**Bleeding at access site**																**63**	**23.3**	**727**	**20.6**
1293	Pts w/out CABG during admission																58	35.6	574	32.3
1294	**Hematoma at access site**																**110**	**40.6**	**1,260**	**35.7**
1295	Pts w/out CABG during admission																100	61.4	998	56.2
1296	**Retroperitoneal bleeding**																**26**	**9.6**	**327**	**9.3**
1297	Pts w/out CABG during admission																19	11.7	238	13.4
1298	**Other vascular complications requiring treatment**	**0**	**48**	**0.0**	**0**	**53**	**0.0**	**0**	**63**	**0.0**	**0**	**61**	**0.0**	**0**	**162**	**0.0**	**93**	**0.2**	**1,155**	**0.2**
1299	Pts w/out CABG during admission	0	46	0.0	0	50	0.0	0	61	0.0	0	56	0.0	0	152	0.0	69	0.1	678	0.1

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Diagnostic Cath (No PCI)
Adverse Events
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1300	**Vascular access site injury requiring treatment or major bleeding**	**0**	**48**	**0.0**	**0**	**53**	**0.0**	**0**	**63**	**0.0**	**0**	**61**	**0.0**	**0**	**162**	**0.0**	**208**	**0.4**	**2,651**	**0.4**
1301	Pts w/out CABG during admission	0	46	0.0	0	50	0.0	0	61	0.0	0	56	0.0	0	152	0.0	172	0.3	1,891	0.3

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Diagnostic Cath with/without PCI
Discharge Information
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1302	Discharge Information																			
1303	**CABG**	**5**	**53**	**9.4**	**2**	**67**	**3.0**	**6**	**71**	**8.5**	**2**	**71**	**2.8**	**9**	**191**	**4.7**	**4,043**	**5.2**	**62,556**	**4.9**
1304	CABG Status																			
1305	Elective	2	5	40.0	2	2	100.0	5	6	83.3	2	2	100.0	6	9	66.7	1,202	29.8	14,622	23.4
1306	Urgent	3	5	60.0	0	2	0.0	1	6	16.7	0	2	0.0	3	9	33.3	2,515	62.3	43,520	69.6
1307	Emergent	0	5	0.0	0	2	0.0	0	6	0.0	0	2	0.0	0	9	0.0	309	7.7	4,211	6.7
1308	Salvage	0	5	0.0	0	2	0.0	0	6	0.0	0	2	0.0	0	9	0.0	12	0.3	151	0.2
1309	**CABG indication**																			
1310	PCI complication	0	5	0.0	0	2	0.0	0	6	0.0	0	2	0.0	0	9	0.0	44	1.1	945	1.5
1311	PCI failure w/out clinical deterioration	0	5	0.0	0	2	0.0	0	6	0.0	0	2	0.0	0	9	0.0	113	2.8	2,045	3.3
1312	Treatment of CAD w/out PCI immediately preceding CABG	4	5	80.0	1	2	50.0	6	6	100.0	2	2	100.0	7	9	77.8	3,588	88.9	55,581	88.9
1313	PCI/CABG hybrid procedure	1	5	20.0	1	2	50.0	0	6	0.0	0	2	0.0	2	9	22.2	292	7.2	3,926	6.3
1314	**Location**																			
1315	At your facility	0	5	0.0	0	2	0.0	0	6	0.0	0	2	0.0	0	9	0.0	1,413	35.0	55,931	89.5
1316	Transferred to other facility	5	5	100.0	2	2	100.0	6	6	100.0	2	2	100.0	9	9	100.0	2,624	65.0	6,589	10.5
1317	**Other major surgery**	**2**	**53**	**3.8**	**2**	**66**	**3.0**	**2**	**71**	**2.8**	**6**	**71**	**8.5**	**10**	**190**	**5.3**	**1,569**	**2.0**	**35,431**	**2.8**
1318	**Discharge status**																			
1319	Alive	50	53	94.3	67	67	100.0	69	71	97.2	69	71	97.2	186	191	97.4	77,427	98.9	1,258,816	98.9
1320	Expired (excluding donors)	3	53	5.7	0	67	0.0	2	71	2.8	2	71	2.8	5	191	2.6	823	1.1	14,282	1.1
1321	Expired (excluding donors and pts w/ PCI during same admission)	2	48	4.2	0	53	0.0	0	63	0.0	1	61	1.6	3	162	1.9	312	0.6	6,025	0.8
1322	Expired (excluding donors and pts w/ PCI, CABG or other major surgery)	2	42	4.8	0	49	0.0	0	55	0.0	0	54	0.0	2	145	1.4	264	0.6	4,033	0.6
1323	Death in lab	0	3	0.0				0	2	0.0	0	2	0.0	0	5	0.0	99	12.0	1,356	9.5

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Diagnostic Cath (No PCI)
Length of Stay
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1324	Length of stay (LOS) - pts w/out PCI																			
1325	**Total LOS- all pts**																			
1326	Mean	2.2			1.9			2.0			2.3			2.1			2.7		3.0	
1327	Median	1.0			1.0			2.0			1.0			1.0			1.0		1.0	
1328	Standard deviation	4.14			2.85			2.44			2.70			3.22			16.68		23.19	
1329	**Pre-procedure LOS- all pts**																			
1330	Mean	1.2			1.1			1.3			1.1			1.1			1.3		1.2	
1331	Median	1.0			1.0			1.0			0.0			1.0			0.0		0.0	
1332	Standard deviation	2.15			1.42			2.17			1.73			1.76			15.72		22.40	
1333	**Post-procedure LOS- all pts**																			
1334	Mean	1.0			0.9			0.7			1.1			1.0			1.3		1.8	
1335	Median	0.0			0.0			0.0			0.0			0.0			0.0		0.0	
1336	Standard deviation	2.18			1.78			1.06			1.79			1.90			4.99		5.61	
1337	**Total LOS- pts w/ CABG or other major surgery**																			
1338	Mean	2.0			6.0			4.1			5.6			4.3			6.2		10.8	
1339	Median	2.5			6.0			4.5			5.0			3.5			4.0		8.0	
1340	Standard deviation	1.67			5.00			2.47			3.74			3.65			12.26		26.55	
1341	**Pre-procedure LOS- pts w/ CABG or other major surgery**																			
1342	Mean	0.8			2.0			3.0			3.0			2.0			1.6		1.8	
1343	Median	0.5			3.0			2.5			2.0			1.5			1.0		1.0	
1344	Standard deviation	0.98			1.73			2.51			3.27			2.45			5.96		24.76	
1345	**Post-procedure LOS- pts w/ CABG or other major surgery**																			
1346	Mean	1.2			4.0			1.1			2.6			2.3			4.6		9.0	
1347	Median	0.5			3.0			0.5			3.0			2.0			1.0		7.0	
1348	Standard deviation	1.47			3.61			1.36			2.23			2.36			10.50		9.13	
1349	**Total LOS- pts w/out CABG or other major surgery**																			
1350	Mean	2.1			1.7			1.9			1.8			1.9			2.3		2.1	
1351	Median	1.0			1.0			1.0			1.0			1.0			1.0		0.0	
1352	Standard deviation	4.22			2.55			2.41			2.21			3.04			16.88		22.54	
1353	**Pre-procedure LOS- pts w/out CABG or other major surgery**																			
1354	Mean	1.3			1.0			1.3			0.9			1.0			1.3		1.1	

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Diagnostic Cath (No PCI)
Length of Stay
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1355	Median	1.0			0.0			1.0			0.0			0.0			0.0		0.0	
1356	Standard deviation	2.19			1.41			2.19			1.26			1.63			16.08		22.04	
1357	**Post-procedure LOS- pts w/out CABG or other major surgery**																			
1358	Mean	0.9			0.7			0.6			0.9			0.8			1.0		1.0	
1359	Median	0.0			0.0			0.0			0.0			0.0			0.0		0.0	
1360	Standard deviation	2.19			1.47			1.02			1.64			1.77			4.51		4.40	

PCI
Demographics and Payors
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1361	Demographics																			
1362	**Sex**																			
1363	Male	3	5	60.0	11	14	78.6	4	8	50.0	8	10	80.0	22	29	75.9	18,775	67.9	417,442	67.4
1364	Female	2	5	40.0	3	14	21.4	4	8	50.0	2	10	20.0	7	29	24.1	8,869	32.1	202,137	32.6
1365	**Age at admission**																			
1366	Mean age	63			58			65			72			64			64		65	
1367	Median age	63			55			59			71			59			63		65	
1368	18-44	1	5	20.0	3	14	21.4	1	8	12.5	0	10	0.0	4	29	13.8	1,582	5.7	29,000	4.7
1369	45-54	1	5	20.0	3	14	21.4	1	8	12.5	0	10	0.0	4	29	13.8	5,205	18.8	101,872	16.4
1370	55-64	1	5	20.0	5	14	35.7	4	8	50.0	4	10	40.0	10	29	34.5	8,044	29.1	173,014	27.9
1371	65-69	0	5	0.0	0	14	0.0	0	8	0.0	1	10	10.0	1	29	3.5	3,829	13.9	93,300	15.1
1372	70-74	0	5	0.0	0	14	0.0	0	8	0.0	1	10	10.0	1	29	3.5	3,133	11.3	79,641	12.9
1373	75-79	0	5	0.0	2	14	14.3	0	8	0.0	1	10	10.0	3	29	10.3	2,637	9.5	66,136	10.7
1374	>= 80	2	5	40.0	1	14	7.1	2	8	25.0	3	10	30.0	6	29	20.7	3,214	11.6	76,611	12.4
1375	Medicare age (>= 65)	2	5	40.0	3	14	21.4	2	8	25.0	6	10	60.0	11	29	37.9	12,813	46.4	315,691	51.0
1376	**Race**																			
1377	White	4	5	80.0	14	14	100.0	7	8	87.5	10	10	100.0	28	29	96.6	23,965	86.7	545,464	88.0
1378	Black/African American	0	5	0.0	0	14	0.0	1	8	12.5	0	10	0.0	0	29	0.0	2,596	9.4	50,913	8.2
1379	Asian	1	5	20.0	0	14	0.0	0	8	0.0	0	10	0.0	1	29	3.5	634	2.3	13,795	2.2
1380	American Indian/Alaskan	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	222	0.8	3,278	0.5
1381	Hawaiian/Pacific Islander	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	70	0.3	1,179	0.2
1382	**Hispanic or Latino ethnicity**	**1**	**5**	**20.0**	**2**	**14**	**14.3**	**1**	**8**	**12.5**	**0**	**10**	**0.0**	**3**	**29**	**10.3**	**1,849**	**6.7**	**30,597**	**5.0**
1383	**Admission source**																			
1384	Emergency department	5	5	100.0	14	14	100.0	8	8	100.0	9	10	90.0	28	29	96.6	17,055	61.8	223,626	36.1
1385	Transfer in from another acute care facility	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	1,337	4.9	116,704	18.9
1386	Other	0	5	0.0	0	14	0.0	0	8	0.0	1	10	10.0	1	29	3.5	9,196	33.3	278,627	45.0
1387	**Hospital status**																			
1388	Outpt	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	4,080	14.8	151,494	24.5
1389	Outpt converted to inpt	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	5,322	19.3	111,290	18.0
1390	Inpt	5	5	100.0	14	14	100.0	8	8	100.0	10	10	100.0	29	29	100.0	18,226	66.0	356,614	57.6
1391	**Insurance Payors**																			
1392	Private health insurance	3	5	60.0	11	14	78.6	6	8	75.0	7	10	70.0	21	29	72.4	16,226	58.7	393,846	63.6
1393	Medicare	2	5	40.0	3	14	21.4	2	8	25.0	4	10	40.0	9	29	31.0	12,245	44.3	317,735	51.3
1394	Medicaid	0	5	0.0	0	14	0.0	1	8	12.5	1	10	10.0	1	29	3.5	2,407	8.7	59,313	9.6
1395	Military health care	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	630	2.3	17,171	2.8
1396	State-specific (non-medicaid)	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	629	2.3	9,015	1.5

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PCI
Demographics and Payors
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1397	Indian Health Service	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	69	0.3	1,042	0.2
1398	Non-U.S. insurance	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	19	0.1	547	0.1
1399	None	0	5	0.0	1	14	7.1	0	8	0.0	2	10	20.0	3	29	10.3	2,376	8.6	40,799	6.6

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PCI
History and Risk Factors (on arrival)
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1400	History and risk factors (on arrival to CathPCI facility)																			
1401	**Current/recent smoker**	**0**	**5**	**0.0**	**3**	**14**	**21.4**	**3**	**8**	**37.5**	**4**	**10**	**40.0**	**7**	**29**	**24.1**	**8,614**	**31.2**	**171,212**	**27.7**
1402	**Hypertension**	**3**	**5**	**60.0**	**8**	**14**	**57.1**	**5**	**8**	**62.5**	**8**	**10**	**80.0**	**19**	**29**	**65.5**	**20,946**	**75.8**	**507,910**	**82.0**
1403	**Dyslipidemia**	**2**	**5**	**40.0**	**6**	**14**	**42.9**	**2**	**8**	**25.0**	**8**	**10**	**80.0**	**16**	**29**	**55.2**	**19,767**	**71.6**	**494,960**	**80.0**
1404	**Body mass index data**																			
1405	Overweight (BMI>=25)	4	5	80.0	12	14	85.7	7	8	87.5	7	10	70.0	23	29	79.3	21,975	79.7	494,675	80.0
1406	Obese (BMI>=30)	0	5	0.0	5	14	35.7	3	8	37.5	1	10	10.0	6	29	20.7	11,845	43.0	270,587	43.8
1407	Morbidly obese (BMI>=40)	0	5	0.0	2	14	14.3	0	8	0.0	0	10	0.0	2	29	6.9	1,976	7.2	43,479	7.0
1408	**Family history of premature CAD**	**2**	**5**	**40.0**	**3**	**14**	**21.4**	**2**	**8**	**25.0**	**3**	**10**	**30.0**	**8**	**29**	**27.6**	**8,263**	**29.9**	**153,941**	**24.9**
1409	**Prior MI (>7 days)**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**1**	**8**	**12.5**	**3**	**10**	**30.0**	**3**	**29**	**10.3**	**7,084**	**25.6**	**186,170**	**30.1**
1410	**Prior heart failure**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**2**	**10**	**20.0**	**2**	**29**	**6.9**	**2,417**	**8.8**	**74,097**	**12.0**
1411	**Prior valve surgery/procedure**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**328**	**1.2**	**9,098**	**1.5**
1412	**Prior PCI**	**1**	**5**	**20.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**2**	**10**	**20.0**	**3**	**29**	**10.3**	**8,765**	**31.7**	**252,138**	**40.7**
1413	Previous PCI timeframe prior to arrival																			
1414	<=1 year	0	1	0.0							0	2	0.0	0	3	0.0	2,784	32.5	85,959	34.5
1415	>1 year	1	1	100.0							2	2	100.0	3	3	100.0	5,795	67.6	163,016	65.5
1416	**Prior CABG**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**3,275**	**11.9**	**114,601**	**18.5**
1417	Prior CABG timeframe																			
1418	<=5 years																784	24.3	28,282	25.0
1419	> 5 years																2,442	75.7	84,939	75.0
1420	Other History																			
1421	**Currently on dialysis**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**610**	**2.2**	**14,654**	**2.4**
1422	**Cerebrovascular disease**	**1**	**5**	**20.0**	**1**	**14**	**7.1**	**1**	**8**	**12.5**	**4**	**10**	**40.0**	**6**	**29**	**20.7**	**2,552**	**9.2**	**76,721**	**12.4**
1423	**Peripheral arterial disease**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**4**	**10**	**40.0**	**4**	**29**	**13.8**	**2,570**	**9.3**	**77,949**	**12.6**
1424	**Chronic lung disease**	**0**	**5**	**0.0**	**1**	**14**	**7.1**	**0**	**8**	**0.0**	**2**	**10**	**20.0**	**3**	**29**	**10.3**	**3,739**	**13.5**	**94,424**	**15.3**
1425	**Diabetes mellitus**	**1**	**5**	**20.0**	**3**	**14**	**21.4**	**1**	**8**	**12.5**	**5**	**10**	**50.0**	**9**	**29**	**31.0**	**9,111**	**33.0**	**226,226**	**36.5**
1426	Diabetes control																			
1427	None	0	1	0.0	0	3	0.0	0	1	0.0	0	5	0.0	0	9	0.0	591	6.5	10,882	4.8
1428	Diet	0	1	0.0	0	3	0.0	0	1	0.0	1	5	20.0	1	9	11.1	630	6.9	14,674	6.5
1429	Oral	1	1	100.0	3	3	100.0	0	1	0.0	2	5	40.0	6	9	66.7	4,742	52.1	116,717	51.7
1430	Insulin	0	1	0.0	0	3	0.0	1	1	100.0	2	5	40.0	2	9	22.2	3,084	33.9	82,694	36.6
1431	Other	0	1	0.0	0	3	0.0	0	1	0.0	0	5	0.0	0	9	0.0	47	0.5	827	0.4

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PCI
Clinical Evaluation Leading to the Procedure
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1432	Clinical eval leading to the PCI																			
1433	**CAD presentation**	**5**	**5**	**100.0**	**14**	**14**	**100.0**	**8**	**8**	**100.0**	**10**	**10**	**100.0**	**29**	**29**	**100.0**	**28,163**	**100.0**	**636,294**	**100.0**
1434	No symptoms and no angina	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	1,970	7.0	58,759	9.2
1435	Symptoms unlikely to be ischemic	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	697	2.5	18,469	2.9
1436	Stable angina	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	3,970	14.1	108,417	17.0
1437	Unstable angina	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	8,413	29.9	233,994	36.8
1438	Non-STEMI	0	5	0.0	0	14	0.0	0	8	0.0	1	10	10.0	1	29	3.5	5,024	17.8	115,589	18.2
1439	STEMI	5	5	100.0	14	14	100.0	8	8	100.0	9	10	90.0	28	29	96.6	8,089	28.7	101,066	15.9
1440	Timeframe from symptom onset to procedure (for AMIs)																			
1441	<=6 hrs	4	5	80.0	10	14	71.4	6	8	75.0	7	10	70.0	21	29	72.4	6,264	47.8	76,033	35.1
1442	>6 hrs	0	5	0.0	3	14	21.4	0	8	0.0	0	10	0.0	3	29	10.3	4,065	31.0	83,140	38.4
1443	Timeframe not available	2	5	40.0	5	14	35.7	2	8	25.0	4	10	40.0	11	29	37.9	1,187	9.1	15,384	7.1
1444	**Anginal/CCS class w/in past 2 wks**																			
1445	No symptoms	0	5	0.0	0	14	0.0	0	8	0.0	1	10	10.0	1	29	3.5	5,410	19.3	84,305	13.3
1446	CCS Class I	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	2,234	8.0	37,838	6.0
1447	CCS Class II	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	6,087	21.8	126,942	20.0
1448	CCS Class III	0	5	0.0	0	14	0.0	0	8	0.0	2	10	20.0	2	29	6.9	6,284	22.5	203,154	32.0
1449	CCS Class IV	5	5	100.0	14	14	100.0	8	8	100.0	7	10	70.0	26	29	89.7	7,967	28.5	182,626	28.8
1450	**Anti-anginal medications w/in past two wks (patients w/out ACS)**																			
1451	Pts having one anti-anginal medication prescribed																2,808	42.4	90,576	48.8
1452	Pts having 2 or more anti-anginal medications prescribed																994	15.0	41,049	22.1
1453	Anti-anginal medication (pts w/ ACS)	2	5	40.0	2	14	14.3	3	8	37.5	5	10	50.0	9	29	31.0	10,875	50.7	305,229	67.8
1454	Anti-anginal medication (pts w/out ACS)																3,804	57.4	131,745	71.0
1455	Beta blockers																3,255	85.6	115,688	87.8
1456	Calcium channel blockers																724	19.0	31,883	24.2
1457	Long-acting nitrates																611	16.1	24,797	18.8
1458	Ranolazine																61	1.6	3,056	2.3
1459	Other anti-anginal medication not specified above																315	8.3	4,864	3.7
1460	**Heart failure w/in past two wks**	**0**	**5**	**0.0**	**1**	**14**	**7.1**	**0**	**8**	**0.0**	**2**	**10**	**20.0**	**3**	**29**	**10.3**	**2,257**	**8.0**	**61,392**	**9.7**

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PCI
Clinical Evaluation Leading to the Procedure
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1461	**NYHA w/in past two wks**																			
1462	Class I				0	1	0.0				0	2	0.0	0	3	0.0	256	11.4	6,886	11.3
1463	Class II				0	1	0.0				1	2	50.0	1	3	33.3	676	30.2	17,485	28.6
1464	Class III				0	1	0.0				1	2	50.0	1	3	33.3	799	35.7	21,586	35.3
1465	Class IV				1	1	100.0				0	2	0.0	1	3	33.3	510	22.8	15,151	24.8
1466	**Cardiogenic shock**																			
1467	Cardiogenic shock w/in the past 24 hrs and/or at start of PCI	1	5	20.0	2	14	14.3	2	8	25.0	2	10	20.0	5	29	17.2	1,118	4.0	17,606	2.8
1468	Cardiogenic shock w/in the past 24 hrs	1	5	20.0	2	14	14.3	2	8	25.0	2	10	20.0	5	29	17.2	799	2.8	12,610	2.0
1469	Cardiogenic shock at start of PCI	1	5	20.0	2	14	14.3	2	8	25.0	2	10	20.0	5	29	17.2	926	3.3	14,199	2.2
1470	**Cardiac arrest w/in the past 24 hrs**	**1**	**5**	**20.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**1**	**29**	**3.5**	**888**	**3.2**	**12,355**	**1.9**
1471	**Cardiomyopathy or LV systolic dysfunction**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**3**	**10**	**30.0**	**3**	**29**	**10.3**	**2,150**	**7.6**	**63,385**	**10.0**
1472	**Pre-operative evaluation before non-cardiac surgery**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**443**	**1.6**	**12,580**	**2.0**

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PCI
Procedure Indications
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1473	**PCI indication**																			
1474	Immediate PCI for STEMI	5	5	100.0	14	14	100.0	8	8	100.0	9	10	90.0	28	29	96.6	7,681	27.3	88,737	14.0
1475	PCI for STEMI (unstable, >12 hrs from Sx onset)	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	343	1.2	5,664	0.9
1476	PCI for STEMI (stable, >12 hrs from Sx onset)	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	230	0.8	3,744	0.6
1477	PCI for STEMI (stable after successful full dose lytics)	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	56	0.2	2,743	0.4
1478	Rescue PCI for STEMI (after failed full-dose lytics)	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	57	0.2	3,207	0.5
1479	PCI for high risk Non-STEMI or unstable angina	0	5	0.0	0	14	0.0	0	8	0.0	1	10	10.0	1	29	3.5	11,709	41.6	287,748	45.2
1480	Staged PCI	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	2,173	7.7	48,915	7.7
1481	Other	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	5,910	21.0	195,451	30.7
1482	**Immediate PCI - STEMI first noted:**																			
1483	First ECG	4	5	80.0	10	14	71.4	5	8	62.5	6	9	66.7	20	28	71.4	6,822	88.9	79,334	89.5
1484	Subsequent ECG	1	5	20.0	4	14	28.6	3	8	37.5	3	9	33.3	8	28	28.6	850	11.1	9,277	10.5
1485	**Non-system reason for delay in PCI for immediate PCI**																			
1486	Difficult vascular access	0	5	0.0	0	14	0.0	1	8	12.5	0	9	0.0	0	28	0.0	100	1.3	1,104	1.3
1487	Cardiac arrest and/or need for intubation before PCI	0	5	0.0	2	14	14.3	0	8	0.0	1	9	11.1	3	28	10.7	432	5.6	5,269	6.0
1488	Pt delays in providing consent for the procedure	1	5	20.0	0	14	0.0	0	8	0.0	0	9	0.0	1	28	3.6	60	0.8	639	0.7
1489	Difficulty crossing the culprit lesion during the PCI procedure	0	5	0.0	0	14	0.0	0	8	0.0	2	9	22.2	2	28	7.1	277	3.6	2,521	2.9
1490	Other	0	5	0.0	2	14	14.3	2	8	25.0	2	9	22.2	4	28	14.3	476	6.2	4,883	5.5
1491	None	4	5	80.0	10	14	71.4	5	8	62.5	4	9	44.4	18	28	64.3	6,324	82.5	74,128	83.7
1492	**Thrombolytic therapy for STEMI pts**																			
1493	Pts who received thrombolytic therapy	0			0			0			0			0			268		6,958	
1494	**Door to balloon times (excluding transfers)**																			
1495	Total number of immediate PCI procedures	5			14			8			9			28			7,303		67,309	
1496	Median	68.0			72.5			76.0			91.0			80.0			69.0		64.0	
1497	<= 90 minutes	4	5	80.0	11	14	78.6	6	8	75.0	4	9	44.4	19	28	67.9	5,816	79.6	55,669	82.7
1498	**Door to balloon times (excluding transfers and**																			

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PCI
Procedure Indications
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
	pts w/ a reason for delay)																			
1499	Total number of immediate PCI procedures	4			11			6			4			19			6,601		61,784	
1500	Median	66.0			67.0			71.5			76.0			67.0			67.0		62.0	
1501	<= 90 minutes	4	4	100.0	11	11	100.0	6	6	100.0	4	4	100.0	19	19	100.0	5,816	88.1	55,669	90.1
1502	**D2B times - Pts transferred in from another acute care facility only (excluding reason for delays)**	**0**			**0**			**0**			**0**			**0**			**317**		**18,188**	
1503	Median door to door time																72.0		83.0	
1504	Median																101.5		113.0	
1505	<= 90 minutes																112	35.3	4,801	26.4

PCI
Stress and Imaging Studies
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1506	Stress or imaging study																			
1507	Stress or imaging study performed	0	5	0.0	0	14	0.0	0	8	0.0	1	10	10.0	1	29	3.5	7,884	28.6	206,619	33.4
1508	Positive stress or imaging study	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	6,017	21.8	168,835	27.3
1509	Positive stress or imaging study w/ intermediate risk of ischemia	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	1,912	6.9	51,649	8.3
1510	Positive stress or imaging study w/ high risk of ischemia	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	1,210	4.4	31,278	5.1
1511	Proportion of elective PCI procedures with a positive antecedent stress or imaging study (suggestive of ischemia) or with a FFR Ratio of <= 0.8																2,072	56.2	70,063	58.6
1512	Positive stress or imaging study w/ high risk or extent of ischemia prior to elective PCI																760	7.8	21,148	7.6
1513	**Standard exercise stress test performed**										**1**	**1**	**100.0**	**1**	**1**	**100.0**	**676**	**8.6**	**15,583**	**7.5**
1514	Result																			
1515	Negative										0	1	0.0	0	1	0.0	100	14.8	1,836	11.8
1516	Positive										0	1	0.0	0	1	0.0	486	71.9	12,272	78.8
1517	Indeterminant										1	1	100.0	1	1	100.0	48	7.1	923	5.9
1518	Unavailable										0	1	0.0	0	1	0.0	40	5.9	544	3.5
1519	Risk or extent of ischemia for positive stress tests																			
1520	Low																36	7.4	624	5.1
1521	Intermediate																134	27.6	2,836	23.1
1522	High																99	20.4	2,212	18.0
1523	Unavailable																215	44.2	6,586	53.7
1524	**Stress echocardiogram**										**1**	**1**	**100.0**	**1**	**1**	**100.0**	**1,266**	**16.0**	**21,111**	**10.2**
1525	Result																			
1526	Negative										1	1	100.0	1	1	100.0	188	14.9	2,524	12.0
1527	Positive										0	1	0.0	0	1	0.0	964	76.2	16,892	80.0
1528	Indeterminant										0	1	0.0	0	1	0.0	80	6.3	1,296	6.1
1529	Unavailable										0	1	0.0	0	1	0.0	30	2.4	376	1.8
1530	Risk or extent of ischemia for positive stress echos																			
1531	Low																86	8.9	1,645	9.7
1532	Intermediate																264	27.4	5,342	31.6
1533	High																238	24.7	3,715	22.0

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PCI
Stress and Imaging Studies
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		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1534	Unavailable																375	38.9	6,175	36.6
1535	**Stress testing w/ SPECT MPI**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**5,416**	**68.5**	**163,355**	**78.5**
1536	Result																			
1537	Negative																516	9.5	15,476	9.5
1538	Positive																4,608	85.1	141,046	86.3
1539	Indeterminant																206	3.8	4,683	2.9
1540	Unavailable																74	1.4	2,046	1.3
1541	Risk or extent of ischemia for positive SPECT MPI																			
1542	Low																528	11.5	17,865	12.7
1543	Intermediate																1,514	32.9	43,800	31.1
1544	High																877	19.0	25,449	18.0
1545	Unavailable																1,685	36.6	53,764	38.1
1546	**Stress testing w/CMR**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**84**	**1.1**	**1,441**	**0.7**
1547	Result																			
1548	Negative																6	7.1	114	7.9
1549	Positive																72	85.7	1,244	86.3
1550	Indeterminant																1	1.2	43	3.0
1551	Unavailable																5	6.0	38	2.6
1552	Risk or extent of ischemia for positive CMR tests																			
1553	Low																5	6.9	159	12.8
1554	Intermediate																30	41.7	344	27.7
1555	High																15	20.8	334	26.9
1556	Unavailable																22	30.6	406	32.6
1557	**CTA**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**140**	**1.8**	**5,776**	**2.8**
1558	Results of CTA																			
1559	No disease																7	5.0	147	2.6
1560	One vessel disease																40	28.6	2,133	36.9
1561	Two vessel disease																29	20.7	1,494	25.9
1562	Three vessel disease																47	33.6	1,258	21.8
1563	Indeterminant																6	4.3	218	3.8
1564	Unavailable																11	7.9	516	8.9
1565	**Coronary calcium score**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**92**	**1.2**	**3,411**	**1.6**
1566	Calcium scores																			
1567	<=100 (none to mild)																7	7.6	397	11.6
1568	101-400 (moderate)																26	28.3	845	24.8

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PCI
Stress and Imaging Studies
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1569	>400 (extensive)																56	60.9	2,056	60.3

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PCI
Appropriate Use Criteria
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1570	**PCI Appropriate Use Criteria**																			
1571	**PCIs eligible for AUC reporting**	**5**			**14**						**10**			**29**			**28,171**		**636,415**	
1572	PCIs evaluated using AUC	5	5	100.0	14	14	100.0				10	10	100.0	29	29	100.0	24,825	88.1	538,435	84.6
1573	**Appropriate Use (Overall)**																			
1574	Appropriate (Among evaluated PCIs)	5	5	100.0	14	14	100.0				10	10	100.0	29	29	100.0	21,887	89.7	459,270	86.6
1575	Uncertain (Among evaluated PCIs)	0	5	0.0	0	14	0.0				0	10	0.0	0	29	0.0	1,792	7.4	52,940	10.0
1576	Inappropriate (Among evaluated PCIs)	0	5	0.0	0	14	0.0				0	10	0.0	0	29	0.0	718	2.9	18,056	3.4
1577	**Appropriate Use Stratified by ACS**																			
1578	**Patients with ACS (Table 1)**	**5**			**14**						**10**			**29**			**20,244**		**394,801**	
1579	Appropriate (Among evaluated PCIs)	5	5	100.0	14	14	100.0				10	10	100.0	29	29	100.0	20,041	99.0	390,636	99.0
1580	Uncertain (Among evaluated PCIs)	0	5	0.0	0	14	0.0				0	10	0.0	0	29	0.0	19	0.1	922	0.2
1581	Inappropriate (Among evaluated PCIs)	0	5	0.0	0	14	0.0				0	10	0.0	0	29	0.0	184	0.9	3,243	0.8
1582	**Patients without ACS (Table 2 and 3)**	**0**			**0**						**0**			**0**			**4,153**		**135,465**	
1583	Appropriate (Among evaluated PCIs)																1,846	44.5	68,634	50.7
1584	Uncertain (Among evaluated PCIs)																1,773	42.7	52,018	38.4
1585	Inappropriate (Among evaluated PCIs)																534	12.9	14,813	10.9
1586	**AUC Reporting Data Quality/Completeness**																			
1587	**PCIs not classifiable for AUC reporting**	**0**	**5**	**0.0**	**0**	**14**	**0.0**				**0**	**10**	**0.0**	**0**	**29**	**0.0**	**3,346**	**11.9**	**97,980**	**15.4**
1588	No Stress Test Performed																1,710	51.1	50,826	51.9
1589	Stress/Imaging Risk Of Ischemia not documented																1,326	39.6	40,530	41.4
1590	Other																310	9.3	6,624	6.8

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PCI
Medications
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1591	PCI procedure medications (w/in 24 hrs prior to and during the procedure)																			
1592	**Aspirin**	**5**	**5**	**100.0**	**14**	**14**	**100.0**	**8**	**8**	**100.0**	**10**	**10**	**100.0**	**29**	**29**	**100.0**	**23,686**	**84.6**	**560,412**	**88.7**
1593	Among pts w/ ACS (STEMI, NSTEMI or unstable angina)	5	5	100.0	14	14	100.0	8	8	100.0	10	10	100.0	29	29	100.0	18,360	85.9	400,024	89.5
1594	**Anticoagulants**	**5**	**5**	**100.0**	**14**	**14**	**100.0**	**8**	**8**	**100.0**	**10**	**10**	**100.0**	**29**	**29**	**100.0**	**17,898**	**63.6**	**369,894**	**58.2**
1595	Fondaparinux	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	583	2.1	6,299	1.0
1596	Low molecular weight heparin (any)	1	5	20.0	0	14	0.0	0	8	0.0	0	10	0.0	1	29	3.5	2,875	10.2	60,952	9.6
1597	Unfractionated heparin (any)	4	5	80.0	14	14	100.0	8	8	100.0	10	10	100.0	28	29	96.6	15,616	55.5	326,497	51.4
1598	**Direct thrombin inhibitors**		**5**			**14**			**8**			**10**			**29**		**14,962**	**53.2**	**364,634**	**57.4**
1599	Bivalirudin	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	14,662	52.1	361,693	56.9
1600	Direct thrombin inhibitor (other than bivalirudin)	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	692	2.5	6,342	1.0
1601	Pts that received bivalirudin, unfractionated heparin,and/ or other direct thrombin inhibitors administered	4	5	80.0	14	14	100.0	8	8	100.0	10	10	100.0	28	29	96.6	26,653	94.7	610,114	95.9
1602	**Glycoprotein IIb/IIIa Inhibitors (any)**	**4**	**5**	**80.0**	**13**	**14**	**92.9**	**5**	**8**	**62.5**	**4**	**10**	**40.0**	**21**	**29**	**72.4**	**10,788**	**38.4**	**175,967**	**27.7**
1603	Among pts w/ ACS (STEMI, NSTEMI or unstable angina)	4	5	80.0	13	14	92.9	5	8	62.5	4	10	40.0	21	29	72.4	9,228	43.0	147,832	32.9
1604	Among pts w/ USA/NSTEMI w/out clopidogrel administration (p64)											1			1		1,105	8.2	24,651	7.1
1605	**Thienopyridine**	**5**	**5**	**100.0**	**13**	**14**	**92.9**	**8**	**8**	**100.0**	**7**	**10**	**70.0**	**25**	**29**	**86.2**	**24,227**	**86.1**	**555,028**	**87.4**
1606	Clopidogrel	5	5	100.0	13	13	100.0	8	8	100.0	7	9	77.8	25	27	92.6	20,591	73.5	475,019	75.2
1607	Prasugrel	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	3,814	13.6	85,053	13.4
1608	Ticlopidine	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	78	0.3	1,429	0.2

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PCI
Procedure Information
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1609	Procedures																			
1610	**PCI only**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**2,319**	**8.2**	**85,179**	**13.4**
1611	PCI and dx cath during same lab visit	5	5	100.0	14	14	100.0	8	8	100.0	10	10	100.0	29	29	100.0	25,657	91.1	540,061	84.9
1612	PCI w/ dx coronary angiography during same lab visit	5	5	100.0	13	14	92.9	8	8	100.0	10	10	100.0	28	29	96.6	25,238	98.4	528,974	98.0
1613	PCI w/ left heart cath during same lab visit	5	5	100.0	14	14	100.0	6	8	75.0	10	10	100.0	29	29	100.0	21,117	82.3	463,268	85.8
1614	PCI performed in conjunction w/ other procedure	0	5	0.0	1	14	7.1	0	8	0.0	2	10	20.0	3	29	10.3	4,199	14.9	111,718	17.6
1615	Repeat target vessel revascularization	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	111	0.4	3,293	0.5
1616	**Status of PCI**																			
1617	Elective	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	9,776	34.7	280,512	44.1
1618	Urgent	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	9,459	33.6	242,860	38.2
1619	Emergent	5	5	100.0	14	14	100.0	8	8	100.0	10	10	100.0	29	29	100.0	8,777	31.2	110,693	17.4
1620	Salvage	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	143	0.5	2,019	0.3
1621	**Fluoro time in minutes (excluding other procedures)**																			
1622	Count of procedures w/ using fluoro time	5	5	100.0	13	13	100.0	8	8	100.0	8	8	100.0	26	26	100.0	23,364	99.1	505,562	98.7
1623	Mean	9.8			12.3			13.5			20.2			14.2			14.1		14.0	
1624	Median	10.4			10.2			13.3			11.6			10.4			11.2		11.0	
1625	Pts w/ CABG prior to PCI																15.7		14.8	
1626	Median 1 vessel/lesion																14.7		13.4	
1627	Median >1 vessel/lesion																19.9		19.0	
1628	Pts w/out CABG prior to PCI	9.1			10.3			13.3			11.6			10.4			10.7		10.3	
1629	Median 1 vessel/lesion	9.1			9.3			13.4			9.7			9.5			9.8		9.1	
1630	Median >1 vessel/lesion				15.0			13.3			33.5			15.6			14.9		14.3	
1631	**Fluoro dose in milligrays (excluding other procedures)**	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1632	Count of procedures w/ fluoro dose in milligrays	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1633	Mean	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1634	Median	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1635	Pts w/ CABG prior to PCI	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1636	Median 1 vessel/lesion	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1637	Median >1 vessel/lesion	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*

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Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1638	Pts w/out CABG prior to PCI	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1639	Median 1 vessel/lesion	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1640	Median >1 vessel/lesion	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
1641	**Contrast volume in milliliters**																			
1642	Count of procedures w/ contrast volume coded	5	5	100.0	13	13	100.0	8	8	100.0	8	8	100.0	26	26	100.0	23,881	99.6	523,140	99.7
1643	Mean	153.0			179.3			171.3			183.1			175.4			197.7		191.6	
1644	Median	180.0			170.0			185.0			200.0			180.0			185.0		180.0	
1645	Pts w/ CABG prior to PCI																200.0		195.0	
1646	Median 1 vessel/lesion																195.0		180.0	
1647	Median >1 vessel/lesion				205.0			202.5			225.0			220.0			220.0		210.0	
1648	Pts w/out CABG prior to PCI	160.0			170.0			185.0			200.0			175.0			180.0		175.0	
1649	Median 1 vessel/lesion	160.0			170.0			177.5			90.0			170.0			175.0		165.0	
1650	Median >1 vessel/lesion				205.0			202.5			225.0			220.0			220.0		210.0	
1651	**Arterial Access Site**																			
1652	Femoral	5	5	100.0	14	14	100.0	8	8	100.0	10	10	100.0	29	29	100.0	26,211	93.1	582,281	91.5
1653	Brachial	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	83	0.3	2,168	0.3
1654	Radial	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	1,853	6.6	51,580	8.1
1655	Other	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	7	0.0	178	0.0
1656	**Methods of closure for arterial access site**																			
1657	Manual compression	0	2	0.0	0	10	0.0	0	6	0.0	0	6	0.0	0	18	0.0	8,569	31.9	250,383	38.4
1658	Mechanical compression	0	2	0.0	0	10	0.0	0	6	0.0	1	6	16.7	1	18	5.6	2,699	10.1	85,960	13.2
1659	Suture	0	2	0.0	0	10	0.0	0	6	0.0	0	6	0.0	0	18	0.0	1,846	6.9	55,597	8.5
1660	Staple	0	2	0.0	0	10	0.0	0	6	0.0	0	6	0.0	0	18	0.0	29	0.1	59	0.0
1661	Sealant	2	2	100.0	10	10	100.0	6	6	100.0	5	6	83.3	17	18	94.4	10,844	40.4	186,880	28.7
1662	Patch	0	2	0.0	0	10	0.0	0	6	0.0	0	6	0.0	0	18	0.0	1,680	6.3	48,655	7.5
1663	Other, unspecified device	0	2	0.0	0	10	0.0	0	6	0.0	0	6	0.0	0	18	0.0	1,197	4.5	24,275	3.7
1664	**Mechanical ventricular support**																			
1665	Any mechanical ventricular support (IABP, LVAD or other support)	1	5	20.0	2	14	14.3	1	8	12.5	1	10	10.0	4	29	13.8	1,216	4.3	18,715	2.9
1666	Intra-aortic balloon pump	1	5	20.0	2	14	14.3	1	8	12.5	1	10	10.0	4	29	13.8	1,102	3.9	16,666	2.6
1667	In place at start of procedure	0	1	0.0	0	2	0.0	0	1	0.0	0	1	0.0	0	4	0.0	62	5.6	1,631	9.8
1668	Inserted during procedure and prior to PCI	1	1	100.0	2	2	100.0	0	1	0.0	1	1	100.0	4	4	100.0	292	26.5	4,643	27.9
1669	Inserted after start of PCI	0	1	0.0	0	2	0.0	1	1	100.0	0	1	0.0	0	4	0.0	748	67.9	10,379	62.3

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Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1670	Other mechanical ventricular support (LVAD, etc)	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	213	0.8	2,916	0.5
1671	In place at start of procedure																118	55.4	1,028	35.3
1672	Inserted during procedure and prior to PCI																50	23.5	1,369	47.0
1673	Inserted after start of PCI																45	21.1	517	17.7

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		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1674	PCI procedure findings																			
1675	**Coronary dominance**																			
1676	Left	2	5	40.0	1	14	7.1	0	8	0.0	1	10	10.0	4	29	13.8	3,209	11.8	56,987	9.3
1677	Right	3	5	60.0	12	14	85.7	7	8	87.5	9	10	90.0	24	29	82.8	21,490	78.7	507,150	82.9
1678	Mixed	0	5	0.0	1	14	7.1	1	8	12.5	0	10	0.0	1	29	3.5	2,610	9.6	48,017	7.8
1679	**Diseased vessels (including left main disease)**																			
1680	LM disease (>=50%)	1	5	20.0	1	14	7.1	0	8	0.0	0	10	0.0	2	29	6.9	1,308	4.6	40,345	6.3
1681	LM and RCA disease (triple vessel)	1	5	20.0	1	14	7.1	0	8	0.0	0	10	0.0	2	29	6.9	844	3.0	23,103	3.6
1682	LM w/out RCA disease (double vessel)	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	464	1.7	17,242	2.7
1683	**Diseased vessels (w/ or w/out LM disease)**																			
1684	Single vessel disease	2	5	40.0	5	14	35.7	6	8	75.0	6	10	60.0	13	29	44.8	15,851	56.3	341,741	53.7
1685	Double vessel disease	2	5	40.0	5	14	35.7	2	8	25.0	2	10	20.0	9	29	31.0	8,274	29.4	197,826	31.1
1686	Triple vessel disease	1	5	20.0	4	14	28.6	0	8	0.0	2	10	20.0	7	29	24.1	3,555	12.6	84,456	13.3
1687	**EF (at start of PCI)**																			
1688	Normal (EF >=50%)	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	11,846	42.1	318,681	50.1
1689	Mildly reduced (EF 40-49%)	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	2,500	8.9	68,328	10.7
1690	Moderately reduced (EF 25-39%)	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	1,675	6.0	47,319	7.4
1691	Severely reduced (EF <25%)	0	5	0.0	0	14	0.0	0	8	0.0	1	10	10.0	1	29	3.5	439	1.6	14,260	2.2
1692	**Ejection Fraction (closest to discharge)**																			
1693	Normal (EF >=50%)	0	5	0.0	6	14	42.9	5	8	62.5	3	10	30.0	9	29	31.0	14,564	52.7	321,466	51.9
1694	Mildly reduced (EF 40-49%)	0	5	0.0	5	14	35.7	2	8	25.0	2	10	20.0	7	29	24.1	3,455	12.5	73,265	11.8
1695	Moderately reduced (EF 25-39%)	0	5	0.0	2	14	14.3	1	8	12.5	2	10	20.0	4	29	13.8	2,356	8.5	50,954	8.2
1696	Severely reduced (EF <25%)	0	5	0.0	1	14	7.1	0	8	0.0	2	10	20.0	3	29	10.3	565	2.0	14,301	2.3
1697	Intraprocedure events																			
1698	**Significant dissection**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**363**	**1.3**	**8,372**	**1.3**
1699	**Perforation**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**133**	**0.5**	**2,415**	**0.4**
1700	**Number of lesions attempted**																			
1701	PCI procedures w/ one lesion attempted	4	5	80.0	10	14	71.4	4	8	50.0	7	10	70.0	21	29	72.4	21,717	77.1	458,977	72.1
1702	PCI procedures w/ two lesions attempted	0	5	0.0	3	14	21.4	4	8	50.0	2	10	20.0	5	29	17.2	5,282	18.8	138,889	21.8
1703	PCI procedures w/ three lesions attempted	1	5	20.0	1	14	7.1	0	8	0.0	1	10	10.0	3	29	10.3	969	3.4	30,962	4.9

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Line#	**Description**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**%**	**Num**	**%**
1704	PCI procedures w/ more than 3 lesions attempted	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	203	0.7	7,587	1.2
1705	**Number of procedures w/ a culprit artery identified (in pts w/ ACS)**	**5**	**5**	**100.0**	**14**	**14**	**100.0**	**8**	**8**	**100.0**	**10**	**10**	**100.0**	**29**	**29**	**100.0**	**18,824**	**88.5**	**376,414**	**84.2**

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PCI
PCI Lesion Information
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1706	**Lesion location**																			
1707	Number of lesions attempted in the left main coronary artery	0	7	0.0	0	19	0.0	0	12	0.0	0	14	0.0	0	40	0.0	312	0.8	15,218	1.6
1708	Number of lesions attempted in the proximal LAD	0	7	0.0	3	19	15.8	4	12	33.3	4	14	28.6	7	40	17.5	5,287	13.9	115,508	12.4
1709	Number of lesions attempted in the mid/distal LAD	3	7	42.9	3	19	15.8	1	12	8.3	3	14	21.4	9	40	22.5	8,801	24.7	222,020	25.9
1710	Number of lesions attempted in the circumflex	1	7	14.3	9	19	47.4	0	12	0.0	1	14	7.1	11	40	27.5	8,267	23.2	211,775	24.7
1711	Number of lesions attempted in the RCA	3	7	42.9	3	19	15.8	7	12	58.3	6	14	42.9	12	40	30.0	13,178	37.0	301,102	35.1
1712	Number of lesions attempted in the ramus	0	7	0.0	1	19	5.3	0	12	0.0	0	14	0.0	1	40	2.5	524	1.5	14,826	1.7
1713	**Lesion in graft**																			
1714	Not in graft	7	7	100.0	19	19	100.0	12	12	100.0	14	14	100.0	40	40	100.0	34,430	95.8	810,143	94.1
1715	Vein	0	7	0.0	0	19	0.0	0	12	0.0	0	14	0.0	0	40	0.0	1,386	3.9	47,246	5.5
1716	Left internal mammary artery (LIMA)	0	7	0.0	0	19	0.0	0	12	0.0	0	14	0.0	0	40	0.0	71	0.2	2,516	0.3
1717	Other artery	0	7	0.0	0	19	0.0	0	12	0.0	0	14	0.0	0	40	0.0	56	0.2	1,234	0.1
1718	Location in graft																			
1719	Aortic anastomosis of vein graft																253	17.0	10,595	20.9
1720	Aortic anastomosis of arterial graft																21	1.4	707	1.4
1721	Body of vein graft																857	57.5	27,464	54.2
1722	Body of arterial graft																62	4.2	1,448	2.9
1723	Distal anastomosis of vein graft																257	17.3	8,941	17.6
1724	Distal anastomosis of arterial graft																40	2.7	1,525	3.0
1725	**Chronic total occlusions**	**0**	**6**	**0.0**	**0**	**8**	**0.0**	**0**	**9**	**0.0**	**0**	**8**	**0.0**	**0**	**22**	**0.0**	**1,119**	**14.0**	**21,821**	**17.4**
1726	**Intermediate coronary stenosis**																			
1727	Lesions w/ intermediate coronary stenosis 40-70%	0	7	0.0	0	19	0.0	0	12	0.0	0	14	0.0	0	40	0.0	3,646	10.1	112,731	13.1
1728	Lesions w/ intermediate coronary stenosis 40-70% w/ no further invasive evaluation																2,665	76.3	82,580	74.5
1729	Lesions w/ intermediate coronary stenosis w/ confirmation by intravascular ultrasound (IVUS)																551	15.7	20,780	18.7

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Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1730	Lesions w/ intermediate coronary stenosis w/ confirmation by fractional flow reserve (FFR)																312	8.9	8,978	8.1
1731	FFR ratio <= 0.75																104	3.0	3,588	3.2
1732	FFR ratio > 0.75																208	5.9	5,337	4.8
1733	**Pre-procedure TIMI flow**																			
1734	TIMI 0 - No flow/no perfusion	7	7	100.0	19	19	100.0	12	12	100.0	10	14	71.4	36	40	90.0	8,573	23.9	127,414	14.8
1735	TIMI 1 - Slow penetration w/out perfusion	0	7	0.0	0	19	0.0	0	12	0.0	2	14	14.3	2	40	5.0	5,277	14.7	72,038	8.4
1736	TIMI 2 - Partial flow/partial perfusion	0	7	0.0	0	19	0.0	0	12	0.0	2	14	14.3	2	40	5.0	7,411	20.6	160,908	18.7
1737	TIMI 3 - Complete and brisk flow/complete perfusion	0	7	0.0	0	19	0.0	0	12	0.0	0	14	0.0	0	40	0.0	14,652	40.8	498,619	58.1
1738	**Previously treated lesions**																			
1739	Previously treated lesions	0	7	0.0	0	19	0.0	0	12	0.0	2	14	14.3	2	40	5.0	3,337	9.3	89,409	10.4
1740	Previously treated timeframe																			
1741	<1 month										0	2	0.0	0	2	0.0	312	9.4	6,309	7.1
1742	1-5 months										0	2	0.0	0	2	0.0	356	10.7	11,277	12.6
1743	6-12 months										0	2	0.0	0	2	0.0	390	11.7	12,146	13.6
1744	1-2 years										1	2	50.0	1	2	50.0	440	13.2	12,515	14.0
1745	>2 years										1	2	50.0	1	2	50.0	1,517	45.5	40,099	44.9
1746	Timeframe unknown										0	2	0.0	0	2	0.0	321	9.6	6,885	7.7
1747	Previously treated w/ stent										2	2	100.0	2	2	100.0	2,975	89.3	83,422	93.5
1748	In-stent restenosis										1	2	50.0	1	2	50.0	2,377	80.0	73,664	88.4
1749	In-stent thrombosis										1	2	50.0	1	2	50.0	749	25.2	12,756	15.3
1750	Stent type																			
1751	Drug eluting stent										0	2	0.0	0	2	0.0	1,336	45.2	44,387	53.3
1752	Non-drug eluting stent										1	2	50.0	1	2	50.0	573	19.4	18,101	21.8
1753	Stent type unknown										1	2	50.0	1	2	50.0	1,049	35.5	20,724	24.9
1754	**Lesion complexity**																			
1755	Non-high/Non-C	0	7	0.0	8	19	42.1	7	12	58.3	9	14	64.3	17	40	42.5	17,584	49.0	441,544	51.3
1756	High/C	7	7	100.0	11	19	57.9	5	12	41.7	5	14	35.7	23	40	57.5	18,334	51.0	418,743	48.7
1757	**SCAI lesion classification system**																			
1758	Type I lesion (does not meet criteria for high risk lesion and patent)	0	7	0.0	5	19	26.3	2	12	16.7	5	14	35.7	10	40	25.0	15,192	42.1	405,667	47.1
1759	Type II lesion (high risk and patent)	1	7	14.3	5	19	26.3	1	12	8.3	1	14	7.1	7	40	17.5	12,625	35.0	327,150	38.0

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PCI
PCI Lesion Information
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1760	Type III lesions (does not meet criteria for high risk and occluded)	0	7	0.0	3	19	15.8	5	12	41.7	4	14	28.6	7	40	17.5	2,372	6.6	35,489	4.1
1761	Type IV lesions (high risk and occluded)	6	7	85.7	6	19	31.6	4	12	33.3	4	14	28.6	16	40	40.0	5,691	15.8	91,299	10.6
1762	**Lesion length**																			
1763	< 20 mm	4	7	57.1	9	19	47.4	7	12	58.3	9	14	64.3	22	40	55.0	23,322	66.6	548,701	64.5
1764	>= 20 mm	3	7	42.9	10	19	52.6	5	12	41.7	5	14	35.7	18	40	45.0	11,694	33.4	301,995	35.5
1765	**Thrombus present**	**2**	**7**	**28.6**	**13**	**19**	**68.4**	**6**	**12**	**50.0**	**5**	**14**	**35.7**	**20**	**40**	**50.0**	**7,554**	**21.0**	**106,731**	**12.4**
1766	**Bifurcation lesion**	**0**	**7**	**0.0**	**3**	**19**	**15.8**	**0**	**12**	**0.0**	**0**	**14**	**0.0**	**3**	**40**	**7.5**	**4,104**	**11.4**	**104,931**	**12.2**
1767	**Guidewire across lesion**	**7**	**7**	**100.0**	**19**	**19**	**100.0**	**12**	**12**	**100.0**	**14**	**14**	**100.0**	**40**	**40**	**100.0**	**35,378**	**98.3**	**848,457**	**98.5**
1768	**Post-procedure TIMI flow**																			
1769	TIMI 0 - No flow/no perfusion	0	7	0.0	0	19	0.0	0	12	0.0	1	14	7.1	1	40	2.5	397	1.1	6,593	0.8
1770	TIMI 1 - Slow penetration w/out perfusion	0	7	0.0	0	19	0.0	0	12	0.0	0	14	0.0	0	40	0.0	174	0.5	2,779	0.3
1771	TIMI 2 - Partial flow/partial perfusion	0	7	0.0	0	19	0.0	0	12	0.0	0	14	0.0	0	40	0.0	743	2.1	10,575	1.3
1772	TIMI 3 - Complete and brisk flow/complete perfusion	7	7	100.0	19	19	100.0	12	12	100.0	13	14	92.9	39	40	97.5	33,959	96.3	826,836	97.6
1773	**Devices deployed**	**7**	**7**	**100.0**	**19**	**19**	**100.0**	**12**	**12**	**100.0**	**14**	**14**	**100.0**	**40**	**40**	**100.0**	**34,660**	**98.1**	**838,427**	**98.9**
1774	**Intracoronary devices used**																			
1775	Atherectomy	0	13	0.0	0	53	0.0	0	26	0.0	0	35	0.0	0	101	0.0	75	0.1	8,048	0.4
1776	Balloon	5	13	38.5	21	53	39.6	10	26	38.5	20	35	57.1	46	101	45.5	38,138	47.7	925,351	47.9
1777	Brachytherapy	0	13	0.0	0	53	0.0	0	26	0.0	0	35	0.0	0	101	0.0	13	0.0	190	0.0
1778	Cutting balloon	0	13	0.0	0	53	0.0	0	26	0.0	0	35	0.0	0	101	0.0	988	1.2	40,149	2.1
1779	Chronic total occlusion device	0	13	0.0	0	53	0.0	0	26	0.0	0	35	0.0	0	101	0.0	38	0.1	253	0.0
1780	Embolic protection	0	13	0.0	0	53	0.0	0	26	0.0	0	35	0.0	0	101	0.0	148	0.2	9,439	0.5
1781	Embolic protection in PCI vein grafts																128	4.2	8,655	7.7
1782	Laser	0	13	0.0	0	53	0.0	0	26	0.0	0	35	0.0	0	101	0.0	2	0.0	899	0.1
1783	Stent - bare metal	5	13	38.5	15	53	28.3	9	26	34.6	6	35	17.1	26	101	25.7	10,404	13.0	206,166	10.7
1784	Stent - covered and coated	0	13	0.0	0	53	0.0	0	26	0.0	0	35	0.0	0	101	0.0	13	0.0	434	0.0
1785	Stent - drug eluting (DES)	1	13	7.7	5	53	9.4	3	26	11.5	5	35	14.3	11	101	10.9	26,862	33.6	685,714	35.5
1786	Thrombectomy	1	13	7.7	5	53	9.4	3	26	11.5	4	35	11.4	10	101	9.9	2,078	2.6	35,476	1.8
1787	Blinded	0	13	0.0	0	53	0.0	0	26	0.0	0	35	0.0	0	101	0.0	9	0.0	297	0.0
1788	**Stent usage**																			
1789	Stents per pt admission	1.2			1.4			1.5			1.1			1.3			1.4		1.4	
1790	DES per pt admission	0.2			0.4			0.4			0.5			0.4			1.0		1.1	
1791	**Overall angiographic success**																			

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PCI
PCI Lesion Information
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1792	Angiographic success for stented lesions (<=20%) (excludes CTOs)	5	5	100.0	19	19	100.0	11	11	100.0	10	10	100.0	34	34	100.0	29,889	98.1	728,696	99.1
1793	Angiographic success for non-stent devices (excludes CTOs)	2	2	100.0				1	1	100.0	3	4	75.0	5	6	83.3	3,254	72.6	80,963	77.3

PCI (all patients)
Adverse Events
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1794	Post-procedure events (all pts)																			
1795	**Any adverse event**	**0**	**5**	**0.0**	**1**	**14**	**7.1**	**0**	**8**	**0.0**	**1**	**10**	**10.0**	**2**	**29**	**6.9**	**2,744**	**9.8**	**45,711**	**7.2**
1796	Pts w/out CABG during admission	0	5	0.0	1	14	7.1	0	8	0.0	1	9	11.1	2	28	7.1	2,562	9.3	38,946	6.3
1797	**Composite:Death, emergency CABG, stroke or repeat target vessel revascularization.**	**1**	**5**	**20.0**	**0**	**14**	**0.0**	**2**	**8**	**25.0**	**1**	**10**	**10.0**	**2**	**29**	**6.9**	**817**	**3.0**	**14,328**	**2.3**
1798	**Post procedure MI (all pts)**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**1,240**	**4.4**	**13,870**	**2.2**
1799	Post procedure MI (among hospitals routinely collecting post-PCI biomarkers)																48	2.3	2,301	3.8
1800	Post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)																102	1.3	3,097	1.4
1801	Post procedure MI for pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	9	0.0	0	28	0.0	1,204	4.4	13,114	2.1
1802	**Cardiogenic shock**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**533**	**1.9**	**7,137**	**1.1**
1803	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	9	0.0	0	28	0.0	495	1.8	5,926	1.0
1804	**Heart failure**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**372**	**1.3**	**6,786**	**1.1**
1805	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	9	0.0	0	28	0.0	345	1.3	5,861	1.0
1806	**CVA/Stroke**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**62**	**0.2**	**1,404**	**0.2**
1807	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	9	0.0	0	28	0.0	58	0.2	1,196	0.2
1808	**Hemorrhagic stroke**																**18**	**29.0**	**265**	**19.0**
1809	Pts w/out CABG during admission																17	29.3	227	19.1
1810	**Cardiac tamponade**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**29**	**0.1**	**563**	**0.1**
1811	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	9	0.0	0	28	0.0	21	0.1	330	0.1
1812	**New requirement for dialysis**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**74**	**0.3**	**1,650**	**0.3**
1813	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	9	0.0	0	28	0.0	66	0.2	1,244	0.2
1814	Post-procedure bleeding (all pts)																			
1815	**Bleeding event w/in 72 hrs of the procedure**	**0**	**5**	**0.0**	**1**	**14**	**7.1**	**0**	**8**	**0.0**	**1**	**10**	**10.0**	**2**	**29**	**6.9**	**610**	**2.2**	**10,941**	**1.7**
1816	Pts w/out CABG during admission	0	5	0.0	1	14	7.1	0	8	0.0	1	9	11.1	2	28	7.1	563	2.0	9,440	1.5
1817	**Bleeding at access site w/in 72 hrs**				**0**	**1**	**0.0**				**0**	**1**	**0.0**	**0**	**2**	**0.0**	**218**	**35.7**	**3,125**	**28.6**

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PCI (all patients)
Adverse Events
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1818	Pts w/out CABG during admission				0	1	0.0				0	1	0.0	0	2	0.0	200	35.5	2,812	29.8
1819	**Hematoma at access site w/in 72 hrs**				**0**	**1**	**0.0**				**0**	**1**	**0.0**	**0**	**2**	**0.0**	**271**	**44.4**	**4,691**	**42.9**
1820	Size																			
1821	<3 cm																75	27.7	1,423	30.5
1822	3-5 cm																72	26.6	1,247	26.7
1823	>5-10 cm																63	23.3	1,130	24.2
1824	>10 cm																61	22.5	871	18.7
1825	**Retroperitoneal bleeding w/in 72 hrs**				**0**	**1**	**0.0**				**0**	**1**	**0.0**	**0**	**2**	**0.0**	**75**	**12.3**	**1,234**	**11.3**
1826	Pts w/out CABG during admission				0	1	0.0				0	1	0.0	0	2	0.0	71	12.6	1,061	11.3
1827	**GI bleed**				**1**	**1**	**100.0**				**0**	**1**	**0.0**	**1**	**2**	**50.0**	**100**	**16.4**	**1,871**	**17.1**
1828	Pts w/out CABG during admission				1	1	100.0				0	1	0.0	1	2	50.0	92	16.3	1,621	17.2
1829	**GU bleed**				**0**	**1**	**0.0**				**1**	**1**	**100.0**	**1**	**2**	**50.0**	**29**	**4.8**	**421**	**3.9**
1830	Pts w/out CABG during admission				0	1	0.0				1	1	100.0	1	2	50.0	27	4.8	358	3.8
1831	**Other bleed, not specified above**				**0**	**1**	**0.0**				**0**	**1**	**0.0**	**0**	**2**	**0.0**	**93**	**15.3**	**2,087**	**19.1**
1832	Pts w/out CABG during admission				0	1	0.0				0	1	0.0	0	2	0.0	77	13.7	1,484	15.7
1833	**Other vascular complications requiring treatment**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**136**	**0.5**	**2,821**	**0.4**
1834	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	9	0.0	0	28	0.0	110	0.4	2,127	0.3
1835	**Vascular access site injury requiring treatment or major bleeding**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**0**	**29**	**0.0**	**502**	**1.8**	**8,902**	**1.4**
1836	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	9	0.0	0	28	0.0	459	1.7	7,765	1.3
1837	**RBC/whole blood transfusion**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**1**	**10**	**10.0**	**1**	**29**	**3.5**	**651**	**2.3**	**17,189**	**2.7**
1838	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	1	9	11.1	1	28	3.6	541	2.0	12,214	2.0
1839	Hgb prior to transfusion <8 g/dL										0	1	0.0	0	1	0.0	193	29.7	5,982	34.9
1840	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	169	31.2	4,290	35.2

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PCI (patients with STEMI)
Adverse Events
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1841	Post-procedure events for pts w/ STEMI																			
1842	**Any adverse event**	**0**	**5**	**0.0**	**1**	**14**	**7.1**	**0**	**8**	**0.0**	**1**	**9**	**11.1**	**2**	**28**	**7.1**	**1,463**	**18.1**	**15,300**	**15.2**
1843	Pts w/out CABG during admission	0	5	0.0	1	14	7.1	0	8	0.0	1	8	12.5	2	27	7.4	1,374	17.5	12,818	13.4
1844	**Cardiogenic shock**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**9**	**0.0**	**0**	**28**	**0.0**	**405**	**5.0**	**4,305**	**4.3**
1845	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	8	0.0	0	27	0.0	382	4.9	3,693	3.9
1846	**Heart failure**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**9**	**0.0**	**0**	**28**	**0.0**	**240**	**3.0**	**3,602**	**3.6**
1847	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	8	0.0	0	27	0.0	223	2.8	3,130	3.3
1848	**CVA/Stroke**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**9**	**0.0**	**0**	**28**	**0.0**	**31**	**0.4**	**542**	**0.5**
1849	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	8	0.0	0	27	0.0	29	0.4	456	0.5
1850	**Hemorrhagic stroke**																**8**	**25.8**	**120**	**22.2**
1851	Pts w/out CABG during admission																7	24.1	103	22.7
1852	**Cardiac tamponade**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**9**	**0.0**	**0**	**28**	**0.0**	**11**	**0.1**	**165**	**0.2**
1853	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	8	0.0	0	27	0.0	7	0.1	92	0.1
1854	**New requirement for dialysis**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**9**	**0.0**	**0**	**28**	**0.0**	**35**	**0.4**	**642**	**0.6**
1855	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	8	0.0	0	27	0.0	31	0.4	456	0.5
1856	Post-procedure bleeding for pts w/ STEMI																			
1857	**Bleeding event w/in 72 hrs of the procedure**	**0**	**5**	**0.0**	**1**	**14**	**7.1**	**0**	**8**	**0.0**	**1**	**9**	**11.1**	**2**	**28**	**7.1**	**288**	**3.6**	**3,774**	**3.7**
1858	Pts w/out CABG during admission	0	5	0.0	1	14	7.1	0	8	0.0	1	8	12.5	2	27	7.4	264	3.4	3,242	3.4
1859	**Bleeding at access site w/in 72 hrs**				**0**	**1**	**0.0**				**0**	**1**	**0.0**	**0**	**2**	**0.0**	**96**	**33.3**	**968**	**25.7**
1860	Pts w/out CABG during admission				0	1	0.0				0	1	0.0	0	2	0.0	87	33.0	877	27.1
1861	**Hematoma at access site w/in 72 hrs**				**0**	**1**	**0.0**				**0**	**1**	**0.0**	**0**	**2**	**0.0**	**103**	**35.8**	**1,238**	**32.8**
1862	Size																			
1863	<3 cm																29	28.2	352	28.5
1864	3-5 cm																29	28.2	348	28.2
1865	>5-10 cm																23	22.3	309	25.0
1866	>10 cm																22	21.4	225	18.2
1867	**Retroperitoneal bleeding**				**0**	**1**	**0.0**				**0**	**1**	**0.0**	**0**	**2**	**0.0**	**37**	**12.9**	**380**	**10.1**

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PCI (patients with STEMI)
Adverse Events
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		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
	w/in 72 hrs																			
1868	Pts w/out CABG during admission				0	1	0.0				0	1	0.0	0	2	0.0	35	13.3	339	10.5
1869	**GI bleed**				**1**	**1**	**100.0**				**0**	**1**	**0.0**	**1**	**2**	**50.0**	**58**	**20.1**	**834**	**22.1**
1870	Pts w/out CABG during admission				1	1	100.0				0	1	0.0	1	2	50.0	52	19.7	727	22.5
1871	**GU bleed**				**0**	**1**	**0.0**				**1**	**1**	**100.0**	**1**	**2**	**50.0**	**16**	**5.6**	**183**	**4.9**
1872	Pts w/out CABG during admission				0	1	0.0				1	1	100.0	1	2	50.0	15	5.7	157	4.9
1873	**Other bleed, not specified above**				**0**	**1**	**0.0**				**0**	**1**	**0.0**	**0**	**2**	**0.0**	**60**	**20.8**	**956**	**25.4**
1874	Pts w/out CABG during admission				0	1	0.0				0	1	0.0	0	2	0.0	51	19.3	697	21.5
1875	**Other vascular complications requiring treatment**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**9**	**0.0**	**0**	**28**	**0.0**	**53**	**0.7**	**566**	**0.6**
1876	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	8	0.0	0	27	0.0	42	0.5	404	0.4
1877	**Vascular access site injury requiring treatment or major bleeding**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**0**	**9**	**0.0**	**0**	**28**	**0.0**	**206**	**2.6**	**2,384**	**2.4**
1878	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	0	8	0.0	0	27	0.0	187	2.4	2,091	2.2
1879	**RBC/Whole blood transfusion**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**1**	**9**	**11.1**	**1**	**28**	**3.6**	**329**	**4.1**	**5,645**	**5.6**
1880	Pts w/out CABG during admission	0	5	0.0	0	14	0.0	0	8	0.0	1	8	12.5	1	27	3.7	276	3.5	3,801	4.0
1881	**Hgb prior to transfusion <8 g/dL**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**101**	**30.8**	**1,922**	**34.2**
1882	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	89	32.3	1,355	35.7

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PCI (patients without STEMI)
Adverse Events
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1883	Post-procedure events (pts w/out STEMI)																			
1884	**Any adverse event**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**1,272**	**6.4**	**30,342**	**5.7**
1885	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	1,183	6.0	26,090	5.0
1886	**Post procedure MI**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**585**	**2.9**	**10,926**	**2.0**
1887	Post procedure MI (among hospitals routinely collecting post-PCI biomarkers)																48	2.3	2,289	3.8
1888	Post procedure MI (among hospitals who do not routinely collecting post-PCI biomarkers)																97	1.3	3,054	1.4
1889	Post procedure MI for pts w/out CABG during admission										0	1	0.0	0	1	0.0	569	2.9	10,377	2.0
1890	**Cardiogenic shock**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**128**	**0.6**	**2,830**	**0.5**
1891	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	0	0.0	0	0.0
1892	**Heart failure**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**132**	**0.7**	**3,180**	**0.6**
1893	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	122	0.6	2,727	0.5
1894	**CVA/Stroke**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**31**	**0.2**	**862**	**0.2**
1895	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	29	0.2	740	0.1
1896	**Hemorrhagic stroke**																**10**	**32.3**	**145**	**16.9**
1897	Pts w/out CABG during admission																10	34.5	124	16.9
1898	**Cardiac tamponade**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**18**	**0.1**	**397**	**0.1**
1899	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	14	0.1	237	0.1
1900	**New requirement for dialysis**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**39**	**0.2**	**1,008**	**0.2**
1901	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	35	0.2	788	0.2
1902	Post-procedure bleeding for pts w/out STEMI																			
1903	**Bleeding event w/in 72 hrs of the procedure**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**322**	**1.6**	**7,165**	**1.3**
1904	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	299	1.5	6,196	1.2
1905	**Bleeding at access site w/in 72 hrs**																**122**	**37.9**	**2,157**	**30.1**
1906	Pts w/out CABG during admission																113	37.8	1,935	31.2

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PCI (patients without STEMI)
Adverse Events
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1907	**Hematoma at access site w/in 72 hrs**																**168**	**52.2**	**3,453**	**48.2**
1908	Size																			
1909	<3 cm																46	27.4	1,071	31.2
1910	3-5 cm																43	25.6	899	26.2
1911	>5-10 cm																40	23.8	821	23.9
1912	>10 cm																39	23.2	646	18.8
1913	**Retroperitoneal bleeding w/in 72 hrs**																**38**	**11.8**	**854**	**11.9**
1914	Pts w/out CABG during admission																36	12.0	722	11.7
1915	**GI bleed**																**42**	**13.0**	**1,036**	**14.5**
1916	Pts w/out CABG during admission																40	13.4	893	14.4
1917	**GU bleed**																**13**	**4.0**	**238**	**3.3**
1918	Pts w/out CABG during admission																12	4.0	201	3.3
1919	**Other bleed, not specified above**																**33**	**10.3**	**1,130**	**15.8**
1920	Pts w/out CABG during admission																26	8.7	786	12.7
1921	**Other vascular complications requiring treatment**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**83**	**0.4**	**2,255**	**0.4**
1922	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	68	0.3	1,723	0.3
1923	**Vascular access site injury requiring treatment or major bleeding**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**296**	**1.5**	**6,518**	**1.2**
1924	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	272	1.4	5,674	1.1
1925	**RBC/Whole blood transfusion**										**0**	**1**	**0.0**	**0**	**1**	**0.0**	**322**	**1.6**	**11,542**	**2.2**
1926	Pts w/out CABG during admission										0	1	0.0	0	1	0.0	265	1.3	8,412	1.6
1927	**Hgb prior to transfusion <8 g/dL**																**92**	**28.6**	**4,060**	**35.3**
1928	Pts w/out CABG during admission																80	30.2	2,935	35.0

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PCI
Lab Results
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1929	Labs (all pts)																			
1930	**Proportion of elective inpts who have biomarkers collected post PCI**																**3,275**	**49.5**	**75,548**	**48.4**
1931	**PCIs w/ Cr assessed pre-procedure**	**5**	**5**	**100.0**	**14**	**14**	**100.0**	**8**	**8**	**100.0**	**10**	**10**	**100.0**	**29**	**29**	**100.0**	**26,831**	**95.2**	**597,675**	**93.9**
1932	PCIs w/ Cr assessed pre- and post-procedure (LOS >= 1 day)	4	5	80.0	12	14	85.7	8	8	100.0	7	10	70.0	23	29	79.3	23,060	81.9	518,223	81.4
1933	Acute kidney injury (Cr increase >50%) –excluding pts on dialysis pre-procedure and w/ a LOS <1 day		4			12		2	8	25.0		7			23		256	2.1	6,533	2.3
1934	**Pts w/ a pre- and post-procedure Hgb**	**5**	**5**	**100.0**	**14**	**14**	**100.0**	**8**	**8**	**100.0**	**7**	**10**	**70.0**	**26**	**29**	**89.7**	**22,169**	**80.2**	**492,704**	**79.5**
1935	Proportion of pts w/ a Hgb decrease of >5 g/dL	0	5	0.0	0	14	0.0	0	8	0.0	0	7	0.0	0	26	0.0	17	0.1	328	0.1

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PCI
Discharge Information
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
1936	Discharge																			
1937	**CABG**	**1**	**5**	**20.0**	**1**	**14**	**7.1**	**0**	**8**	**0.0**	**0**	**10**	**0.0**	**2**	**29**	**6.9**	**402**	**1.5**	**7,677**	**1.2**
1938	CABG status																			
1939	Elective	0	5	0.0	1	14	7.1	0	8	0.0	0	10	0.0	1	29	3.5	61	0.2	1,225	0.2
1940	Urgent	1	5	20.0	0	14	0.0	0	8	0.0	0	10	0.0	1	29	3.5	214	0.8	4,634	0.8
1941	Emergent	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	118	0.4	1,708	0.3
1942	Salvage	0	5	0.0	0	14	0.0	0	8	0.0	0	10	0.0	0	29	0.0	9	0.0	101	0.0
1943	**CABG indication**																			
1944	PCI complication	0	1	0.0	0	1	0.0							0	2	0.0	44	11.0	917	12.0
1945	PCI failure w/out clinical deterioration	0	1	0.0	0	1	0.0							0	2	0.0	100	24.9	1,925	25.1
1946	Treatment of CAD w/out PCI immediately preceding CABG	0	1	0.0	0	1	0.0							0	2	0.0	60	14.9	1,393	18.2
1947	PCI/CABG hybrid procedure	1	1	100.0	1	1	100.0							2	2	100.0	198	49.3	3,422	44.7
1948	**CABG location**																			
1949	At your facility	0	1	0.0	0	1	0.0							0	2	0.0	138	34.3	7,073	92.2
1950	Transferred to other facility	1	1	100.0	1	1	100.0							2	2	100.0	264	65.7	595	7.8
1951	**Other major surgery during this admission**	**0**	**5**	**0.0**	**0**	**14**	**0.0**	**0**	**8**	**0.0**	**1**	**10**	**10.0**	**1**	**29**	**3.5**	**378**	**1.4**	**10,058**	**1.6**
1952	**Cardiac rehabilitation referral**	**0**	**3**	**0.0**	**0**	**11**	**0.0**	**0**	**6**	**0.0**	**0**	**6**	**0.0**	**0**	**20**	**0.0**	**13,823**	**56.1**	**338,168**	**59.3**
1953	Medications prescribed at discharge																			
1954	**Angiotensin converting enzyme (ACE) inhibitors**	**1**	**3**	**33.3**	**6**	**11**	**54.6**	**5**	**6**	**83.3**	**4**	**6**	**66.7**	**11**	**20**	**55.0**	**13,949**	**55.6**	**314,368**	**53.9**
1955	Among pts w/ EF < 40%				1	1	100.0				2	2	100.0	3	3	100.0	1,933	70.3	49,015	71.1
1956	**Angiotensin II receptor blocker (ARB)**	**0**	**3**	**0.0**	**1**	**11**	**9.1**	**1**	**6**	**16.7**	**1**	**6**	**16.7**	**2**	**20**	**10.0**	**2,484**	**9.8**	**80,783**	**13.7**
1957	Among pts w/ EF < 40%				0	1	0.0				0	2	0.0	0	3	0.0	277	10.0	8,431	12.0
1958	**ACE or ARB among pts w/ EF < 40%**																**1,346**	**75.1**	**43,255**	**79.5**
1959	**Aspirin**	**3**	**3**	**100.0**	**11**	**11**	**100.0**	**6**	**6**	**100.0**	**6**	**6**	**100.0**	**20**	**20**	**100.0**	**24,592**	**95.8**	**583,052**	**97.6**
1960	Among pts w/ ACS	3	3	100.0	11	11	100.0	6	6	100.0	6	6	100.0	20	20	100.0	18,765	96.5	415,072	97.8
1961	**Beta blockers**	**2**	**3**	**66.7**	**11**	**11**	**100.0**	**6**	**6**	**100.0**	**6**	**6**	**100.0**	**19**	**20**	**95.0**	**21,500**	**85.2**	**499,986**	**85.2**
1962	Among pts w/ Acute MI	2	3	66.7	11	11	100.0	6	6	100.0	6	6	100.0	19	20	95.0	10,488	93.0	186,386	94.5
1963	**Lipid lowering agents (any)**	**3**	**3**	**100.0**	**11**	**11**	**100.0**	**6**	**6**	**100.0**	**6**	**6**	**100.0**	**20**	**20**	**100.0**	**23,470**	**90.9**	**551,668**	**91.8**
1964	Statins	3	3	100.0	11	11	100.0	6	6	100.0	6	6	100.0	20	20	100.0	22,877	89.5	534,660	90.2
1965	Nonstatins	0	3	0.0	0	11	0.0	0	6	0.0	0	6	0.0	0	20	0.0	3,046	11.8	96,882	16.1
1966	Among pts w/ dyslipidemia	1	1	100.0	5	5	100.0	2	2	100.0	6	6	100.0	12	12	100.0	17,252	92.3	452,068	93.7
1967	**Thienopyridine**	**2**	**3**	**66.7**	**11**	**11**	**100.0**	**6**	**6**	**100.0**	**6**	**6**	**100.0**	**19**	**20**	**95.0**	**24,790**	**96.0**	**584,356**	**97.2**

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PCI
Discharge Information
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	**Description**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**%**	**Num**	**%**
1968	Among pts w/ stents	2	2	100.0	11	11	100.0	6	6	100.0	5	5	100.0	18	18	100.0	23,134	97.4	545,807	98.6
1969	**Discharge status**																			
1970	Alive	4	5	80.0	14	14	100.0	6	8	75.0	9	10	90.0	27	29	93.1	27,099	98.0	610,923	98.6
1971	Dead (unadjusted)	1	5	20.0	0	14	0.0	2	8	25.0	1	10	10.0	2	29	6.9	545	2.0	8,656	1.4
1972	Dead (unadjusted - excluding CABG and other major surgery)	1	4	25.0	0	13	0.0	2	8	25.0	1	9	11.1	2	26	7.7	516	1.9	7,652	1.3
1973	Death in lab (all pts)	0	1	0.0				0	2	0.0	0	1	0.0	0	2	0.0	87	16.0	1,102	12.7
1974	Primary cause of death	1	1	100.0				2	2	100.0	1	1	100.0	2	2	100.0	544	100.0	8,636	100.0
1975	Cardiac	0	1	0.0				1	2	50.0	0	1	0.0	0	2	0.0	380	69.9	6,346	73.5
1976	Neurologic	0	1	0.0				0	2	0.0	0	1	0.0	0	2	0.0	43	7.9	520	6.0
1977	Renal	0	1	0.0				0	2	0.0	0	1	0.0	0	2	0.0	4	0.7	86	1.0
1978	Vascular	0	1	0.0				0	2	0.0	0	1	0.0	0	2	0.0	5	0.9	111	1.3
1979	Infection	0	1	0.0				0	2	0.0	0	1	0.0	0	2	0.0	13	2.4	206	2.4
1980	Valvular	0	1	0.0				0	2	0.0	0	1	0.0	0	2	0.0	12	2.2	191	2.2
1981	Pulmonary	0	1	0.0				1	2	50.0	1	1	100.0	1	2	50.0	31	5.7	443	5.1
1982	Unknown	0	1	0.0				0	2	0.0	0	1	0.0	0	2	0.0	27	5.0	325	3.8
1983	Other	1	1	100.0				0	2	0.0	0	1	0.0	1	2	50.0	29	5.3	408	4.7
1984	**Discharge location**	**4**	**4**	**100.0**	**14**	**14**	**100.0**	**6**	**6**	**100.0**	**9**	**9**	**100.0**	**27**	**27**	**100.0**	**27,086**	**100.0**	**610,716**	**100.0**
1985	Home	2	4	50.0	9	14	64.3	6	6	100.0	5	9	55.6	16	27	59.3	24,966	92.2	585,400	95.9
1986	Extended care, transitional care or rehab facility	0	4	0.0	0	14	0.0	0	6	0.0	0	9	0.0	0	27	0.0	587	2.2	11,648	1.9
1987	Other acute care hospital	1	4	25.0	3	14	21.4	0	6	0.0	3	9	33.3	7	27	25.9	1,009	3.7	4,594	0.8
1988	Nursing home	1	4	25.0	1	14	7.1	0	6	0.0	1	9	11.1	3	27	11.1	288	1.1	5,444	0.9
1989	Hospice	0	4	0.0	0	14	0.0	0	6	0.0	0	9	0.0	0	27	0.0	47	0.2	1,000	0.2
1990	Other	0	4	0.0	1	14	7.1	0	6	0.0	0	9	0.0	1	27	3.7	117	0.4	1,320	0.2
1991	Left against medical advice (AMA)	0	4	0.0	0	14	0.0	0	6	0.0	0	9	0.0	0	27	0.0	72	0.3	1,310	0.2
1992	**Risk adjusted mortality (RAM) - all pts**																			
1993	Eligible pts (LFHS)	4			11						7			22			26,048		603,333	
1994	Observed Mortality (among eligible) (LFHS)	1			0						1			2			545		8,656	
1995	Expected Mortality (among eligible) (LFHS)	0.07			0.33						0.33			0.74			495.79		8,735.23	
1996	Observed/Expected Mortality Ratio	14.15			0.00						3.00			2.72			1.10		0.99	
1997	Risk Adjusted Mortality Rate (%)	18.23									4.18			3.90					1.42	
1998	Registry Aggregate Observed	1.29			1.51			1.55			1.39			1.43					1.43	

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PCI
Discharge Information
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
	Mortality																			
1999	Lower 95% confidence interval	0.97			0.00						0.22			0.69					1.40	
2000	Upper 95% confidence interval	48.83			10.52						13.67			10.74					1.45	
2001	**RAM for pts w/ STEMI**																			
2002	Eligible pts	4			11						6			21			7,342		96,972	
2003	Observed Mortality (among eligible)	1			0						1			2			397		5,309	
2004	Expected Mortality (among eligible)	0.07			0.33						0.30			0.70			360.87		5,262.31	
2005	Observed/Expected Mortality Ratio	14.15			0.00						3.39			2.86			1.10		1.01	
2006	Risk Adjusted Mortality Rate (%)	72.68									17.92			15.67					5.52	
2007	Registry Aggregate Observed Mortality	5.14			5.65			5.80			5.29			5.47					5.47	
2008	Lower 95% confidence interval	3.88			0.00						0.95			2.79					5.41	
2009	Upper 95% confidence interval	194.68			39.53						54.32			42.54					5.64	
2010	**RAM STEMI pts excluded**																			
2011	Eligible pts										1			1			18,706		506,361	
2012	Observed Mortality (among eligible)										0			0			148		3,347	
2013	Expected Mortality (among eligible)										0.04			0.04			134.92		3,472.92	
2014	Observed/Expected Mortality Ratio										0.00			0.00			1.10		0.96	
2015	Risk Adjusted Mortality Rate (%)																		0.64	
2016	Registry Aggregate Observed Mortality	0.58			0.69			0.73			0.65			0.66					0.66	
2017	Lower 95% confidence interval										0.00			0.00					0.62	
2018	Upper 95% confidence interval										13.66			13.97					0.66	

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PCI (all patients)
Length of Stay
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
2019	Length of stay (LOS) - all pts																			
2020	Pts w/ CABG or other major surgery	1			1						1			3			756		16,905	
2021	Pts w/out CABG or other major surgery	5			14			8			10			29			27,619		618,717	
2022	**Total LOS - all pts**																			
2023	Mean	3.2			3.2			3.5			3.7			3.4			3.2		3.1	
2024	Median	2.0			2.0			3.0			2.5			2.0			2.0		2.0	
2025	Standard deviation	3.42			3.21			2.51			3.68			3.30			8.51		9.09	
2026	**Pre-procedure LOS - all pts**																			
2027	Mean	0.2			0.0			0.1			0.1			0.1			0.8		0.8	
2028	Median	0.0			0.0			0.0			0.0			0.0			0.0		0.0	
2029	Standard deviation	0.45			0.00			0.35			0.32			0.26			7.31		7.45	
2030	**Post-procedure LOS - all pts**																			
2031	Mean	3.0			3.2			3.4			3.6			3.3			2.4		2.3	
2032	Median	2.0			2.0			2.5			2.5			2.0			1.0		1.0	
2033	Standard deviation	3.00			3.21			2.56			3.50			3.17			4.29		5.07	
2034	**Total LOS - pts w/ CABG or other major surgery**																			
2035	Mean	0.0			0.0						10.0			3.3			7.0		10.9	
2036	Median	0.0			0.0						10.0			0.0			4.5		8.0	
2037	Standard deviation													5.77			8.69		13.19	
2038	**Pre-procedure LOS - pts w/ CABG or other major surgery**																			
2039	Mean	0.0			0.0						1.0			0.3			1.3		1.7	
2040	Median	0.0			0.0						1.0			0.0			0.0		0.0	
2041	Standard deviation													0.58			2.95		7.42	
2042	**Post-procedure LOS - pts w/ CABG or other major surgery**																			
2043	Mean	0.0			0.0						9.0			3.0			5.7		9.2	
2044	Median	0.0			0.0						9.0			0.0			3.0		7.0	
2045	Standard deviation													5.20			7.97		10.74	
2046	**Total LOS - pts w/out CABG or other major surgery**																			
2047	Mean	3.2			3.2			3.5			3.7			3.4			3.2		3.0	
2048	Median	2.0			2.0			3.0			2.5			2.0			2.0		2.0	
2049	Standard deviation	3.42			3.21			2.51			3.68			3.30			8.51		9.06	

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PCI (all patients)
Length of Stay
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	**Description**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**Den**	**%**	**Num**	**%**	**Num**	**%**
2050	**Pre-procedure LOS - pts w/out CABG or other major surgery**																			
2051	Mean	0.2			0.0			0.1			0.1			0.1			0.8		0.8	
2052	Median	0.0			0.0			0.0			0.0			0.0			0.0		0.0	
2053	Standard deviation	0.45			0.00			0.35			0.32			0.26			7.31		7.44	
2054	**Post-procedure LOS - pts w/out CABG or other major surgery**																			
2055	Mean	3.0			3.2			3.4			3.6			3.3			2.4		2.2	
2056	Median	2.0			2.0			2.5			2.5			2.0			1.0		1.0	
2057	Standard deviation	3.00			3.21			2.56			3.50			3.17			4.28		5.02	

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PCI (patients with STEMI)
Length of Stay
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
2058	Length of stay (LOS) - pts w/ STEMI																			
2059	Pts w/ STEMI and CABG or other major surgery	1			1						1			3			373		5,459	
2060	Pts w/ STEMI and w/out CABG or other major surgery	5			14			8			9			28			8,033		100,056	
2061	**Total LOS - all pts w/ STEMI**																			
2062	Mean	3.2			3.2			3.5			3.6			3.3			3.8		4.4	
2063	Median	2.0			2.0			3.0			2.0			2.0			3.0		3.0	
2064	Standard deviation	3.42			3.21			2.51			3.88			3.35			7.18		9.25	
2065	**Pre-procedure LOS - all pts w/ STEMI**																			
2066	Mean	0.2			0.0			0.1			0.1			0.1			0.2		0.3	
2067	Median	0.0			0.0			0.0			0.0			0.0			0.0		0.0	
2068	Standard deviation	0.45			0.00			0.35			0.33			0.26			4.16		6.58	
2069	**Post-procedure LOS - all pts w/ STEMI**																			
2070	Mean	3.0			3.2			3.4			3.4			3.3			3.6		4.1	
2071	Median	2.0			2.0			2.5			2.0			2.0			3.0		3.0	
2072	Standard deviation	3.00			3.21			2.56			3.68			3.22			5.84		6.45	
2073	**Total LOS - pts w/ STEMI and CABG or other major surgery**																			
2074	Mean	0.0			0.0						10.0			3.3			6.5		11.5	
2075	Median	0.0			0.0						10.0			0.0			4.0		9.0	
2076	Standard deviation													5.77			9.55		13.40	
2077	**Pre-procedure LOS - pts w/ STEMI and CABG or other major surgery**																			
2078	Mean	0.0			0.0						1.0			0.3			0.4		0.4	
2079	Median	0.0			0.0						1.0			0.0			0.0		0.0	
2080	Standard deviation													0.58			1.61		2.24	
2081	**Post-procedure LOS - pts w/ STEMI and CABG or other major surgery**																			
2082	Mean	0.0			0.0						9.0			3.0			6.1		11.1	
2083	Median	0.0			0.0						9.0			0.0			3.0		8.0	
2084	Standard deviation													5.20			9.39		13.13	
2085	**Total LOS – pts w/ STEMI and w/out CABG or other major surgery**																			

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PCI (patients with STEMI)
Length of Stay
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
2086	Mean	3.2			3.2			3.5			3.6			3.3			3.8		4.4	
2087	Median	2.0			2.0			3.0			2.0			2.0			3.0		3.0	
2088	Standard deviation	3.42			3.21			2.51			3.88			3.35			7.16		9.19	
2089	**Pre-procedure LOS - pts w/ STEMI and w/out CABG or other major surgery**																			
2090	Mean	0.2			0.0			0.1			0.1			0.1			0.2		0.3	
2091	Median	0.0			0.0			0.0			0.0			0.0			0.0		0.0	
2092	Standard deviation	0.45			0.00			0.35			0.33			0.26			4.16		6.59	
2093	**Post-procedure LOS - pts w/ STEMI and w/out CABG or other major surgery**																			
2094	Mean	3.0			3.2			3.4			3.4			3.3			3.6		4.1	
2095	Median	2.0			2.0			2.5			2.0			2.0			3.0		3.0	
2096	Standard deviation	3.00			3.21			2.56			3.68			3.22			5.82		6.36	

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PCI (patients without STEMI)
Length of Stay
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
2097	Length of stay (LOS) for pts w/out STEMI																			
2098	Pts w/out STEMI and w/ CABG or other major surgery																382		11,442	
2099	Pts w/out STEMI and w/out CABG or other major surgery										1			1			19,581		518,584	
2100	**Total LOS - all pts w/out STEMI**																			
2101	Mean										5.0			5.0			3.0		2.8	
2102	Median										5.0			5.0			2.0		1.0	
2103	Standard deviation																8.99		9.04	
2104	**Pre-procedure LOS - all pts w/out STEMI**																			
2105	Mean										0.0			0.0			1.1		0.9	
2106	Median										0.0			0.0			0.0		0.0	
2107	Standard deviation																8.25		7.60	
2108	**Post-procedure LOS - all pts w/out STEMI**																			
2109	Mean										5.0			5.0			1.9		1.9	
2110	Median										5.0			5.0			1.0		1.0	
2111	Standard deviation																3.34		4.67	
2112	**Total LOS - pts w/out STEMI and w/ CABG or other major surgery**																			
2113	Mean																7.4		10.6	
2114	Median																5.0		8.0	
2115	Standard deviation																7.75		13.08	
2116	**Pre-procedure LOS - pts w/ STEMI and w/ CABG or other major surgery**																			
2117	Mean																2.1		2.3	
2118	Median																1.0		1.0	
2119	Standard deviation																3.64		8.82	
2120	**Post-procedure LOS - pts w/out STEMI and w/ CABG or other major surgery**																			
2121	Mean																5.4		8.3	
2122	Median																4.0		6.0	
2123	Standard deviation																6.30		9.25	
2124	**Total LOS - pts w/out STEMI and w/out CABG or other major surgery**																			

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PCI (patients without STEMI)
Length of Stay
Greenwich Hospital (187346)

		2010Q3			2010Q4			2011Q1			2011Q2			My Hospital R4Q			Vol Group Pts R4Q		All Registry Pts R4Q	
Line#	Description	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	Den	%	Num	%	Num	%
2125	Mean										5.0			5.0			3.0		2.8	
2126	Median										5.0			5.0			2.0		1.0	
2127	Standard deviation																8.99		9.01	
2128	**Pre-procedure LOS - pts w/out STEMI and w/out CABG or other major surgery**																			
2129	Mean										0.0			0.0			1.1		0.9	
2130	Median										0.0			0.0			0.0		0.0	
2131	Standard deviation																8.25		7.59	
2132	**Post-procedure LOS - pts w/out STEMI and w/out CABG or other major surgery**																			
2133	Mean										5.0			5.0			1.9		1.9	
2134	Median										5.0			5.0			1.0		1.0	
2135	Standard deviation																3.33		4.64	

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ATTACHMENT XII

Greenwich Hospital's Letter of Intent to the Office of Health Care Access dated March 9, 2011 (PAMI Outcomes Limitations)

GREENWICH HOSPITAL
YALE NEW HAVEN HEALTH

March 9, 2011

Kimberly Martone
Director of Operations
Office of Health Care Access
State of Connecticut Department of Public Health
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: Docket Number 03-30148-CON, as modified by Docket Number 06-30148-MDF, Docket Number 08-30148-MDF and Docket Number 09-30148-MDF (Establishment of a Primary Interventional Cardiac Service at Greenwich Hospital)

Dear Ms. Martone:

This letter is in follow up to a phone conversation that we had earlier this year with staff of the Office of Health Care Access ("OHCA") regarding the reporting obligations of Greenwich Hospital under the above-referenced docket. Pursuant to Docket Number 09-30148-MDF, in the event that Greenwich Hospital participates in the American College of Cardiology National Cardiovascular Database (the "ACC-NCDR"), it is required to submit to OHCA, on an annual basis, any and all Executive Summary pages from the Institutional Outcomes Reports received from the ACC-NCDR. Greenwich Hospital may, however, determine not to participate in the ACC-NCDR, provided that it so notifies OHCA of its decision.

Greenwich Hospital has, since September of 2008, participated in the ACC-NCDR and has made various submissions to OHCA in compliance with Docket Number 09-30148-MDF. ACC-NCDR has, however, recently modified its database criteria to require reporting on additional measures, many of which apply to programs that provide for both primary and elective angioplasty services. In addition, the ACC-NCDR reports provide comparative benchmarking for all participating programs, and do not separately benchmark programs that provide only primary/emergency angioplasty (so-called "PAMI only programs") such as that in operation at Greenwich Hospital. As a result, the report shows an "apples to oranges" comparison of data and is not a good indication of performance for PAMI only programs such as Greenwich Hospital's program.

As a result, Greenwich Hospital's performance is benchmarked against programs that have significantly higher volumes that include elective angioplasty cases. This results in benchmarking that is skewed, can be incorrectly interpreted, and limits valid comparisons. However, at this time the ACC-NCDR data appears to be the only benchmarking data set available to hospitals. The ACC-NCDR data is not designed to be used in the public domain but rather is designed to be used as an internal document for benchmarking purposes by hospitals. The public may not be aware of the data discrepancies outlined above and, therefore, not be able to correctly either interpret the data or draw correct conclusions about a hospital's performance based on the data. Upon Greenwich Hospital's submission of the ACC-NCDR data to the Office of Health Care Access, the data becomes available to the public under Freedom of Information laws where it may be incorrectly interpreted as discussed above.

Enclosed are the Greenwich Hospital ACC-NCDR Executive Summary pages for the period from July 1, 2009 through June 30, 2010 in compliance with its obligations under Docket Number 09-30148-MDF.

<u>In light of the concerns about the data and results obtained from ACC-NCDR, Greenwich Hospital respectfully requests that the Executive Summary be qualified by the information contained in this letter and that any disclosure or other use of the Executive Summary or the data contained therein be accompanied by a copy of this letter.</u>

Thank you for your consideration. Please feel free to contact me at (203) 863-3909 should you have any questions.

Sincerely,

Nancy M. Hamson

Nancy M. Hamson
Planning Director

cc: Frank A. Corvino
Gayle Capozzalo
Nancy Levitt Rosenthal
Christopher Howes, MD
Peggy Martino

Executive Summary

CathPCI Registry®

Greenwich Hospital(187346) compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2010Q2

Section I: PCI Performance Measures

Endorsed by the National Quality Forum and appropriate for public reporting

PCI Performance Measures

Distribution of Data

10th percentile — Better → — 90th percentile

1 **PCI in-hospital risk adjusted mortality (all patients)**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
2.54		1.42	0.77

Your hospital's PCI in-hospital risk adjusted mortality rate for all patients adjusted using the NCDR® risk adjustment model. [Detail Line:1979]



Note

In-hospital risk adjusted mortality for PCI is the only performance measure in the CathPCI Registry® that has been endorsed by the National Quality Forum. Such performance measures meeting the requirement for approval are intended not only for clinical quality improvement, but also may be considered for purposes of public reporting.

The "Registry Metrics" on the subsequent pages of this report are those measures that have been developed to support self assessment and quality improvement at the provider, hospital, and/or health care system level. While these metrics have not been formally developed by the American College of Cardiology/American Heart Association Task Force for Performance Measures Task Force, they may be identified as evolving measures worthy of consideration for further development into performance measures.

Any disclosure of this data should be accompanied by the Greenwich Hospital cover letter dated March 9, 2011

Executive Summary

CathPCI Registry®

Greenwich Hospital(187346) compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2010Q2

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

PCI Process Metrics

Distribution of Data

10th percentile · Better → · 90th percentile

2 **Positive stress or imaging study prior to elective PCI**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
	50.5%	52.4%	70.9%

Proportion of elective PCI procedures (excluding patients with ACS) with an antecedent stress or imaging study with a positive result (suggestive of ischemia) or with a fractional flow reserve assessed during the procedure. [Detail Line:1515]

3 **Median time to immediate PCI for STEMI patients (in minutes)**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
76.5	67.0	64.0	52.1

Your hospital's median time from hospital arrival to immediate PCI for STEMI patients in minutes. Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1504]

4 **Proportion of STEMI patients receiving immediate PCI w/in 90"**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
88.5%	87.2%	87.9%	98.4%

Proportion of STEMI patients with a time from your hospital arrival (or subsequent ECG if ST elevation first noted on subsequent ECG) to immediate PCI <=90". Exclusions: Patients transferred in from another acute care facility; Reasons for delay does not equal none. [Detail Line:1505]

5 **Median time from ED arrival at STEMI transferring facility to ED arrival at STEMI receiving facility among transferred patients.**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
	76.0	86.0	57.5

Your hospital's median time from arrival at transferring facility to ED arrival at STEMI receiving facility among transferred patients. [Detail Line:1507]

6 **Median time from ED arrival at STEMI transferring facility to immediate PCI at STEMI receiving facility among transferred patients (in minutes)**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
	109.0	118.0	84.9

Your hospital's median time from arrival at referring facility to immediate PCI at STEMI receiving facility among transferred patients. Exclusions: Reasons for delay does not equal none. [Detail Line:1508]

7 **Median fluoro time (in minutes)**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
12.1	9.6	8.8	6.5

Inclusion criteria: PCI of one vessel/lesion. Exclusion criteria: Prior CABG, or "other" procedure during the same lab visit; PCI of >1 vessel/lesion. [Detail Line:1612]

8 **Aspirin prescribed at discharge**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
100.0%	95.3%	97.0%	99.8%

Proportion of patients (without a documented contraindication) with aspirin prescribed at discharge. [Detail Line:1941]

9 **Thienopyridine prescribed at discharge (patients with stents)**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
100.0%	97.3%	98.1%	100.0%

Proportion of patients (without a documented contraindication) with a stent implanted that had a thienopyridine prescribed at discharge. [Detail Line: 1950]

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Executive Summary

CathPCI Registry®

Greenwich Hospital(187346) compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2010Q2

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

10 **Lipid lowering agent prescribed at discharge (pts with dyslipidemia)**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
80.0%	90.8%	92.4%	98.0%

Proportion of patients (without a documented contraindication) prescribed a lipid lowering agent at discharge.
Inclusions: History of dyslipidemia [Detail Line:1948]

PCI Outcome Metrics — **Distribution of Data** (10th percentile … 90th percentile; better →)

11 **Vascular access site injury requiring treatment or major bleeding***

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
0.0%	1.9%	1.4%	0.0%

Your hospital's proportion of patients (excluding CABG or other surgery during same admission) with major access site related injury requiring treatment or major bleeding. [Detail Line:1818]

12 **Emergency CABG**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
0.0%	0.5%	0.3%	0.0%

Your hospital's proportion of patients having emergency CABG (at your facility or transferred to another facility). [Detail Line:1923]

13 **Post procedure MI (among hospitals routinely collecting post-PCI biomarkers)****

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
	3.2%	3.0%	0.7%

Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with >= 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1781]

14 **Post procedure MI (among hospitals who do not routinely collect post-PCI biomarkers)****

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
	2.0%	1.4%	0.4%

Your hospital's proportion of biomarker positive, post procedure myocardial infarction. Inclusions: Submissions with < 90% of pts with biomarkers coded; LOS>=1; Elective patients [Detail Line:1782]

15 **Acute kidney injury*****

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
3.6%	1.9%	2.2%	0.9%

Your hospital's proportion of patients who had a rise of serum creatinine of > 50% over the pre-procedure baseline (excluding patients on dialysis pre-procedure).
Inclusions: >= 90% of patients with a pre and post creatinine coded; LOS >=1 day. [Detail Line:1915]

16 **Post procedure stroke**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
0.0%	0.2%	0.2%	0.0%

Your hospital's proportion of patients with stroke post procedure. [Detail Line:1788]

17 **Composite: Death, emergency CABG, stroke or repeat target vessel revascularization**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
5.7%	2.8%	2.3%	0.8%

Your hospital's proportion of patients with death, emergency CABG, stroke or repeat target vessel revascularization post procedure up to hospital discharge.
Exclusions: Staged PCI during same admission. [Detail Line:1779]

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Executive Summary

CathPCI Registry®

Greenwich Hospital(187346) compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2010Q2

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

18 **PCI In-hospital risk adjusted mortality (patients with STEMI)**

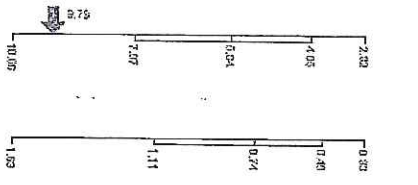
My Hospital	Vol Group R4Q	All Hosp	90th Pctl
9.78		5.51	2.82

Your hospital's PCI In-hospital risk adjusted mortality rate for patients with STEMI adjusted using the NCDR® risk adjustment model. [Detail Line:1988]

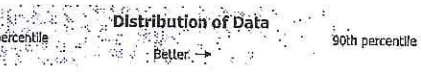
19 **PCI In-hospital risk adjusted mortality (STEMI patients excluded)**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
		0.67	0.33

Your hospital's PCI In-hospital risk adjusted mortality rate for patients with other diagnoses (not STEMI) using the NCDR® risk adjustment model. [Detail Line:1997]



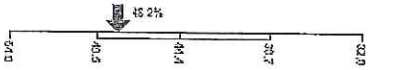
Diagnostic Cath Process Metrics



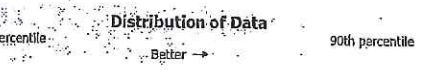
20 **Incidence of non-obstructive CAD (elective patients only)**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
48.2%	48.0%	44.2%	32.8%

Patients with an elective diagnostic cath and coronary angiography with all native coronary territories <50%
Exclusions: Patients with prior CABG, cardiac transplant evaluation; pre-op evaluation for non-cardiac surgery and diagnostic cath treatment recommendation of "other cardiac therapy without CABG or PCI". [Detail Line:1254]



Diagnostic Cath Outcomes Metrics



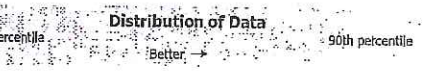
21 **Vascular access site injury requiring treatment or major bleeding***

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
0.4%	0.4%	0.3%	0.0%

Your hospital's proportion of patients with major access site related injury requiring treatment or major bleeding. [Detail Line:1303]



Utilization Metrics



22 **Median post-procedure length of stay (in days) for PCI patients with STEMI**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
2.0	3.0	3.0	1.7

Your hospital's median post-procedure length of stay (in days) for PCI patients with STEMI. [Detail Line:2053]



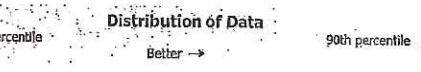
23 **Median post-procedure length of stay (in days) for PCI patients with no STEMI**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
	1.0	1.0	0.6

Your hospital's median post-procedure length of stay (in days) for PCI patients with no STEMI. [Detail Line:2092]



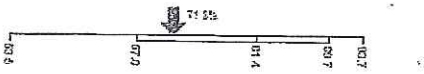
Data Quality Metrics



24 **Creatinine assessed pre and post PCI procedure**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
71.8%	78.9%	76.0%	93.7%

Proportion of PCI patients with creatinine assessed pre and post procedure. Inclusions: LOS >=1 day. [Detail Line:1914]



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Executive Summary

CathPCI Registry®

Greenwich Hospital(187346) compared to Rolling Four Quarters (R4Q) for All Hospitals ending 2010Q2

Section II: Quality Metrics – to support self assessment and quality improvement at the provider, hospital, and/or health care system level.

Test Metrics

Distribution of Data

10th percentile | 90th percentile | Better →

25 **Test Metric: Transfusion of whole blood or RBCs**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
0.0%	2.1%	2.0%	0.0%

Proportion of patients who received a transfusion of whole blood or red blood cells after a PCI procedure. Exclusions: Patients having CABG or other major surgery during the same admission. [Detail Line:1820]



26 **Test Data Quality Metric: Biomarkers assessed post-PCI for elective inpatients**

My Hospital	Vol Group R4Q	All Hosp	90th Pctl
	51.8%	45.2%	96.0%

Proportion of elective procedures with biomarkers assessed post PCI. Inclusion criteria: LOS >= 1 day and hospital status is "not outpatient". [Detail Line:1912]



Executive Summary Footnotes

*Vascular access site injury requiring treatment or major bleeding is defined as:

1.Bleeding at access site, hematoma at access site, or retroperitoneal bleed that occur within 72 hours of the procedure. To qualify, the event must be associated with a hemoglobin drop of >3 g/dL; transfusion of whole or packed red blood cells, or a procedural intervention/surgery at the bleeding site to reverse/stop or correct the bleeding. This excludes "GI", "GU" and "Other" bleeds.

2.Major access site related injury requiring treatment includes access site occlusion, peripheral embolization, dissection, pseudoaneurysm, AV fistula requiring treatment anytime from the procedure until discharge.

**Your rate of post procedure MI cannot be reported if you only collected cardiac biomarkers on <90% of your patients who were in the hospital >=1 day.

***Your rate of acute kidney injury cannot be reported if you only collected creatinine pre and post procedure on <90% of your patients who were in the hospital >=1 day.

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ATTACHMENT XIII

Internal Revenue Service
Tax Exempt Status

Internal Revenue Service

Date: October 4, 2007

GREENWICH HOSPITAL
% CHRIS CONNOR
5 PERRYRIDGE RD
GREENWICH CT 06830-4608

Department of the Treasury
P. O. Box 2508
Cincinnati, OH 45201

Person to Contact:
Mary Holland 17-57088
Customer Service Representative
Toll Free Telephone Number:
877-829-5500
Federal Identification Number:
06-0646659

Dear Sir or Madam:

This is in response to your request of October 4, 2007, regarding your organization's tax-exempt status.

In February 1972 we issued a determination letter that recognized your organization as exempt from federal income tax. Our records indicate that your organization is currently exempt under section 501(c)(3) of the Internal Revenue Code.

Our records indicate that your organization is also classified as a public charity under sections 509(a)(1) and 170(b)(1)(A)(vi) of the Internal Revenue Code.

Our records indicate that contributions to your organization are deductible under section 170 of the Code, and that you are qualified to receive tax deductible bequests, devises, transfers or gifts under section 2055, 2106 or 2522 of the Internal Revenue Code.

If you have any questions, please call us at the telephone number shown in the heading of this letter.

Sincerely,

Michele M. Sullivan

Michele M. Sullivan, Oper. Mgr.
Accounts Management Operations 1

STATE OF CONNECTICUT
DEPARTMENT OF REVENUE SERVICES
92 Farmington Avenue, Hartford, CT 06105

TAX EXEMPTION PERMIT ISSUED UNDER THE SALES AND USE TAXES ACT

In accordance with the provisions of the Sales and Use Taxes Act and the regulations thereunder, it is hereby certified that the charitable or religious organization named below is exempt from all sales and use taxes on purchases of tangible personal property made by it for the sole and exclusive purposes of the organizations.

Duplicate

Permit No. E-0933 Date Issued 4/18/91

The Greenwich Hospital Association
Perryridge Road
Greenwich, CT 06830-4697

This permit is NOT assignable or transferrable

JAMES F. KEEHAN, Commissioner of Revenue Services

-251 (Rev. 2/90)

IRS Department of the Treasury
Internal Revenue Service

OGDEN UT 84201-0038

In reply refer to: 0441981549
Nov. 01, 2010 LTR 4168C E0
06-0646652 000000 00
00029143
BODC: TE

YALE NEW HAVEN HOSPITAL
% LAURIE CAHILL
20 YORK ST
NEW HAVEN CT 06510-3220

025077

Employer Identification Number: 06-0646652
Person to Contact: Mr. Ludlow
Toll Free Telephone Number: 1-877-829-5500

Dear Taxpayer:

This is in response to your Oct. 21, 2010, request for information regarding your tax-exempt status.

Our records indicate that you were recognized as exempt under section 501(c)(3) of the Internal Revenue Code in a determination letter issued in November 1966.

Our records also indicate that you are not a private foundation within the meaning of section 509(a) of the Code because you are described in section(s) 509(a)(1) and 170(b)(1)(A)(iii).

Donors may deduct contributions to you as provided in section 170 of the Code. Bequests, legacies, devises, transfers, or gifts to you or for your use are deductible for Federal estate and gift tax purposes if they meet the applicable provisions of sections 2055, 2106, and 2522 of the Code.

Please refer to our website www.irs.gov/eo for information regarding filing requirements. Specifically, section 6033(j) of the Code provides that failure to file an annual information return for three consecutive years results in revocation of tax-exempt status as of the filing due date of the third return for organizations required to file.

If you have any questions, please call us at the telephone number shown in the heading of this letter.

Sincerely yours,

Rita A. Leete

Rita A. Leete
Accounts Management II

IRS Department of the Treasury
Internal Revenue Service

OGDEN UT 84201-0038

025077.788528.0120.003 1 MB 0.382.540

YALE NEW HAVEN HOSPITAL
% LAURIE CAHILL
20 YORK ST
NEW HAVEN CT 06510-3220

025077

CUT OUT AND RETURN THE VOUCHER AT THE BOTTOM OF THIS PAGE IF YOU ARE MAKING A PAYMENT, EVEN IF YOU ALSO HAVE AN INQUIRY.

The IRS address must appear in the window. Use for payments

0441981549

BODCD-TE

Letter Number: LTR4168C
Letter Date : 2010-11-01
Tax Period : 000000

060646652

YALE NEW HAVEN HOSPITAL
% LAURIE CAHILL
20 YORK ST
NEW HAVEN CT 06510-3220

INTERNAL REVENUE SERVICE

OGDEN UT 84201-0038

060646652 20 YALE 00 2 000000 670 00000000000

ATTACHMENT XIV

State of Connecticut Department of Public Health
Hospital License

STATE OF CONNECTICUT

Department of Public Health

License No. 0045

General Hospital

In accordance with the provisions of the General Statutes of Connecticut Section 19a-493:

Greenwich Hospital of Greenwich, CT, d/b/a Greenwich Hospital is hereby licensed to maintain and operate a General Hospital.

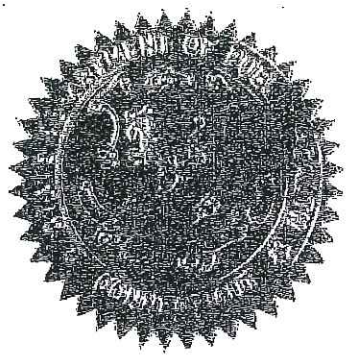
Greenwich Hospital is located at 5 Perryridge Road, Greenwich, CT 06830

The maximum number of beds shall not exceed at any time:
32 Bassinets
174 General Hospital beds

This license expires **September 30, 2013** and may be revoked for cause at any time.

Dated at Hartford, Connecticut, October 1, 2011. RENEWAL.

Satellites:
The Endoscopy Center of Greenwich Hospital, 500 West Putnam Avenue, Greenwich, CT



Jewel Mullen, MD, MPH, MPA
Commissioner

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Division of Health Systems Regulation

DEBORAH Z. WOODWORTH

JAN 30 2012

ASST. TO THE PRESIDENT

TO: Administrator
Yale-New Haven Hospital, Inc.
20 York Street
New Haven, CT 06504

FROM: Colleen Judge
Processing Technician

DATE: January 25, 2012

We are enclosing a corrected license showing a change for your facility:

( ) Change of Administrator

( ) Change of Medical Director

( ) Change of Director of Nurses

(X) Increase of bed capacity from 874 General Hospital Beds to 896 General Hospital Beds Eff: 1/11/12.

(X) Increase of bed capacity from 92 Bassinets to 112 Bassinets, effective 1/11/12.

( ) Decrease of bed capacity from _____ to _____ Eff: _____.

(X) Other change, describe below:
Added (1) Satellite – P.T. Barnum Pediatric Center located at 226 Mill Hill Avenue, Bridgeport CT 06610 effective 1/11/12.

Please note that this license is in effect only for the operation of the facility as it is now organized. This division should be notified immediately if you:

1. Change your Administrator
2. Change your Director of Nurses
3. Change your Medical Director
4. Plan to relocate
5. Plan to sell your facility
6. Plan to discontinue operation.

Any of these changes or proposed changes also require written notification to this division.

If we can be of any assistance, please do not hesitate to call the licensure office.

Phone: (860) 509-7444
Telephone Device for the Deaf (860) 509-7191
410 Capitol Avenue - MS # 12HFL
P.O. Box 340308 Hartford, CT 06134
An Equal Opportunity Employer

STATE OF CONNECTICUT

Department of Public Health

LICENSE

License No. 0044

General Hospital

In accordance with the provisions of the General Statutes of Connecticut Section 19a-493:
Yale-New Haven Hospital, Inc. of New Haven, CT d/b/a Yale-New Haven Hospital, Inc. is hereby licensed to maintain and operate a General Hospital.

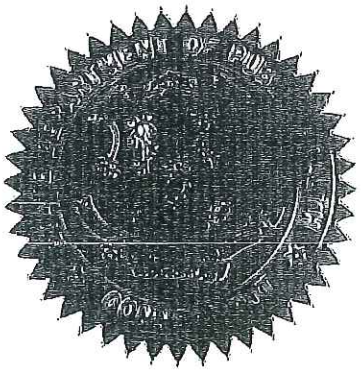
Yale-New Haven Hospital, Inc. is located at 20 York Street, New Haven, CT 06504.

The maximum number of beds shall not exceed at any time:
112 Bassinets
896 General Hospital Beds

This license expires **September 30, 2013** and may be revoked for cause at any time.
Dated at Hartford, Connecticut, October 1, 2011.

Satellites:
Hill Regional Career High School, 140 Legion Avenue, New Haven, CT
Branford High School Based Health Center, 185 East Main Street, Branford, CT
Walsh Middle School, 185 Damascus Road, Branford, CT
James Hillhouse High School Based Health Center, 480 Sherman Parkway, New Haven, CT
Weller Building, 425 George Street, New Haven, CT
Yale-New Haven Psychiatric Hospital, 184 Liberty Street, New Haven, CT
Yale-New Haven Shoreline Medical Center, 111 Goose Lane, Guilford, CT
Pediatric Dentistry Center, 860 Howard Avenue, New Haven, CT
YNHASC Temple Surgical Center, 60 Temple Street, New Haven, CT
YNHASC Women's Surgical Center, 40 Temple Street, New Haven, CT
Mauro-Sheridan School Based Health Center, 191 Fountain Street, New Haven, CT
Yale-New Haven Hospital Dental Center, 2560 Dixwell Avenue, Hamden, CT
Murphy School Based Health Center, 14 Brushy Plain Road, Branford, CT
*P.T. Barnum Pediatric Center, 226 Mill Hill Avenue, Bridgeport, CT

License Revised to Reflect:
*Increased Bassinets by 20 Beds and Increased General Beds by 22 effective 1/11/12
*Added (1) Satellite effective 1/11/12



Jewel Mullen, MD, MPH, MPA
Commissioner

ATTACHMENT XV

Financial Attachment I

12. C (i). Please provide one year of actual results and three years of projections of **Total Facility** revenue, expense and volume statistics without, incremental to and with the CON proposal in the following reporting format:

Total Facility: Description	FY 2011 Actual Results	FY 2012 Projected W/out CON	FY 2012 Projected Incremental	FY 2012 Projected With CON	FY 2013 Projected W/out CON	FY 2013 Projected Incremental	FY 2013 Projected With CON	FY 2014 Projected W/out CON	FY 2014 Projected Incremental	FY 2014 Projected With CON	FY 2015 Projected W/out CON	FY 2015 Projected Incremental	FY 2015 Projected With CON
NET PATIENT REVENUE													
Non-Government	$209,127	$226,486	$0	$226,486	$236,815	$1,520	$238,335	$247,637	$1,769	$249,406	$259,027	$2,073	$261,100
Medicare	$78,070	$81,275	$0	$81,275	$83,113	$1,364	$84,477	$84,924	$1,587	$86,511	$86,779	$1,841	$88,620
Medicaid and Other Medical Assistance	$9,813	$9,915	$0	$9,915	$9,859	$51	$9,910	$9,926	$58	$9,984	$9,959	$65	$10,024
Other Government		$0		$0	$0		$0	$0		$0	$0		$0
Total Net Patient Patient Revenue	$297,010	$317,676	$0	$317,676	$329,787	$2,935	$332,722	$342,487	$3,413	$345,900	$355,765	$3,978	$359,743
Other Operating Revenue	$18,563	$17,760	$0	$17,760	$17,938	$0	$17,938	$18,117	$0	$18,117	$18,298		$18,298
Revenue from Operations	$315,573	$335,436	$0	$335,436	$347,725	$2,935	$350,660	$360,604	$3,413	$364,017	$374,063	$3,978	$378,041
OPERATING EXPENSES													
Salaries and Fringe Benefits	$164,310	$156,863	$0	$156,863	$163,295	$518	$163,813	$170,069	$604	$170,673	$177,201	$709	$177,910
Professional / Contracted Services	$36,873	$55,158		$55,158	$50,599		$50,599	$51,834		$51,834	$53,215		$53,215
Supplies and Drugs	$49,000	$53,490	$0	$53,490	$55,410	$1,835	$57,245	$57,403	$2,140	$59,543	$59,471	$2,513	$61,984
Bad Debts	$9,270	$11,714		$11,714	$12,330		$12,330	$12,977		$12,977	$13,660		$13,660
Other Operating Expense	$27,142	$30,933		$30,933	$33,555		$33,555	$35,065		$35,065	$36,265		$36,265
Subtotal	$286,595	$308,158	$0	$308,158	$315,189	$2,353	$317,542	$327,348	$2,744	$330,092	$339,812	$3,222	$343,034
Depreciation/Amortization	$18,906	$20,177		$20,177	$22,000		$22,000	$22,000		$22,000	$22,000		$22,000
Interest Expense	$425	$404		$404	$437		$437	$419		$419	$400		$400
Lease Expense				$0			$0			$0			$0
Total Operating Expense	$305,926	$328,739	$0	$328,739	$337,626	$2,353	$339,979	$349,767	$2,744	$352,511	$362,212	$3,222	$365,434
Gain/(Loss) from Operations	$9,647	$6,697	$0	$6,697	$10,099	$582	$10,681	$10,837	$669	$11,506	$11,851	$756	$12,607
Plus: Non-Operating Revenue	($3,625)	$168		$168	$78		$78	$22		$22	$1		$1
Revenue Over/(Under) Expense	$6,022	$6,865	$0	$6,865	$10,177	$582	$10,759	$10,859	$669	$11,528	$11,852	$756	$12,608
FTEs	1613	1509	0.00	1509	1515	4.5	1520	1521	5.2	1526.2	1527	5.9	1532.9
*Volume Statistics:	38	38	0	38	38	158	196	38	179	217	38	204	242

Provide projected inpatient and/or outpatient statistics for any new services and provide actual and projected inpatient and/or outpatient statistics for any existing services which will change due to the proposal.

ATTACHMENT XVI

Financial Attachment II

12.C(ii). Please provide **three** years of projections of incremental revenue, expense and volume statistics **attributable to the proposal** in the following reporting format:

Type of Service Description	Angioplasty
Type of Unit Description:	cases
# of Months in Operation	12

FY _2013_____ **FY Projected Incremental** Total Incremental Expenses: **$2,352,146**	(1)	(2) Rate	(3) Units	(4) Gross Revenue Col. 2 * Col. 3	(5) Allowances/ Deductions	(6) Charity Care	(7) Bad Debt	(8) Net Revenue Col.4 - Col.5 -Col.6 - Col.7	(9) Operating Expenses Col. 1 Total * Col. 4 / Col. 4 Total	(10) Gain/(Loss) from Operations Col. 8 - Col. 9
Total Facility by Payer Category:										
Medicare		$93,257	64	$5,968,448	$ 4,604,359.21			$1,364,089	$952,768	$411,321
Medicaid		$93,257	9	$839,313	$788,467			$50,846	$133,983	($83,137)
CHAMPUS/TriCare		$93,257		$0	$0			$0	$0	$0
Total Governmental			73	$6,807,761	$5,392,827	$0	$0	$1,414,934	$1,086,751	$328,183
Commericial Insurers		$93,257	77	$7,180,789	$5,661,119			$1,519,670	$1,146,299	$373,371
Uninsured		$93,257	8	$746,056	$0	$746,056		$0	$119,096	($119,096)
Total NonGovernment		$93,257	85	$7,926,845	$5,661,119	$746,056	$0	$1,519,670	$1,265,395	$254,275
Total All Payers		$93,257	158	$14,734,606	$11,053,945	$746,056	$0	$2,934,605	$2,352,146	$582,459

12.C(ii). Please provide **three** years of projections of incremental revenue, expense and volume statistics **attributable to the proposal** in the following reporting format:

Type of Service Description: Angioplasty
Type of Unit Description: cases
# of Months in Operation: 12

FY 2014_____ **FY Projected Incremental** Total Incremental Expenses: **$2,744,716** **Total Facility by Payer Category:**	(1)	(2) Rate	(3) Units	(4) Gross Revenue Col. 2 * Col. 3	(5) Allowances/ Deductions	(6) Charity Care	(7) Bad Debt	(8) Net Revenue Col.4 - Col.5 -Col.6 - Col.7	(9) Operating Expenses Col. 1 Total * Col. 4 / Col. 4 Total	(10) Gain/(Loss) from Operations Col. 8 - Col. 9
Medicare		$100,252	73	$7,318,396	$ 5,731,328.64			$1,587,067	$1,119,353	$467,714
Medicaid		$100,252	10	$1,002,520	$944,895			$57,625	$153,336	($95,711)
CHAMPUS/TriCare		$100,252	0	$0	$0			$0	$0	$0
Total Governmental			83	$8,320,916	$6,676,224	$0	$0	$1,644,692	$1,272,690	$372,003
Commericial Insurers		$100,252	87	$8,721,924	$6,953,379			$1,768,545	$1,334,024	$434,521
Uninsured		$100,252	9	$902,268	$0	$902,268		$0	$138,002	($138,002)
Total NonGovernment		$100,252	96	$9,624,192	$6,953,379	$902,268	$0	$1,768,545	$1,472,026	$296,518
Total All Payers		$100,252	179	$17,945,108	$13,629,603	$902,268	$0	$3,413,237	$2,744,716	$668,521

12.C(ii). Please provide **three** years of projections of incremental revenue, expense and volume statistics **attributable to the proposal** in the following reporting format:

Type of Service Description	cases									
Type of Unit Description:										
# of Months in Operation	12									
FY _2015	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
FY Projected Incremental		Rate	Units	Gross Revenue Col. 2 * Col. 3	Allowances/ Deductions	Charity Care	Bad Debt	Net Revenue Col.4 - Col.5 -Col.6 - Col.7	Operating Expenses Col. 1 Total * Col. 4 / Col. 4 Total	Gain/(Loss) from Operations Col. 8 - Col. 9
Total Incremental Expenses:	**$3,221,898**									
Total Facility by Payer Category:										
Medicare		$107,770	83	$8,944,910	$7,104,405			$1,840,505	$1,310,870	$529,634
Medicaid		$107,770	11	$1,185,470	$1,120,814			$64,656	$173,730	($109,074)
CHAMPUS/TriCare		$107,770	0	$0	$0			$0	$0	$0
Total Governmental			94	$10,130,380	$8,225,220	$0	$0	$1,905,160	$1,484,600	$420,560
Commericial Insurers		$107,770	99	$10,669,230	$8,596,412			$2,072,818	$1,563,568	$509,250
Uninsured		$107,770	11	$1,185,470	$0	$1,185,470		$0	$173,730	($173,730)
Total NonGovernment		$107,770	110	$11,854,700	$8,596,412	$1,185,470	$0	$2,072,818	$1,737,298	$335,520
Total All Payers		$107,770	204	$21,985,080	$16,821,632	$1,185,470	$0	$3,977,978	$3,221,898	$756,080

ATTACHMENT XVII

Assumptions

Greenwich Hospital

Assumptions

Net Revenue Rate Increases	FY 2012	FY 2013	FY 2014	FY 2015
1) Government	0.0 - 2.0%	0.0 - 2.0%	0.0 - 2.0%	0.0 - 2.0%
2) Non-Government	3.0 - 5.0%	3.0 - 5.0%	3.0 - 5.0%	3.0 - 5.0%

	FY 2012	FY 2013	FY 2014	FY 2015
EXPENSES				
Salaries and Fringe Benefits	3.0%	3.0%	3.0%	3.0%
Non-Salary				
1) Medical and Surgical Supplies	3.5%	3.5%	3.5%	3.5%
2) Pharmacy and Solutions	3.0%	3.0%	3.0%	3.0%
3) Malpractice Insurance	5.0%	5.0%	5.0%	5.0%
4) Professional and Contracted Services	2.5%- 3.0%	2.5%- 3.0%	2.5%- 3.0%	2.5%- 3.0%
5) All Other Expenses	3 - 7%	3 - 7%	3 - 7%	3 - 7%

	FY 2012	FY 2013	FY 2014	FY 2015
FTEs				
1) Total estimated FTEs-before new program	1,509	1,515	1,521	1,527

Other

In Addition, Greenwich Hospital currently is responsible to pay $1.8 million for medical staff 24/7 coverage at the hospital.

There are no capital expenditures budgeted, therefore no additional depreciation expense is assumed.

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

March 15, 2012 VIA FAX & EMAIL ONLY

Ms. Jean Ahn
System Director
Yale-New Haven Hospital
Planning & Business Development Office
20 York Street (Howe 3)
New Haven, CT 06504

RE: Certificate of Need Application; Docket Number: 12-31748-CON
Yale-New Haven Hospital and Greenwich Hospital
Proposal to Establish and Operate an Elective Angioplasty
Program without Onsite Surgical Backup at Greenwich Hospital

Dear Ms. Ahn:

On February 14, 2012, the Office of Health Care Access ("OHCA") received your initial Certificate of Need ("CON") application filing on behalf of Yale-New Haven Hospital ("YNHH") and Greenwich Hospital ("Hospital") (collectively the "Applicants") for the establishment and operation of an elective angioplasty program without onsite surgical backup at the Hospital.

Note: Please be advised, administrative notice is being taken of the entire record of the prior CON application in this matter, as identified under Docket Number: 08-31210-CON. A copy of the Final Table of the Record from the aforementioned record has been attached as Exhibit I, identifying all the individual exhibits included in the record.

OHCA has reviewed the CON application and requests the following additional information pursuant to General Statutes §19a-639a(c):

Clear Public Need - pages 15 through 29

1. With respect to the state map presented on page 18 of the CON application, please provide a map legend and notes of a legible size as the application's presentation is difficult to discern.

2. With respect to the table entitled "Number of Patients Discharged Directly from GH to Another Institution for Elective Angioplasty" on page 19 of the CON application, please address the following:

    a. Identify the distance in miles and travel time between Greenwich Hospital and each of the other six hospitals to which Greenwich Hospital transfered patients requiring elective angioplasty over the last four and a quarter fiscal year period.

    b. Describe the existing physician referral patterns that have resulted in 232 patients needing elective angioplasty, not being able to access this service and being transferred to other Connecticut hospitals; 235 to Yale-New Haven Hospital and 2 to Stamford Hospital over four and a quarter fiscal year period.

3. The Applicants point out that: "... transferring patients to another facility creates an unnecessary stressful and uncomfortable situation for patients and family." Further "transferring to another facility is an increased stress for the patients and their families with regard to transportation. For some, in Greenwich Hospital's greater service area, transportation outside the service area is problematic." This being the case, why is Yale-New Haven Hospital the institution of choice when transferring a patient requiring elective angioplasty, as Stamford Hospital presents a much closer Connecticut alternative hospital site?

4. With respect to the table entitled Population Projections- Greenwich Hospital Service Area on page 27 of the CON application, please provide two tables in the same format, the first depicting the population projections for the state of Connecticut and the second depicting the population projections for the state of New York.

5. Please address the following questions regarding existing providers of elective angioplasty closest to the Hospital and its service area:

    a. Please identify all providers that currently offer Elective Angioplasty.
    b. Identify the existing providers that currently offer elective angioplasty with on-site surgical backup.
    c. What impact will this proposal have on these exiting providers financially and on their elective PCI utilization?

6. Provide a copy of the Hospital's protocols related to the proposed elective angioplasty without cardiac surgery backup. Additionally, explain any protocols that will be specific to this program.

2011 ACCF/AHA/SCAI Guidelines for Percutaneous Coronary Intervention-pages 140-230

7. In regard to the Attachment VI: 2011 ACCF/AHA/SCAI Guidelines for Percutaneous Coronary Intervention, please address the following questions:

a. How does the Hospital meet each of the criteria listed in Class IIa, IIb, III and tables 5 & 6?

b. How does the Hospital plan to meet the guidelines regarding the rapid transport to a cardiac surgery operating room in a nearby hospital and without hemodynamic support to transfer?

c. How do ACCF/AHA/SCAI guidelines define "nearby" hospital/operating room?

d. How does the Hospital's transport agreement with YNHH (where majority of the patients have been transferred in the past) relate to or meet the guidelines?

e. The Hospital's median time to immediate PCI for STEMI patients is 67.0 minutes. As reported in the ACC-NCDR report (Attachment XI of the CON application) all hospitals in the 90th percentile have a median time to immediate PCI for STEMI patients of 50.4 minutes. How does Hospital's median time relate to the ACCF/AHA/SCAI guidelines published in November 2011?

8. The Applicants state on page 15, that the Hospital "must address the cost-effectiveness of angioplasty services." Please address how this goal of the Applicants is consistent with the statement in Class III, which states that desires for personal or institutional financial gain…are not appropriate consideration(s) for initiation of a PCI program without on-site cardiac surgery.

9. The guidelines state that "[c]ompetition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interests of the community." Please address your proposal in relation to this statement while taking into consideration the existing providers of elective angioplasty in the Hospital's service area (and geographic) (in CT and NY).

10. Considering that the Hospital does not have access to a helicopter, explain how it expects to meet the protocols related to emergency transportation to a cardiac facility with a cardiac surgery program. In particular, discuss the Hospital's transfer agreement with its affiliate YNNH in this matter.

In responding to the questions contained in this letter, please repeat each question before providing your response. **Paginate and date** your response (i.e., each page in its entirety). Information filed after the initial CON application submission (i.e. completeness response letter, prefile testimony, late file submissions and the like) must be numbered sequentially from the Applicant's document preceding it. Please reference "Docket Number: 12-31748-CON." Submit one (1) original and five (5) hard copies of your response. In addition, please submit a scanned copy of your response including all attachments on CD in an Adobe format (.pdf) and in an MS Word format.

If you have any questions concerning this letter, please feel free to contact me or Steven W. Lazarus at (860) 418-7001.

Sincerely,

Jack A. Huber

Jack A. Huber
Health Care Analyst

Exhibit I

FINAL

TABLE OF THE RECORD

APPLICANTS: **Greenwich Hospital and Yale-New Haven Hospital**

DOCKET NUMBER: **08-31210-CON**

PUBLIC HEARING: **February 24, 2009 at 9:00 a.m.**

PLACE: **410 Capitol Avenue, Third Floor Hearing Room**
Hartford, Connecticut

EXHIBIT	DESCRIPTION
A	Letter from Greenwich Hospital and Yale-New Haven Hospital ("Applicants") dated July 25, 2008, enclosing Letter of Intent forms to establish and operate an elective angioplasty program at Greenwich Hospital, received by the Office of Health Care Access ("OHCA") on July 25, 2008.
B	OHCA's request for legal notification in the *Greenwich Times* and the *New Haven Register* and notification to Applicants of receipt of the Letter of Intent in the matter of the CON application under Docket Number 08 - 31210, dated July 30, 2008.
C	OHCA's letter to the Applicants dated S4eptember 12, 2008, enclosing the Certificate of Need ("CON") application forms under Docket Number 08-31210.
D	Various emails between the Applicants and OHCA beginning September 12, 2008 through November 5, 2008 in the matter of the CON application under Docket Number 08-31210.
E	Email between the Applicants and OHCA dated November 6, 2008 in the matter of the CON application under Docket Number 08-31210.
F	Letter from the Applicants dated November 21, 2008, enclosing the CON application under Docket Number 08-31210, received by OHCA on November 21, 2008.
G	OHCA's letter to the Applicants dated December 8, 2008, requesting additional information and/or clarification in the matter of the CON application under Docket Number 08-31210.

H	Applicants' responses to OHCA's letter of December 8, 2008 dated January 23, 2009, in the matter of the CON application under Docket Number 08-31210, received by OHCA on January 23, 2009.
I	OHCA's request for legal notification in the *Greenwich Times* and the *New Haven Register* and OHCA's Notice to the Applicants of the public hearing scheduled for February 24, 2009, in the matter of the CON application under Docket Number 08-31210, dated February 6, 2009.
J	OHCA's letter to the Applicants dated February 11, 2009, requesting prefile testimony and interrogatories in the matter of the CON application under Docket Number 08-31210.
K	OHCA's email to the Applicants dated February 18, 2009 confirming the hearing scheduled for February 24, 2009 in the matter of the CON application under DN 08-31210.
L	Letter from the Applicants enclosing Prefile Testimony and responses to interrogatories dated February 19, 2009 in the matter of the CON application under Docket Number 08-31210, received by OHCA on February 19, 2009.
M	Petition of The Stamford Hospital dated February 19, 2009, requesting party status or intervenor status with full procedural rights as well as prefile testimonies and a notice of appearance of Jeffers and Ireland in the matter of the CON application under Docket Number 08-31210, received by OHCA on February 19, 2009.
N	Email from The Stamford Hospital to OHCA dated February 20, 2009 attaching their request for status, prefile testimony and exhibits in the matter of the CON application under Docket Number: 08-31210, received by OHCA on February 20, 2009.
O	Email from OHCA to the Applicants dated February 20, 2009 forwarding the email OHCA received from The Stamford Hospital in the matter of the CON application under Docket Number 08-31210.
P	Facsimile letter from Wiggin and Dana LLP to OHCA dated February 20, 2009 noticing their appearance on behalf of the Applicants in the matter of the CON application under Docket Number 08-31210, received by OHCA on February 20, 2009.
Q	Facsimile letter from the Applicants to OHCA dated February 23, 2009 requesting a continuance or rescheduling of the hearing in the matter of the CON application under Docket Number 08-31210, receive by OHCA on February 23, 2009.
R	Facsimile letter from Jeffers & Ireland to OHCA dated February 22, 2009 opposing the request by the Applicants to continue or reschedule the hearing in the matter of the CON application under Docket Number 08-31210, received by OHCA on February 23, 2009.

S	Facsimile letter from the Applicants to OHCA dated February 23, 2009 objecting to the request by The Stamford Hospital for party status in the matter of the CON application under Docket Number 08-31210, received by OHCA on February 23, 2009.
T	Facsimile letter from the Applicants to OHCA dated February 23, 2009 responding to The Stamford Hospital's objection to the Applicants request for continuance or rescheduling of the hearing in the matter of the CON application under Docket Number 08-31210, received by OHCA on February 23, 2009.
U	Letter from OHCA to the Applicants dated February 23, 2009 denying their request for continuance or rescheduling of the hearing in the matter of the CON application under Docket Number 08-31210.
V	Email from Jeffers & Ireland to OHCA dated February 23, 2009 responding to Applicants letter for request of continuance in the matter of the CON application under Docket Number 08-31210, received by OHCA on February 23, 2009.
W	OHCA's Ruling on the Petition of The Stamford Hospital to be granted intervenor status in the matter of the CON application under Docket Number 08-31210, dated February 23, 2009.

Where Applicable faxes will be used as originals.

Administrative Notice is taken of the following items:

1. Greenwich Hospital, Docket Number 07-027AR, FY 2007 Annual Reporting.

2. Yale-New Haven Hospital Docket Number 07-016AR, FY 2007 Annual Reporting

3. OHCA's Administrative Folder containing Agenda, Table of the Record etc. in the matter of the CON application under Docket Number:08-31210

Late Files requested by OHCA at the Hearing on February 24, 2009:

1. Information regarding New York's elective angioplasty.

Late File from the Applicant dated March 9, 2009, received by OHCA on March 10, 2009 in the matter of the CON application under Docket Number: 08-31210.

E-mail from OHCA to the Intervenor dated March 13, 2009 confirming due date Of March 17, 2009 for responses to the Applicants late file.

Intervenors responses dated March16, 2009 received by OHCA on March 17, 2009 in the matter of the CON application under Docket Number: 08-31210.

Email from the Applicant to OHCA confirming their response date to the Intervenors response of March 20, 2009 in the matter of the CON application under Docket Number: 08-31210.

Applicants response to the intervenors responses dated March 20, 2009 in the matter of the CON application under Docket Number 08-31210, received by OHCA on March 20, 2009 (email, faxed and hardcopy received on the same day).

Letter from the Intervenor dated March 23, 2009 responding to Applicants letter dated march 20, 2009 in the matter of the CON application under Docket Number: 08-31210, received by OHCA (fax on March 23, 2009 and hardcopy on March 24, 2009)

Letter from White Plains Hospital dated March 16, 2009 in the matter of the CON application under Docket Number: 08-31210, received by OHCA on March 23, 2009

OHCA's letter dated March 26, 2009 to all parties closing the public hearing in the matter of the CON application under Docket Number: 08-31210.

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	2832
RECIPIENT ADDRESS	912036885013
DESTINATION ID	
ST. TIME	03/15 14:20
TIME USE	04'13
PAGES SENT	9
RESULT	OK

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: JEAN AHN

FAX: (203) 688-5013

AGENCY: YALE-NEW HAVEN HOSPITAL

FROM: JACK HUBER

DATE: 3/15/2012 **Time:** 2~18 pm

NUMBER OF PAGES: 9
(including transmittal sheet)

Comments: Transmitted: Yale-New Haven Hospital & Greenwich Hospital
Proposal to Establish an Elective Angioplasty Program at Greenwich Hospital
Completeness Letter DN: 12-31748-CON

PLEASE PHONE Jack A. Huber at (860) 418-7069
IF THERE ARE ANY TRANSMISSION PROBLEMS.

YALE NEW HAVEN HEALTH

May 14, 2012

RECEIVED
MAY 14 2012

Ms. Kimberly Martone, Director of Operations
Office of Health Care Access
410 Capital Avenue, MS #13HCA
P. O. Box 340308
Hartford, CT 06106

RE: Certificate of Need Application; Docket Number: 12-31748-CON
Yale-New Haven Hospital and Greenwich Hospital
Proposal to Establish and Operate an Elective Angioplasty
Program without Onsite Surgical Backup at Greenwich Hospital

Dear Director Martone,

Enclosed please find Greenwich and Yale-New Haven Hospitals' responses to the completeness questions posed by the Office of Health Care Access (OHCA) on March 15, 2012.

Please do not hesitate to contact me at (203) 688-2609 with any questions.

Thank you for your time and consideration of this project.

Sincerely,

Jean Ahn
System Director, Planning & Business Development

Enclosures

cc: William Aseltyne, Esq.

789 Howard Avenue
New Haven, CT 06519

Greenwich Hospital
Yale-New Haven Hospital

Certificate of Need Application: Proposal to Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital
Docket Number: 12-31748-CON

Responses to Completeness Questions
Table of Contents

	Description	Page Number
	Completeness Question Responses	584-602
Attachments		
I	Map from page 18 of CON Application	603
II	Draft Greenwich Hospital Protocols related to Elective Angioplasty without Cardiac Surgery Backup	604-610
III	*New England Journal of Medicine* Article: "Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery"	611-622
IV	Greenwich Hospital-Yale-New Haven Hospital Transfer Protocol and Agreement	623-626

Greenwich Hospital
Yale-New Haven Hospital

Certificate of Need Application: Proposal to Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital
Docket Number: 12-31748-CON

Responses to Completeness Questions

Clear Public Need – pages 15 through 29

1. With respect to the state map presented on page 18 of the CON application, please provide a map legend and notes of a legible size as the applicant's presentation is difficult to discern.
   Response
   A large size map along with a legend and notes has been provided in Attachment I.

2. With respect to the table entitled "Number of Patients Discharged Directly from GH to Another Institution for Elective Angioplasty" on page 19 of the CON application, please address the following:
   a. Identify the distance in miles and travel time between Greenwich Hospital and each of the other six hospitals to which Greenwich Hospital transferred patients requiring elective angioplasty over the last four and a quarter fiscal year period.
   Response
   The table below summarizes the distance in miles and travel time between Greenwich Hospital and each of the other six hospitals to which Greenwich Hospital transferred patients requiring elective angioplasty.

Hospital	Address	Distance from GH (Miles)	Travel Time from GH (Minutes)
CT Hospitals:			
Stamford Hospital	**30 Shelburne Road, Stamford, CT**	**6 miles**	**13 minutes**
West Haven VA	**950 Campbell Avenue, West Haven, CT**	**44 miles**	**56 minutes**
Yale-New Haven Hospital	**20 York Street, New Haven, CT**	**46 miles**	**60 minutes**
NY Hospitals:			
Westchester Medical Center	**100 Woods Road, Valhalla, NY**	**15 miles**	**24 minutes**
NY Presbyterian –	**525 E. 68th**	**30 miles**	**45 minutes**

Hospital	Address	Distance from GH (Miles)	Travel Time from GH (Minutes)
Weill Cornell	**Street, New York, NY**		
NY Presbyterian – Columbia	**630 West 168th Street, New York, NY**	**27 miles**	**39 minutes**

Source: MapQuest

b. Describe the existing referral patterns that have resulted in 232 patients needing elective angioplasty, not being able to access this service and being transferred to other Connecticut hospitals; 235 to Yale-New Haven Hospital and 2 to Stamford Hospital over four and a quarter fiscal year period.

Response

Greenwich Hospital is a member of the Yale New Haven Health System and has been for more than twelve years. The medical staff at Greenwich Hospital has developed long-standing referral relationships with the physician specialists at the Yale School of Medicine (YSM), who practice at Yale-New Haven Hospital. In the area of cardiology, Yale School of Medicine faculty physicians have been providing clinical oversight and coverage at Greenwich Hospital since the primary angioplasty service began in February 2005. Dr. Christopher Howes and Dr. John Setaro, both Yale School of Medicine physicians, have practices at Greenwich Hospital. Each physician is at Greenwich Hospital for three, 12-hour days each week. Drs. Howes and Setaro are interventional cardiologists and perform the majority of emergency angioplasty procedures at Greenwich Hospital. Drs. Howes and Setaro and their colleagues from YSM have strong referral relationships with internists and medical cardiologists in the Greenwich Hospital service area.

In regard to the two cases transferred to Stamford Hospital, the two patients were transferred due to patient/family and physician preference reasons.

3. The Applicants point out that "…transferring patients to another facility creates an unnecessary stressful and uncomfortable situation for patients and family." Further "transferring to another facility is an increased stress for the patients and their families with regard to transportation. For some, in Greenwich Hospital's greater service area, transportation outside the service area is problematic." This being the case, why is Yale-New Haven Hospital the institution of choice when transferring a patient requiring elective angioplasty, as Stamford Hospital presents a much closer Connecticut alternative hospital site?

Response

As described in response to question 2, Yale School of Medicine physicians are providing the emergency angioplasty services at Greenwich Hospital and have strong referral relationships with internists and medical cardiologists in the

Greenwich Hospital service area. In cases where a patient must be transferred, the decision regarding which hospital is based on a number of factors including the reasons for transfer, the Greenwich Hospital physician's suggested referral, the patient's preferred choice, and the patient's clinical condition. In the overwhelming majority of cases, patients prefer transfer to Yale-New Haven Hospital so that their care may continue to be provided by YSM interventional cardiologists. YNHH's cardiac catheterization laboratory has excellent outcomes and a proven track record of quality. The familiarity, trust and respect that exist between GH and the YSM physicians are the foundation of the existing referral patterns. In addition, because both hospitals are part of the same health system and share information technology systems, angiograms done at GH can immediately be viewed at YNHH which aids in the preparation and initiation of treatment for the patient being transferred.

In addition to the close collaboration between cardiologists at YNHH and Greenwich Hospital, a similar relationship exists between the cardiologists and the cardiac surgeons at YNHH. YNHH's cardiac surgery program offers the latest surgical techniques and equipment and routinely performs many complex surgeries such as Transplants, Left Ventricular Assistive Devices (LVAD), Hypothermic Circulatory Arrest, and Transcatheter Aortic Valve Implantation (TAVI). The YNHH cardiac surgery program capabilities are often preferred by patients and referring physicians and these requests are pursued in cases where transport to YNHH can be done safely. If transport cannot be completed safely, patients would be transported to the closest appropriate facility.

The cardiac care offered by both Greenwich Hospital and YNHH provides a comprehensive cardiac network of services for Greenwich Hospital's service area population. The lack of elective angioplasty at Greenwich Hospital results in disruptive care for patients. Under the current arrangement, Greenwich Hospital patients have to be transferred to other hospitals for elective angioplasty procedures even though experienced YSM interventional cardiologists and catheterization lab support staff are onsite and available 24 hours every day to provide the needed care at Greenwich Hospital. The vast majority of patients are transferred to Yale-New Haven Hospital, where they are treated by the same physicians from whom they would have received the same care at Greenwich Hospital if Greenwich Hospital was approved to provide elective angioplasty.

The physicians at Stamford Hospital are not members of YSM and generally do not have existing referral relationships with most of the Greenwich Hospital physicians. The medical staffs at the two hospitals are quite distinct and there are only a handful of physicians who treat patients at both locations. Patient town of origin data also differs between Stamford and Greenwich Hospitals. According to the CHIME data, the majority (~73%) of patients treated at Stamford Hospital's cardiac catheterization laboratory live in the cities of Stamford and Norwalk and the town of Darien, whereas, Greenwich Hospital's patient population is primarily from Greenwich and Westchester County towns.

It is important to note that the stress and in some cases, transportation difficulties, result due to the transfer itself, not necessarily the distance or time in an ambulance or the distance between Greenwich Hospital and the referral hospital. It is disruptive for patients to be admitted to one institution and then have to be transferred. Of course, there are times when this cannot be avoided, but in the case of elective angioplasty, there are approximately 50 patients each year who would not have to be transferred to another hospital if Greenwich Hospital could perform elective angioplasty. In addition to the patients who are transferred for PCI, there is another subset of patients (approximately 10-20) who do not receive a PCI but who are transferred for an invasive Fractional Flow Reserve (FFR) or Intravascular Ultrasound (IVUS) to further clarify their anatomy. The Hospital has the latest equipment, experienced staff, expert physicians and modern infrastructure to perform emergency angioplasty and these resources are underutilized. The costs, stress and disruptions to care that result in having to transfer these patients now can be avoided.

4. With respect to the table entitled Population Projections – Greenwich Hospital Service Area on page 27 of the CON application, please provide two tables in the same format, the first depicting the population projections for the state of Connecticut and the second depicting the population projections for the state of New York

Response

Two tables are provided below depicting population projections for Connecticut and New York service area towns as requested.

The Applicants wish to emphasize that as a hospital located on the border of Connecticut and New York (Westchester County), a significant portion of the Hospital's volume (>40%) comes from residents of Westchester County, New York. The Hospital's service area is inclusive of the Connecticut and New York towns as outlined in the CON application on page 24. Greenwich Hospital's unique location on the border and its significant role in providing health care services to many Westchester County residents provides a significant benefit to the State of Connecticut in terms of attracting New York residents and health care revenues to the State.

Population to Be Served - CT					
				% Change	
Area & Age Cohort	2000	2011	2016	2000 - 2011	2011 - 2016
CT Service Area Towns					
0-44	220,400	212,035	206,731	-3.8%	-2.5%
45-54	50,513	61,303	57,366	21.4%	-6.4%
55-64	34,245	45,513	52,234	32.9%	14.8%
65-74	25,419	27,515	32,866	8.2%	19.4%
75-84	16,806	16,619	16,574	-1.1%	-0.3%
85+	6,346	7,863	8,590	23.9%	9.2%
Total	**353,729**	**370,848**	**374,361**	**4.8%**	**0.9%**
% 45+	37.7%	42.8%	44.8%		
% 65+	13.7%	14.0%	15.5%		

Population to Be Served - NY					
NY Service Area Towns					
0-44	265,678	251,755	247,369	-5.2%	-1.7%
45-54	60,434	70,382	66,305	16.5%	-5.8%
55-64	41,106	55,530	63,165	35.1%	13.7%
65-74	30,793	32,697	39,550	6.2%	21.0%
75-84	20,403	20,685	20,512	1.4%	-0.8%
85+	8,295	10,311	11,293	24.3%	9.5%
Total	**426,709**	**441,360**	**448,194**	**3.4%**	**1.5%**
% 45+	37.7%	43.0%	44.8%		
% 65+	13.9%	14.4%	15.9%		

5. Please address the following questions regarding existing providers of elective angioplasty closest to the Hospital and its service area:
   a. Please identify all providers that currently offer Elective Angioplasty.

      Response

      The following providers currently offer elective angioplasty in GH's service area:

      Connecticut service area towns:
      Stamford Hospital
      Stamford, CT

      New York service area towns:
      White Plains Hospital
      White Plains, NY

   b. Identify the existing providers that currently offer elective angioplasty with on-site surgical backup.

Response
The following providers offer elective angioplasty with on-site surgical backup in GH's service area:

Connecticut service area towns:
Stamford Hospital
Stamford, CT

New York service area towns:
None

c. What impact will this proposal have on these existing providers financially and on their elective PCI utilization?
Response
As stated in the Applicants' original CON submission on page 28, the vast majority of patients who must be transferred from Greenwich Hospital to another hospital for elective angioplasty are transferred to Yale-New Haven Hospital. The absence of GH's transfer cases at YNHH will not negatively impact YNHH since its cardiac catheterization laboratories perform a large number of procedures and the volume from GH is a small percentage of YNHH's overall volume.

The additional volume proposed is expected to result from physicians who currently bypass GH and send patients to New York hospitals. Greenwich Hospital physicians interviewed indicated they generally do not refer patients to Stamford Hospital and therefore the proposed program is not expected to have a negative impact on Stamford Hospital elective angioplasty volume.

6. Provide a copy of the Hospital's protocols related to the proposed elective angioplasty without cardiac surgery backup. Additionally, explain any protocols that will be specific to this program.
Response
A copy of the draft protocols related to the proposed elective angioplasty without cardiac surgery backup is included as Attachment II.

2011 ACCF/AHA/SCAI Guidelines for Percutaneous

Coronary Intervention-pages 140-230

7. In regard to the Attachment VI: 2011 ACCF/AHA/SCAI Guidelines for Percutaneous Coronary Intervention, please address the following questions:

a. How does the Hospital meet each of the criteria listed in Class IIa, IIb, III and tables 5 & 6?

Response

In regard to Class III, as stated in response to question 7.c. below, since elective angioplasty without cardiac surgery back-up is classified as a Class IIb recommendation in the Guidelines, the Class III references are not applicable. Please refer to page 144 of the original CON application for a summary table of Classification of Recommendations and Level of Evidence, as included in the 2011 ACCF/AHA/SCAI Guidelines for PCI.

With regard to the 2011 PCI Guidelines, section 4.8, PCI in Hospital Without On-Site Surgical backup: Primary PCI for MI has a Class IIa recommendation, and this program has been in place at GH since 2005 and has worked well with an excellent record in all respects. However, the proposed elective PCI program without cardiac surgery backup is a Class IIb recommendation and therefore the Class IIa recommendation does not apply. In addition, the majority of available literature supports this recommendation, including a recent publication in the March 2012 issue of the *New England Journal of Medicine* entitled "Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery" by Aversano, Lemmon & Liu (please see Attachment III).

Through its emergency PCI program, GH provides highly experienced operators (10 participating YSM Senior Interventional Cardiologists with 156 years combined experience as Attending Operators, performing nearly 50,000 PCIs at a high volume tertiary academic medical center since the inception of the YSM program in 1985). Success and complication rates of the YSM interventional cardiologists are equal or superior to those of national registries.

The relevant criteria for the proposed program are listed in Tables 5 and 6 and represent recommendations from an expert consensus document from the Society for Cardiovascular Angiography and Interventions (2007). These recommendations have been incorporated into the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention.

The table below summarizes each of the items listed in Tables 5 and 6 and Greenwich Hospital's status.

Table 5.	
SCAI Expert Consensus Document Personnel and Facility Requirements for PCI Programs Without On-Site Surgical Backup	**Description of Greenwich Hospital's Compliance**

Table 5.	
SCAI Expert Consensus Document Personnel and Facility Requirements for PCI Programs Without On-Site Surgical Backup	**Description of Greenwich Hospital's Compliance**
Experienced nursing and technical laboratory staff with training in interventional laboratories. Personnel must be comfortable treating acutely ill patients with hemodynamic and electrical instability.	Greenwich Hospital's Cath Lab staff consists of highly trained and experienced nurses and technologists. They are dedicated to the cath lab and cardiology department and are skilled and comfortable treating acutely ill patients with hemodynamic and electrical instability. Greenwich Hospital already cares for the most acutely ill of these patients through its established PAMI program. Nurses and technicians are on a rotation to spend time at Yale-New Haven Hospital's Cath Lab where they receive further training, education and experience.
On-call schedule with operation of laboratory 24 hours per day, 365 days per year.	Greenwich Hospital has an agreement with the Yale School of Medicine (YSM) to provide 24/7, 365 coverage. Greenwich has 2 YSM physicians who primarily practice and cover call at Greenwich Hospital. They are covered by additional YSM Interventional Cardiologists. There will be no need to add staff to this on-call schedule.
Experienced coronary care unit nursing staff comfortable with invasive hemodynamic monitoring, operation of temporary pacemaker, and management of IABP. Personnel capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.	Greenwich Hospital has experienced intensive care unit nursing staff that already cares for PAMI patients. Greenwich Hospital has on-site personnel capable of endotracheal intubation and ventilator management. If patients require transfer, ALS paramedics who are capable of endotracheal intubation and ventilator management provide care during transport.
Full support from hospital administration in fulfilling the institutional requirements, including appropriate support services (e.g.	Greenwich Hospital's Administration is in full support of the program. The needed resources are in place, including 24 hour

Table 5.	
SCAI Expert Consensus Document Personnel and Facility Requirements for PCI Programs Without On-Site Surgical Backup	**Description of Greenwich Hospital's Compliance**
respiratory care, blood bank).	respiratory care and a full service blood bank.
Written agreements for emergency transfer of patients to a facility with cardiac surgery. Transport protocols should be developed and tested a minimum of 2 times per year.	Please see Attachment IV for written transfer agreement between Yale-New Haven and Greenwich Hospitals.
Well-equipped and maintained cardiac catheterization laboratory with high resolution digital imaging capability and IABP equipment compatible with transport vehicles. The capability for real-time transfer of images and hemodynamic data (via T-1 transmission line) as well as audio and video images to review terminals for consultation at the facility providing surgical backup is ideal.	Greenwich Hospital has a state-of-the-art Cath Lab which has all of the equipment and capabilities mentioned including the ability to directly transfer images to tertiary care centers.
Appropriate inventory of interventional equipment, including guide catheters, balloons, and stents in multiple sizes; thrombectomy and distal protection devices; covered stents, temporary pacemakers; and pericardiocentesis trays. Pressure wire device and IVUS equipment are optimal but not mandatory. Rotational or other artherectomy devices should be used cautiously in these facilities because of the greater risk of perforation.	Greenwich Hospital currently has a complete inventory of all of these items. Greenwich Hospitals does not use and does not plan to use at this time, rotational or other atherectomy devices due to the risk of perforation.
Meticulous clinical and angiographic selection criteria for PCI (Tables 6 and 7)	Greenwich Hospital would plan to operate an Elective Angioplasty program with the appropriate level of conservative case selection. The program would adhere to all standards in table 6 & 7.
Performance of primary PCI as the treatment of first choice for STEMI to ensure streamlined care paths and increased case volumes. Door to	Each of these items is already in place through Greenwich Hospital's established PAMI program. Door to balloon times are

Table 5.	
SCAI Expert Consensus Document Personnel and Facility Requirements for PCI Programs Without On-Site Surgical Backup	**Description of Greenwich Hospital's Compliance**
balloon times should be tracked, and <90 min outlier cases should be carefully reviewed for process improvement opportunities. On-site rigorous data collection, outcomes analysis, benchmarking, quality improvement, and formalized periodic case review.	tracked and all cases are reviewed via a PCI report card (including outlier and non-outlier cases). Onsite data collection exists and GH examines benchmarks and outcomes via the ACC NCDR Cath PCI registry. Formalized case review is conducted via a regularly scheduled Cath Conference session.
Participation in a national data registry where available, such as the ACC NCDR in the United States.	Greenwich Hospital participates in the Cath PCI registry through ACC NCDR.

Table 6. Interventional cardiologists establish a working relationship with cardiac surgeons at the receiving facility	
SCAI Expert Consensus Document Requirements for Off-Site Surgical Backup	**Description of Greenwich Hospital's Compliance**
1. Cardiac Surgeon must have privileges at the referring facility to allow review of treatment options as time allows.	Currently there are 3 cardiac surgeons with privileges @ Greenwich Hospital. All of these surgeons are from YNHH where the majority of surgical candidates are transferred. GH will approach cardiac surgeons from other cardiac surgery facilities in order to provide them with privileges in the event of transfer.
2. Cardiac Surgeon and receiving hospital agree to provide cardiac surgical backup for urgent cases at all hours and for elective cases at mutually agreed hours.	YNHH currently provides cardiac surgical backup services for urgent cases from Greenwich Hospital's established PAMI program. These services are available 24 hours per day, 7 days per week and 52 weeks per year.

Table 6. Interventional cardiologists establish a working relationship with cardiac surgeons at the receiving facility	
SCAI Expert Consensus Document Requirements for Off-Site Surgical Backup	**Description of Greenwich Hospital's Compliance**
3. Surgeon and receiving facility ensure that patients will be accepted based on medical condition, capacity of surgeon to provide services at the time of request, and availability of resources. If this cannot be ensured before the start of an elective procedure, the case should be done at this time.	The current agreement with YNHH and Greenwich Hospital (PAMI program) ensures that any patient in need of urgent cardiac surgery will be accepted. Agreements with Westchester Medical Center and Stamford Hospital are being pursued.
4. Interventional cardiologists must review with surgeons the immediate needs and status of any patient transferred for urgent surgery.	This process already occurs in Greenwich Hospital's established PAMI program.
5. Hospital administrations from both facilities endorse transfer agreement.	As evidenced by the agreement between YNHH and Greenwich Hospital (included in Attachment IV), administration from both facilities endorse the agreement.
6. Transferring and receiving facilities establish a rigorous protocol for rapid transfer of patients, including the proper personnel, with appropriate experience.	These protocols are in place between YNHH and Greenwich Hospital for its established PAMI program.
7. A transport provider is available to begin transport within 20 minutes of the request and provide vehicle/helicopter with necessary life sustaining equipment, including IABP and monitoring capability.	Access Ambulance has committed to transport within 20 minutes.
8. Transferring physician obtains consent for surgery from patient or appropriate surrogate.	If given approval to perform Elective Angioplasty, GH will fully comply with this standard.

Table 6. Interventional cardiologists establish a working relationship with cardiac surgeons at the receiving facility	
SCAI Expert Consensus Document Requirements for Off-Site Surgical Backup	**Description of Greenwich Hospital's Compliance**
9. Initial informed consent for PCI discloses that the procedure is being done without on-site surgical backup and acknowledges the possibility of risks related to transfer. The consent process should include the risk of urgent surgery (approximately 0.3%) and state that a written plan for transfer exists.	If given approval to perform Elective Angioplasty, GH will fully comply with this standard. Greenwich Hospital will provide informed consent which discloses the procedure is done without onsite surgical backup and the possibility of risks related to transfer. The consent process will also include the risk of urgent surgery (~0.3%) and state that a written plan for transfer exists.
10. As part of the continuous quality improvement program, a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of any improvement opportunities.	If given approval to perform Elective Angioplasty, GH will fully comply with this standard.

b. How does the Hospital plan to meet the guidelines regarding the rapid transport to a cardiac surgery operating room in a nearby hospital and without hemodynamic support to transfer?

Response

Greenwich Hospital has been successfully transferring critically ill patients for the past five years. The institution has the ability to utilize Intra-Aortic Balloon Pumps and has successfully utilized them when appropriate. The Hospital has an agreement with Access Ambulance to rapidly transport patients within 20 minutes who are in need of additional care. The process used is efficient and safe and there has not been a fatality to date during transport.

c. How do ACCF/AHA/SCAI guidelines define "nearby" hospital/operating room?

Response

The guidelines do not define "nearby". The use of the term "nearby" pertains to Class III recommendations. Elective angioplasty without cardiac

surgery back-up is classified as a Class IIb recommendation in these guidelines and therefore the Class III references are not applicable.

d. How does the Hospital's transport agreement with YNHH (where majority of the patients have been transferred in the past) relate to or meet the guidelines?
Response
Agreement (see Attachment IV) indicates that patients requiring transport can go to the nearest cardiac surgery facility or to YNHH or Bridgeport Hospital. As previously noted, Greenwich Hospital will transfer patients to other cardiac surgery programs, such as Westchester Medical Center and Stamford Hospital if requested by a patient or family member or if there is an imminent crisis and the patient must be sent to the closest cardiac surgery facility.

e. The Hospital's median time to immediate PCI for STEMI patients is 67.0 minutes. As reported in the ACC-NCDR report (Attachment XI of the CON application) all hospitals in the 90th percentile have a median time to immediate PCI for STEMI patients of 50.4 minutes. How does Hospital's median time relate to the ACCF/AHA/SCAI guidelines published in November 2011?
Response
Greenwich Hospital's median time of 67 minutes to immediate PCI for STEMI patients meets the ACCF/AHA/SCAI guidelines which specify that for primary PCI in patients with STEMI who present to a hospital with PCI capability, the PCI should be performed within 90 minutes of first medical contact (also referred to as door-to-balloon time).

8. The Applicants state on page 15, that the Hospital "must address the cost-effectiveness of angioplasty services." Please address how this goal of the Applicants is consistent with the statement in Class III, which states that desires for personal or institutional financial gain…are not appropriate consideration(s) for initiation of a PCI program without on-site cardiac surgery.
Response
As noted previously, elective angioplasty without cardiac surgery back-up has received a Class IIb recommendation in the 2011 ACCF/AHA/SCAI guidelines. Therefore, the discussion included above under Class III is not relevant. However, it should be stressed that Greenwich Hospital's financial considerations for the proposed program address cost-effectiveness and not institutional financial gain. The current primary angioplasty program is extremely costly to operate. GH has been committed to providing this life-saving program to the community despite the associated cost and operating losses. However, as hospitals continue to see reimbursement cuts and rising costs, the primary angioplasty program may be at risk for continued operation. By offering an elective angioplasty program along with the primary program, the additional case volume and associated revenues will help to offset the significant fixed costs which exist for the primary program alone and would help to fortify the primary PCI program and ensure its continued

survival for this necessary service needed by the community served by Greenwich Hospital.

Although financial viability is always of concern, the motivation of the elective program is not to establish the proposed program for reasons of institutional financial gain, prestige, market share, or to intensify competition for patients with respect to other institutions (as noted in Class III in the guidelines). The impetus of the program is to provide superior care to the Greenwich community patients by maximizing continuity of care and lessening fear, and anxiety to patients and their families inherent with a transfer process whether the patients are transferred 5 miles or 500 miles as the transfer is disruptive to care and traumatic to patients. The current population served through Greenwich Hospital's primary angioplasty program is limited to patients that present on an emergent basis with ST segment elevation MI or new onset left bundle branch block. This proposal would provide local access to patients requiring interventional cardiology services on an elective and urgent basis as well as the emergent patients who currently have access to these services. The facility, physicians, staff and equipment required to provide elective angioplasty services are already in place at Greenwich Hospital. The current practice of transferring patients who require elective angioplasty has potential negative implications to patient care quality and safety. As well, the majority of these patients are transferred to Yale-New Haven Hospital, where they are treated by the same physicians from whom they would have received the same care at Greenwich Hospital if Greenwich Hospital was approved to provide elective angioplasty.

It is also important to note the financial (as well as emotional) cost to the patients and their families, as well as the added costs to the overall healthcare system by requiring transfer to another facility. As stated above, the Hospital already has the latest equipment, experienced staff, expert physicians and modern infrastructure to perform emergency angioplasty, and therefore, there would be no additional costs for the proposed program. On the other hand, patient transfer requires patients to undergo two procedures rather than one, which increases the cost of care, which could be avoided with the proposed program. Specifically, service area residents who obtain a cardiac catheterization at Greenwich Hospital and require a subsequent angioplasty procedure must undergo two invasive procedures at two institutions. This practice increases the costs of care to patients and payers and ultimately to the health care system as a whole. Patients have to incur the additional out of pocket costs for the second procedure as well as additional transportation costs for themselves and possibly also family members. As an example, the cost of a helicopter ride, if one is needed, is approximately $6,500 plus $100 per mile. An ambulance ride costs $1,177. Additionally there are staff costs related to arranging the patient transfer. With patients receiving two procedures at two separate institutions, payers have increased expenses for the care provided to patients. On average, the hospital facility fee (non-inclusive of the physician fee) is approximately $7,000 per procedure. Aversano, Lemmon & Liu (2012) in their recent NEJM publication on the results of the CPORT-E trial showed that the number of catheterization visits required to complete PCI is 1.73 for programs with on-site

surgery vs. 1.28 for programs without. The study states this higher number is probably due to the impact of cases that had to be transferred to a site with cardiac surgery and thus required an additional cardiac catheterization. Eliminating a second invasive cardiac procedure would improve the cost-effectiveness of angioplasty services for service area residents. In addition, through the fuller use of its existing angioplasty infrastructure at Greenwich Hospital, including physicians and staff, more efficient care and enhanced patient quality and safety will result.

9. The guidelines state that "competition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interests of the community." Please address your proposal in relation to this statement while taking into consideration the existing providers of elective angioplasty in the Hospital's service area (and geographic) (in CT and NY).

Response

As noted in the response to question 8, elective angioplasty without cardiac surgery back-up has received a Class IIb recommendation in the 2011 ACCF/AHA/SCAI guidelines. The reference noted above is contained under Class III and therefore is not relevant. The only programs in the same geographic area are Stamford Hospital and White Plains Hospital. As has been already discussed, GH's referring physician base differs from Stamford Hospital and projected elective angioplasty volume will come from cases now sent to Yale-New Haven Hospital or to New York hospitals.

The motivation of the program is to provide superior care to the Greenwich community patients by maximizing continuity of care and lessening fear and anxiety to patients and their families inherent with a transfer process whether they are transferred 5 miles or 500 miles as the transfer is disruptive to care and traumatic to patients. The clinical and operational infrastructure to provide a high quality full-service cardiac program already exists at Greenwich Hospital, and will be enhanced by the ability to offer elective angioplasties. Greenwich Hospital is already performing angioplasty on more acutely ill patients through its primary angioplasty program and the staff and physicians are well prepared to perform elective angioplasty for less acute patients.

10. Considering that the Hospital does not have access to a helicopter, explain how it expects to meet the protocols related to emergency transportation to a cardiac facility with a cardiac surgery program. In particular, discuss the Hospital's transfer agreement with its affiliate YNHH in this matter.

Response

Greenwich Hospital currently has a land and air transport systems in place for any of its patients requiring emergency transport to another hospital. GH does have access to a medical helicopter located at Westchester Airport which is approximately 7 miles (15 minutes) from GH. Patients are transported via ambulance to the medical helicopter when required. In cases where air transport is not possible, such as inclement weather, land transportation is provided by a local ambulance service that offers advanced life support and IABP capabilities. This

existing land and air transport system will also apply to the elective angioplasty population in need of transport.

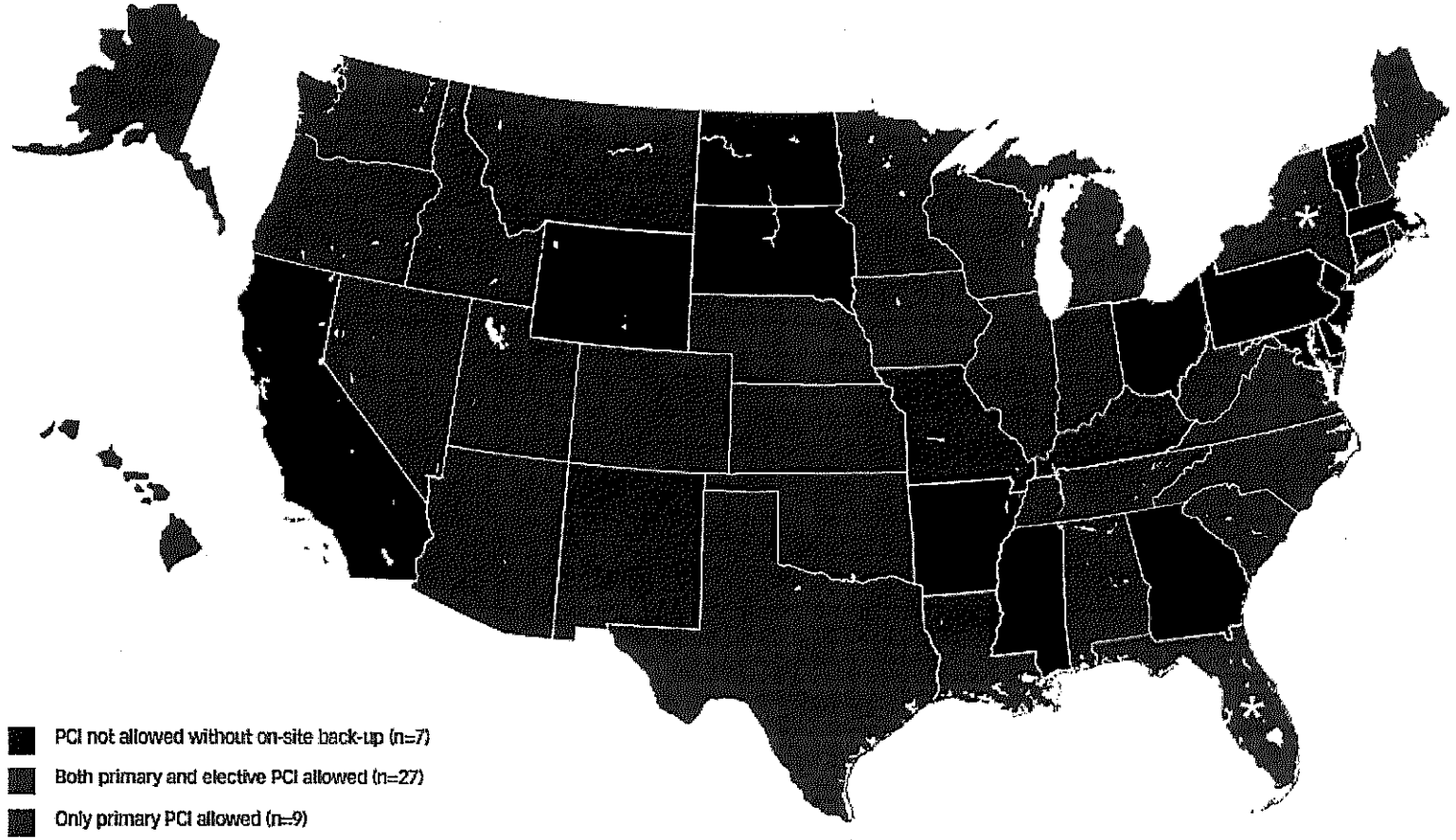
Section A. 3. of the transfer agreement with YNHH is copied below (see Attachment IV), which states that Greenwich Hospital physicians in consultation with YNHH's receiving physician, shall determine selection of the most appropriate transportation:

Greenwich Hospital's transferring physician shall provide necessary medical treatment within the capabilities of the staff and facilities available at Greenwich Hospital in order to minimize the risks of transfer to the patient's health, and in consultation with YNHH's receiving physician, shall determine the selection of appropriate transportation and the level of care required for appropriate management of the patient *en route* to YNHH.

Attachment I

Large Map (from page 18 of CON Application DN 12-31748-CON)

Figure 1: Status of Percutaneous Coronary Intervention without On-site Cardiac Surgical Back-up in the US



There are now only seven states (Arkansas, Delaware, Mississippi, North Dakota, South Dakota, Vermont, and Wyoming) where neither primary nor elective percutaneous coronary intervention (PCI) is allowed without on-site surgery. Legislation is pending in California to allow a carefully monitored demonstration project of elective PCI without on-site back-up. Primary PCI without on-site surgery is allowed in Washington, but not elective PCI. However, Washington has a liberal definition of emergency PCI such that patients with acute coronary syndromes and non-ST-segment elevation myocardial infarction who have stabilized are allowed to undergo PCI at facilities without on-site surgery. Florida and New York both have rule changes pending to allow both primary and elective PCI at selected facilities without on-site surgery. Modified from Dehmer et al., 2007.[19]

Attachment II

Draft Greenwich Hospital Protocols related to Elective Angioplasty without Cardiac Surgery Backup

Greenwich Hospital Greenwich, Connecticut 06830	PATIENT CARE SERVICES POLICY AND PROCEDURE		
Title: **PERCUTANEOUS CORONARY INTERVENTION (ANGIOPLASTY)**			Policy #: CC-13
Date Issued: : 8/2004	Date Reviewed/Revised: :06/2010, 10/2011, 4/2012	Approved By: Medical Director, Interventional Cardiology Senior VP, Patient Care Services	Page 1 of 5
Contact: Clinical Coordinator, Cardiology			

PURPOSE: Balloon angioplasty of the coronary artery and stents (percutaneous coronary intervention, PCI) is a non-surgical procedure that relieves narrowing or obstruction of the arteries to the muscle of the heart. PCI can relieve chest pain (angina), minimize or stop a heart attack, or improve the prognosis of patients with unstable angina. The risk of a failed PCI, requiring emergent surgical intervention is rare, but a recognized risk of the procedure. An emergent transfer procedure is in place and has been used effectively.

POLICY: Coronary angioplasty is performed at Greenwich Hospital by authorized personnel.

PROCEDURE:

RN: **A. Equipment/Supplies:**

1. Complete Emergency Equipment Checklist
   a. Defibrillator
   b. Code cart
   c. Oxygen
   d. Suction Equipment
   e. I – Stat machine and cartridges
   f. Temporary Pacemaker Pulse Generator
   g. 4 or 5 French Pacing Catheter
2. Prepare/Obtain Medications
   a. Lidocaine 1% - 1 vial
   b. Sodium Bicarbonate 8.4% - 1 vial
   c. Heparin flush (1000cc 0.9% NS with 2000 units Heparin) premixed - 2 bags
   d. Medications for Sedation - Fentanyl and Versed

B. **Preparation of Patient on arrival to Cardiac Catheterization Lab:**

1. Use two patient identifiers: Name and date of birth or medical record number to verify patient identification
2. Explain pre-, intra- and post-procedure expectations to patient and/or family
3. Check patient allergies, respiratory and neuro status

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4. Obtain height and weight
5. Check NPO status
6. Check bilateral distal pulses – dorsal pedis and posterior tibial and/or radial pulses
7. Check patency of intravenous line
8. Connect NS 0.9% 500cc at KVO to IV if not already in place
9. Check lab values, if available
    a. CBC
    b. BUN, Creatinine
    c. Lytes
    d. Coagulation Studies (if relevant)
    e. Cardiac Enzymes
    f. Calculate creatinine clearance
10. Check for signed consent
11. History and physical in chart
12. Transfer patient to procedure table
13. Attach patient to monitoring equipment
14. Obtain a set of baseline vital signs and attach patient to O2 – per Physician order
15. Universal Procedure Verification performed by all team members of the procedural team per protocol
16. Administer pre-medications sedation, Fentanyl and Versed, per Physician order and Moderate Sedation/Analgesia for Diagnostic and Therapeutic Procedures
17. Continuously monitor patient's vital signs and patient's response to sedation

Radiology Technician:

1. Turn on Radiology equipment
2. Run fluoroscopy during procedure
3. Assist with Transducer and Procedure table set up
4. Obtain equipment and supplies for angiogram/angioplasty and hand off during procedure
5. Monitor contrast during procedure

6. Assist the physician/scrub tech with attaching lines to flush and pressure transducers

Monitor Technician:

1. Turn on GE Marquette MAC Lab monitoring equipment
2. Enter patient information - labs, height, weight, allergies, current meds, pulses and NPO status in MAC Lab
3. Record Risk Factors/Medical History in MAC Lab (Neuro/Resp/Cardiac/GU/GI).
4. Zero transducers
5. Assist with patient transfer to procedure table
6. Assist with connecting patient to monitoring equipment – NIBP, O2 sat and EKG

Scrub Technician:

1. Patient Preparation
    a. Sterile table set up as indicated by physician
    b. Using clippers prep and clip both groins
    c. Prep and drape patient in sterile fashion
    d. Assist physician with attaching lines to flush and pressure transducers

RESPONSIBILITIES DURING ANGIOPLASTY:

Nurse:

1. Observe patient's response to procedure/medications
2. Follow Moderate Sedation/Analgesia for Diagnostic and Therapeutic Procedures Policy
3. Notify physician with any of the following symptoms:
    Chest, neck, jaw and/or arm discomfort
    Shortness of breath
    Change in vision
    Change in patient's color
    Hives and/or itching
    Change in Vital Signs- EKG, Blood pressure or O2 saturation

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Perform ACT during procedure, if necessary

Radiology Technician:

1. Monitor contrast during procedure
2. Run fluoroscopy equipment during procedure
3. Obtain equipment and supplies for angiogram and angioplasty as ordered by physician.
4. Turn off fluoroscopy at end of procedure

Monitor Technician:

1. Observe EKG and notify MD of arrhythmias, EKG changes, and changes in vital signs
2. Monitor pressure waveforms and notify physician and nurse of abnormalities
3. Record pressure tracings, vital signs, EKG rhythm, LOC, Pain Assessment, per CCL policy
4. Record medication administration throughout procedure
5. Record fluoroscopy time
6. Record amount of IVF and contrast given during procedure
7. Record supplies used during procedure
8. Monitor and record ACTs during procedure

Scrub Technician:

1. Prep and drape patient in sterile fashion
2. Scrub and assist physician
3. Assist with catheter exchange when directed by Physician

RESPONSIBILITIES AFTER ANGIOPLASTY:

Nurse:

1. Instruct patient on post angioplasty orders:
2. Explain post angioplasty instructions
    a. Increase PO fluid intake
    b. Care of catheterization site
    c. Immobilization of limb where angiogram/angioplasty was performed
    d. Bedrest
    e. NPO status

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3. Assist physician with arterial repair, when indicated (RN or Scrub tech)
4. Check pulse(s) distal to angiogram/angioplasty site
5. Evaluate patient's condition after angioplasty (i.e. Neuro, Cardiac, Respiratory, Pain Assessment)
6. Assist patient off table to stretcher/bed
7. Give report to RN on receiving unit using SBAR method.
8. Patient transferred to receiving unit by bed with Physician (if indicated), Technician and RN.

Radiology Technician:

1. Assist patient off table to stretcher or bed
2. Return any unopened equipment
3. Check all radiology equipment is in proper place and turn off fluoroscopy.

Monitor Technician:

1. Monitor patient's vital signs throughout procedure and report any abnormal findings to RN and MD
2. Record procedure in Mac Lab
3. Document in MacLab report
    a. Total Fluoroscopy Time
    b. Total contrast used
4. Print Report at end of procedure and have it signed by Physician, RN and Monitor Technician
5. Scan copy of MacLab report into Epic chart under appropriate Encounter
6. Put signed copy of MacLab report in Cardiology case folder

Scrub Technician:

1. Remove and discard table
2. Discard of sharps and fluid in appropriate receptacles

REFERENCES:

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RELATED POLICIES:

Prevention Wrong Site/Side Protocol - Universal PCIII-56
Medication Reconciliation – PCIII
Patient Identification – PCIII55
Consent – PCI – 5
Moderate Sedation / Analgesia for Diagnostic and Therapeutic Procedures – PC111 - 31

Attachment III

New England Journal of Medicine Article:
"Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery"

ORIGINAL ARTICLE

Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery

Thomas Aversano, M.D., Cynthia C. Lemmon, R.N., B.S.N., M.S., and Li Liu, M.D., for the Atlantic CPORT Investigators

ABSTRACT

BACKGROUND

Performance of percutaneous coronary intervention (PCI) is usually restricted to hospitals with cardiac surgery on site. We conducted a noninferiority trial to compare the outcomes of PCI performed at hospitals without and those with on-site cardiac surgery.

METHODS

We randomly assigned participants to undergo PCI at a hospital with or without on-site cardiac surgery. Patients requiring primary PCI were excluded. The trial had two primary end points: 6-week mortality and 9-month incidence of major adverse cardiac events (the composite of death, Q-wave myocardial infarction, or target-vessel revascularization). Noninferiority margins for the risk difference were 0.4 percentage points for mortality at 6 weeks and 1.8 percentage points for major adverse cardiac events at 9 months.

RESULTS

A total of 18,867 patients were randomly assigned in a 3:1 ratio to undergo PCI at a hospital without on-site cardiac surgery (14,149 patients) or with on-site cardiac surgery (4718 patients). The 6-week mortality rate was 0.9% at hospitals without on-site surgery versus 1.0% at those with on-site surgery (difference, −0.04 percentage points; 95% confidence interval [CI], −0.31 to 0.23; P=0.004 for noninferiority). The 9-month rates of major adverse cardiac events were 12.1% and 11.2% at hospitals without and those with on-site surgery, respectively (difference, 0.92 percentage points; 95% CI, 0.04 to 1.80; P=0.05 for noninferiority). The rate of target-vessel revascularization was higher in hospitals without on-site surgery (6.5% vs. 5.4%, P=0.01).

CONCLUSIONS

We found that PCI performed at hospitals without on-site cardiac surgery was noninferior to PCI performed at hospitals with on-site cardiac surgery with respect to mortality at 6 weeks and major adverse cardiac events at 9 months. (Funded by the Cardiovascular Patient Outcomes Research Team [C-PORT] participating sites; ClinicalTrials.gov number, NCT00549796.)

From Johns Hopkins University, Baltimore (T.A., C.C.L.); and Clinical Trials and Surveys, Owings Mills, MD (L.L.). Address reprint requests to Dr. Aversano at Johns Hopkins Cardiology at the Greater Baltimore Medical Center, Suite 5104, 6701 N. Charles St., Baltimore, MD 21204, or at taversan@jhmi.edu.

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THE POTENTIAL NEED FOR EMERGENCY cardiac surgery to treat complications related to percutaneous coronary intervention (PCI) suggests that performance of PCI may be best limited to hospitals with on-site cardiac surgery. Among Grüntzig's first 50 PCI procedures, 10% of patients required emergency coronary-artery bypass grafting (CABG).[1] Although the need for emergency surgery subsequently diminished dramatically (by 2002, the incidence was 0.15%[2]), concern about the safety and quality of PCI performed without the availability of on-site cardiac surgery has persisted. Hospitals in which PCI is performed but that do not have cardiac surgery programs could have more adverse events and poorer outcomes for a number of reasons (including low institutional volume of PCI procedures and inexperienced staff), in addition to the need for emergency CABG.

Despite these concerns, many hospitals without on-site cardiac surgery developed stand-alone programs for the performance of primary PCI after studies showed that primary PCI was associated with better outcomes than medical therapy in the treatment of myocardial infarction with ST-segment elevation[3] and could be performed safely and effectively at such hospitals.[4] Door-to-balloon times may be shorter, and outcomes consequently better, if primary PCI is widely available. It has further been suggested that, given the relatively low volume of primary PCI procedures at some hospitals, the addition of other PCI procedures (including elective PCI and PCI for acute coronary syndromes without ST-segment elevation) could help sustain and improve these programs.

In addition, previous studies have shown that, for patients with acute coronary syndromes presenting to centers without any revascularization capability, appropriate use of PCI and CABG is limited and outcomes are suboptimal.[5-7] Extension of PCI capability to such hospitals could improve access to appropriate care, particularly in areas where recruitment and retention of cardiologists may be difficult[8] and treatment options for patients are limited.

The Cardiovascular Patient Outcomes Research Team (CPORT) Non-Primary PCI (CPORT-E) trial was designed to help address these issues. CPORT-E was a randomized noninferiority trial that compared outcomes of PCI procedures (excluding primary PCI) at hospitals with and those without on-site cardiac surgery.

METHODS

STUDY DESIGN AND OVERSIGHT

The CPORT-E trial was designed by the study chairman and the protocol-development committee and was funded through financial support provided by participating sites to the Johns Hopkins University and through in-kind support that included the provision of local study coordinators at each site. There was no support from the makers of equipment used in catheterization laboratories or of that used for PCI. The protocol was approved by each participating hospital's institutional review board and the Johns Hopkins institutional review board. Data were gathered by local research coordinators, reviewed for accuracy by central study coordinators at Johns Hopkins, and analyzed by the authors. The authors vouch for the accuracy and completeness of the data and the analysis and for the fidelity of this report to the trial protocol, which is available with the full text of this article at NEJM.org.

TRIAL PARTICIPANTS

Patients were eligible for participation in the trial if they presented for diagnostic cardiac catheterization at 1 of 60 participating hospitals without on-site cardiac surgery located in 10 U.S. states (Maryland, New Jersey, Pennsylvania, Ohio, Georgia, Texas, North Carolina, Illinois, Oregon, and Alabama). During the trial period, patients who did not undergo randomization, whether or not they met the inclusion criteria for the trial, were included in a registry that recorded a limited set of data that excluded identifying private information.

Patients 18 years of age or older with stable coronary artery disease or an acute coronary syndrome were included in the trial. Patients with an acute myocardial infarction with ST-segment elevation were excluded, as were those with an ejection fraction of less than 20% and those who required PCI of an unprotected lesion in the left main coronary artery. In addition, interventionalists could exclude any patient whom they deemed to be at too high a risk for PCI. For each trial participant, all lesions requiring PCI had to be considered treatable at the hospital without on-site cardiac surgery before randomization. Patients who had previously participated in the trial were excluded. Full inclusion and exclusion criteria are available in Table S1 in the Supplementary Appendix, available at NEJM.org.

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PARTICIPATING HOSPITALS AND INTERVENTIONALISTS

Interventionalists were required to meet criteria for competency developed by the American College of Cardiology (ACC), the American Heart Association (AHA), and the Society for Cardiac Angiography and Interventions (SCAI).[9] Participating centers were required to have primary PCI programs available 24 hours per day, 7 days per week, and to be capable of performing 200 PCI procedures annually. Most sites required a waiver from the state department of health to participate. All such waivers allowed for a first-year PCI volume of 100 procedures, increasing to 200 in the second year.

Each site had a formal agreement with a tertiary-care hospital partner specifying that the tertiary-care institution would accept emergency transfers from the enrolling site. However, participants in the trial who were randomly assigned to undergo PCI at a hospital with on-site surgery could have the PCI procedure at any tertiary-care hospital. A formal agreement with an advanced cardiac life-support service capable of transporting patients requiring intraaortic balloon counterpulsation was also required, with an anticipated response time of 30 minutes or less.

Before commencing recruitment, all participating sites were required to complete a formal PCI development program. This program included the development of detailed care plans and pathways, order sets, and logistics and the training of staff in the care of patients undergoing PCI. Details of this program are available in the Supplementary Appendix.

TRIAL PROCEDURES

Before undergoing diagnostic catheterization, study participants provided written informed consent. After catheterization, if PCI was required and all lesions were considered to be treatable at the hospital without on-site cardiac surgery, the participant was randomly assigned in a 3:1 ratio to undergo PCI at either the enrolling site (without on-site cardiac surgery) or another facility with on-site cardiac surgery. Randomization was performed with the use of an automated telephone-response system on a per-site basis in random permuted blocks (of 4, 8, or 12). Patients who were considered to be at too high a risk according to the study-exclusion criteria or in the judgment of the treating physician did not undergo randomization but instead underwent PCI, CABG, or other therapy as clinically indicated.

After randomization, all trial participants were to undergo PCI according to their randomized assignment. The timing of the index PCI procedure depended on individual case acuity, the need to perform PCI on a different day than the visit to the catheterization laboratory to minimize procedural risk (i.e., staged procedure), and scheduling and transportation constraints, but the procedure was to be performed as soon as possible for each participant. All treatments, devices, and drugs were administered and laboratory studies carried out according to routine practice; no specific PCI protocol was prescribed. However, the use of cutting balloons was limited to in-stent restenosis and atherectomy devices were not permitted at hospitals without on-site cardiac surgery.

Participants were contacted by telephone (or mail, if necessary) at 6 weeks and 3, 6, and 9 months after study entry to identify adverse events. Medical records required to document identified events were obtained as needed.

TRIAL OUTCOMES

Two coprimary outcomes were identified: all-cause mortality 6 weeks after the index PCI and the composite rate of major adverse cardiac events, including death from all causes, Q-wave myocardial infarction, and target-vessel revascularization, 9 months after the index PCI. Additional outcomes included the PCI success rate and the incidence of cardiac surgery, bleeding, stroke, renal failure, and any subsequent revascularization.

Except as noted, definitions of data elements followed those in the American College of Cardiology National Cardiovascular Data Registry module on cardiac catheterization, version 3.02.[10] Q-wave myocardial infarction was defined as the development of new Q waves in any two contiguous leads. Target-vessel revascularization was defined as any revascularization intervention (PCI or CABG) occurring in a treated vessel at any time after the index intervention. In randomly assigned participants who did not undergo an index PCI, any revascularization was considered a target-vessel revascularization. Bleeding was defined as any bleeding that required blood transfusion, except for transfusions associated with cardiac surgery. Vascular repair included thrombin injection, ultrasound-guided compression, and surgical repair. Further details of study definitions are available in the Supplementary Appendix.

All events were reported by the enrolling site to the central coordinating center and were con-

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firmed by coordinating-center staff with the source medical records submitted. Occasionally, a review of source documents resulted in the identification of unreported events or the withdrawal of submitted events. A central review committee reviewed electrocardiographic findings without knowledge of the participant's randomized assignment.

STATISTICAL ANALYSIS

The CPORT-E trial was designed as a noninferiority trial. On the basis of previous studies, the 6-week all-cause mortality rate was estimated at 0.8%[11,12] and the rate of major adverse cardiac events at 9 months was estimated at 12.0%.[13-16] Noninferiority margins for the difference in event rates were set at 0.4 percentage points for the 6-week end point and 1.8 percentage points for the 9-month end point. With dual primary end points, the required number of participants for a one-sided test for noninferiority with an alpha level of 0.05 and a beta level of 0.80 was determined to be 18,360.

The primary outcome analysis was performed on data from the intention-to-treat population. Asymptotic normal approximations to the sample proportions were used to generate confidence intervals and P values for noninferiority. Categorical variables were compared with the use of Fisher's exact test or a chi-square test. A per-protocol analysis was also performed, which included only participants who underwent PCI at the site to which they were assigned. All statistical analyses were performed with the use of SAS software, version 9.2.

States that required a waiver from the department of health for trial participation typically specified that the participating hospitals should stop performing PCI when trial enrollment was completed. To allow the creation of a follow-up registry in these states, enrollment continued after the recruitment goal of 18,360 participants was reached. Ultimately, 18,867 participants underwent randomization.

RESULTS

STUDY POPULATION

Enrollment began on April 7, 2006, and ended on March 31, 2011. During that period, there were 99,479 patient visits for diagnostic catheterization at the participating hospitals. Among the 76.1% of patients who provided consent to participate, 21,165 were judged to require PCI after catheterization, and 18,867 underwent randomization (Fig. 1). Excluded were 2298 patients (10.9%) who required PCI but were judged to be at too high a risk for study participation. Reasons for the judgment that the risk was too high are shown in Figure S1 in the Supplementary Appendix. Overall, patients in the registry had fewer risk factors and less severe coronary disease than randomly assigned trial participants (Table S2 in the Supplementary Appendix).

Of the patients who underwent randomization, 319 did not undergo an index PCI. The proportion of patients who did not undergo an index PCI was higher among participants assigned to hospitals with on-site cardiac surgery than among those assigned to hospitals without on-site surgery. Reasons included referral for surgical or medical therapy and lesion resolution (Table S3 in the Supplementary Appendix). Crossovers between study groups were infrequent but were more frequent among participants randomly assigned to hospitals with on-site cardiac surgery (Fig. 1).

The baseline characteristics of the participants are shown in Table 1. There was a higher incidence of prior PCI in participants randomly assigned to hospitals without cardiac surgery on site. In addition, the rate of emergency catheterization was higher, and the rate of urgent catheterizations lower, among participants assigned to hospitals with on-site cardiac surgery.

The median annual volume of catheterizations per hospital was 150 procedures (interquartile range, 99 to 216). The median annual volume of primary PCIs was 51 procedures (interquartile range, 35 to 74). The participation of 12 hospitals was terminated during the trial because of low volume. Data from these sites were included in the data analysis.

PROCEDURE CHARACTERISTICS

A higher percentage of PCIs were staged among participants assigned to hospitals with on-site cardiac surgery than among those assigned to hospitals without on-site surgery, probably because of the need for transfer (Table 2). As a result, the number of visits to the catheterization laboratory that were needed to complete PCI was higher among participants assigned to hospitals with on-

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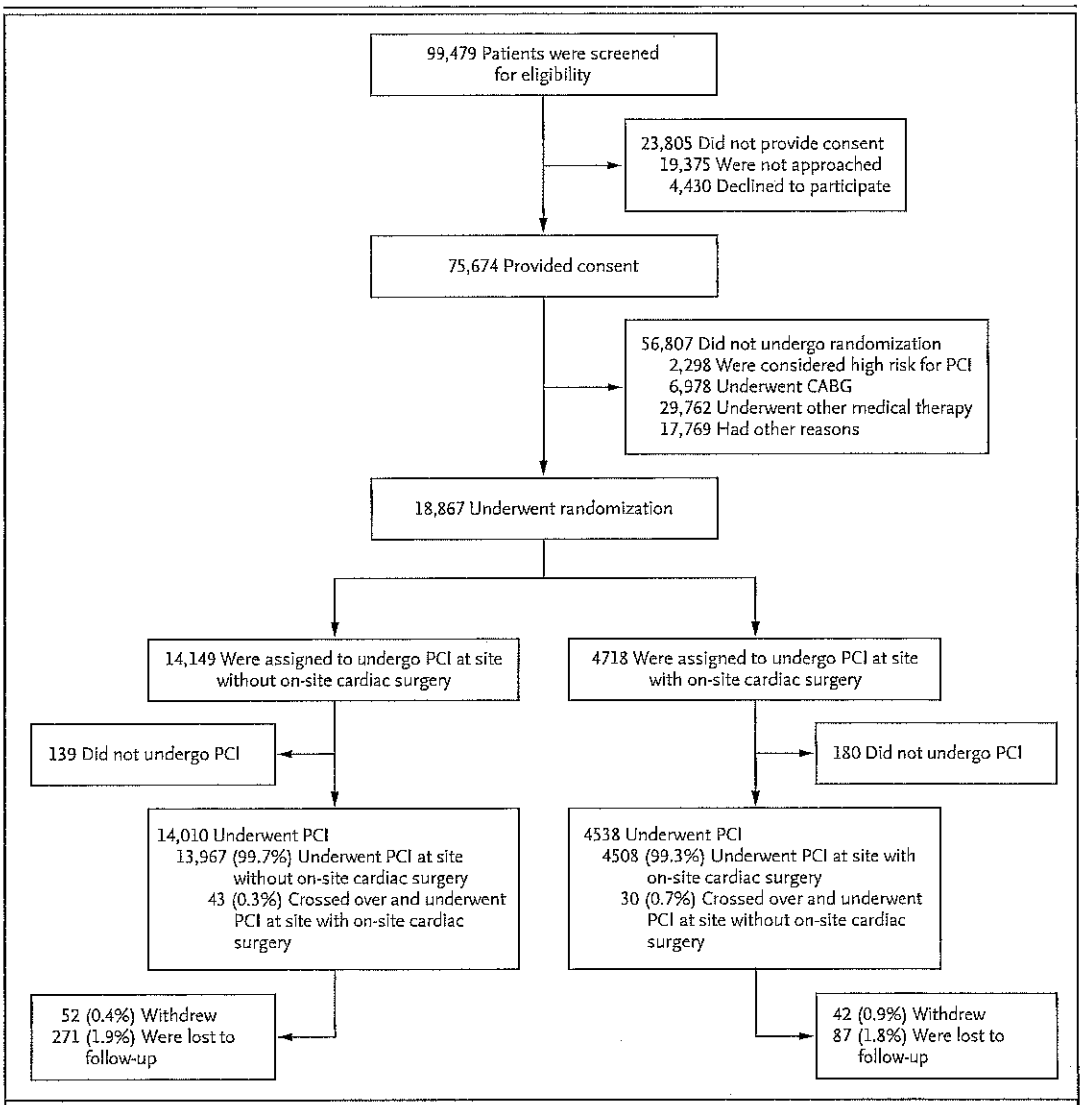

Figure 1. Enrollment and Randomization of the Study Patients.

The percentages for the patients who withdrew or were lost to follow-up are based on the patients assigned to undergo percutaneous coronary intervention (PCI). CABG denotes coronary-artery bypass grafting.

site cardiac surgery. In addition, drug-eluting stents were used more frequently in hospitals with on-site cardiac surgery.

The rate of PCI failure was lower among participants treated at hospitals with on-site cardiac surgery (Table 2). Emergency CABG was associated with high mortality but was rarely performed; it was performed more frequently among participants assigned to hospitals with on-site cardiac surgery. The incidence of unplanned re-catheterization and PCI before discharge was greater at hospitals without on-site cardiac surgery.

OUTCOMES

At 6 weeks after the index PCI, 132 participants assigned to hospitals without on-site cardiac surgery had died and 46 participants assigned to hospitals with on-site cardiac surgery had died. The event rates in the two groups were 0.9% and 1.0%, respectively (difference in event rates, −0.04 percentage points; 95% confidence interval [CI], −0.31 to 0.23; P=0.004 for noninferiority) (Table 3).

At 9 months, there were 1716 major adverse cardiac events in participants at hospitals without on-site cardiac surgery and 529 such events in

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Table 1. Baseline Characteristics of the Study Patients.*

Characteristic	No On-Site Cardiac Surgery (N=14,149)	On-Site Cardiac Surgery (N=4718)
Age — yr	63.9±11.9	64.0±12.0
Male sex — no. (%)	9046 (63.9)	2970 (63.0)
White race — no. (%)†	11,185 (79.1)	3778 (80.1)
Medical history — no. (%)		
Hypertension	11,950 (84.5)	4024 (85.3)
Hypercholesterolemia	11,567 (81.8)	3865 (81.9)
Smoking (current or former)	8,719 (61.6)	2964 (62.8)
Diabetes	5,485 (38.8)	1868 (39.6)
Family history of CAD	7,730 (54.6)	2623 (55.6)
Heart failure	1,531 (10.8)	518 (11.0)
Prior myocardial infarction	6,011 (42.5)	2030 (43.0)
Prior PCI‡	4,506 (31.8)	1430 (30.3)
Prior CABG	1,852 (13.1)	632 (13.4)
Prior stroke or PVD	2,447 (17.3)	868 (18.4)
Angiographic findings at baseline		
One-vessel CAD — no. (%)	5,097 (36.0)	1645 (34.9)
Two-vessel CAD — no. (%)	5,087 (36.0)	1741 (36.9)
Three-vessel CAD — no. (%)	3,959 (28.0)	1326 (28.1)
Left main CAD — no. (%)	465 (3.3)	178 (3.8)
Graft disease — no. (%)	1,323 (9.4)	456 (9.7)
Left ventricular ejection fraction — %	54.2±10.6	54.3±10.7
Procedure status at time of catheterization — no. (%)§		
Elective	10,350 (73.2)	3414 (72.4)
Urgent¶	3,291 (23.3)	1127 (23.9)
Emergency‡	493 (3.5)	175 (3.7)
Clinical status at time of catheterization — no. (%)‖		
STEMI	390 (2.8)	147 (3.1)
NSTEMI	3,471 (24.5)	1210 (25.7)
Unstable angina	5,196 (36.7)	1665 (35.3)
Stable angina	2,011 (14.2)	636 (13.5)
Atypical chest pain	723 (5.1)	268 (5.7)
Other	2,356 (16.7)	790 (16.8)

* Plus–minus values are means ±SD. CABG denotes coronary-artery bypass grafting, CAD coronary artery disease, NSTEMI non–ST-segment elevation myocardial infarction, PCI percutaneous coronary intervention, PVD peripheral vascular disease, and STEMI ST-segment elevation myocardial infarction.

† Race was self-reported.

‡ P<0.05 for the comparison between groups.

§ For procedure status at time of catheterization, data were missing for 15 patients treated at hospitals without on-site cardiac surgery and 2 patients treated at hospitals with on-site cardiac surgery. The definitions for "urgent" and "emergency" were those used in the American College of Cardiology National Cardiovascular Data Registry module on cardiac catheterization, version 3.02.[10]

¶ P<0.01 for the comparison between groups.

‖ For clinical status at time of catheterization, data were missing for 2 patients in each study group. "Other" includes patients presenting with heart failure, arrhythmia, positive stress tests, syncope, and other non–chest-pain syndromes and patients undergoing cardiovascular risk assessment before a noncardiac surgical procedure.

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Table 2. Characteristics of the Index Procedure.*

Characteristic	No On-Site Cardiac Surgery	On-Site Cardiac Surgery	P Value
PCI staged — no./total no. (%)†	3652/14,010 (26.1)	3084/4538 (68.0)	<0.001
Single-vessel PCI — no./total no. (%)	11,212/14,010 (80.0)	3716/4538 (81.9)	
Multivessel PCI — no./total no. (%)	2937/14,010 (21.0)	1002/4538 (22.1)	
No. of catheterization laboratory visits needed to complete index PCI	1.28	1.73	<0.001
No. of days from randomization to index PCI — median (IQR)	0 (0–3)	1 (0–3)	<0.001
Stent use — no./total no. (%)			0.03
DES only	10,074/14,010 (71.9)	3343/4538 (73.7)	
BMS only	2790/14,010 (19.9)	877/4538 (19.3)	
Both DES and BMS	596/14,010 (4.3)	156/4538 (3.4)	
Balloon only	550/14,010 (3.9)	162/4538 (3.6)	
PCI success — no./total no. (%)			
By patient‡			0.007
Complete success	12,714/14,010 (90.7)	4148/4538 (91.4)	
Partial success	808/14,010 (5.8)	253/4538 (5.6)	
Failure	482/14,010 (3.4)	113/4538 (2.5)	
By lesion§			0.04
Success	19,886/21,292 (93.4)	6499/6907 (94.1)	
Failure	1406/21,292 (6.6)	408/6907 (5.9)	
Emergency procedures			
Emergency PCI — no./total no. (%)	23/14,010 (0.2)	6/4538 (0.1)	
Death associated with emergency PCI — no. of deaths/total no. of emergency PCI procedures (%)	1/23 (4.3)	0	
Emergency CABG — no./total no. (%)	13/14,010 (0.1)	10/4538 (0.2)	0.11
Death associated with emergency CABG — no. of deaths/total no. of emergency CABG procedures (%)	2/13 (15.4)	2/10 (20.0)	

* Data are for all randomly assigned patients who underwent PCI. BMS denotes bare-metal stent, DES drug-eluting stent, and IQR interquartile range.

† Staged PCI indicates that PCI was performed on a different day than the visit to the catheterization laboratory to minimize procedural risk.

‡ Thirty patients (6 in hospitals without on-site cardiac surgery and 24 in hospitals with on-site cardiac surgery) did not have valid postprocedure data available on coronary-artery flow (according to the Thrombolysis in Myocardial Infarction [TIMI] scale, which ranges from 0 to 3, with 0 indicating no flow and 3 normal flow) or percentage of residual stenosis. These 30 patients were excluded from the analysis of PCI success by patient. Complete success was defined as a postprocedure TIMI flow grade of 3 and residual stenosis not exceeding 20% in all treated lesions. Partial success was defined as a postprocedure TIMI flow grade of 3 and residual stenosis not exceeding 20% in at least one (but not all) treated lesions. Failure was defined as no treated lesions with a postprocedure TIMI flow grade of 3 and residual stenosis of more than 20%.

§ Success by lesion was defined as a postprocedure TIMI flow grade of 3 and residual stenosis not exceeding 20%. Failure was defined as a postprocedure TIMI flow grade of less than 3 or residual stenosis of more than 20%.

patients at hospitals with on-site cardiac surgery (12.1% vs. 11.2%; difference in event rates, 0.92 percentage points; 95% CI, 0.04 to 1.80; P=0.05 for noninferiority) (Table 3). There were no significant differences in all-cause mortality or Q-wave myocardial infarction between the two groups, but there was a significant difference in the rate of target-vessel revascularization — 6.5% among participants at hospitals without on-site cardiac surgery versus 5.4% among those at hospitals with on-site cardiac surgery (P=0.01).

Several exploratory analyses were conducted (Table 3). If CABG was not considered to qualify as target-vessel revascularization when it was performed as an initial procedure (i.e., for participants who did not undergo the intended index PCI), the rates of major adverse cardiac events at 9 months among participants at hospitals with-

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Table 3. Trial Outcomes.*

Outcome	No On-Site Cardiac Surgery	On-Site Cardiac Surgery	Difference in Rate (Asymptotic One-Sided 95% CI)	P Value	
				Noninferiority	Superiority
	no./total no. (%)		*percentage points*		
Primary end point (intention-to-treat population)					
Death at 6 wk	132/14,149 (0.9)	46/4718 (1.0)	−0.04 (−0.31 to 0.23)	0.004	
9-mo outcomes					
Death	454/14,149 (3.2)	150/4718 (3.2)			
TVR	915/14,149 (6.5)	255/4718 (5.4)			0.01
Q-wave myocardial infarction	434/14,149 (3.1)	144/4718 (3.1)			
Major adverse cardiac event	1716/14,149 (12.1)	529/4718 (11.2)	0.92 (0.04 to 1.80)	0.05	
Exploratory analyses (intention-to-treat population)					
Major adverse cardiac event, including withdrawal and loss to follow-up	2026/14,149 (14.3)	653/4718 (13.8)	0.48 (−0.48 to 1.44)	0.01	
CABG as initial procedure not included in TVR definition					
TVR	873/14,149 (6.2)	218/4718 (4.6)			<0.001
Major adverse cardiac event	1678/14,149 (11.9)	495/4718 (10.5)	1.37 (0.51 to 2.23)	0.21	
TVR according to stent type					
DES only	484/10,074 (4.8)	120/3343 (3.6)			0.005
BMS only	223/2790 (8.0)	53/877 (6.0)			
Both DES and BMS	39/596 (6.5)	8/156 (5.1)			
Balloon only	138/550 (25.1)	34/162 (21.0)			
Per-protocol analyses					
Death at 6 wk	129/13,967 (0.9)	38/4508 (0.8)	0.08 (−0.18 to 0.34)	0.03	
TVR	860/13,967 (6.2)	202/4508 (4.5)			<0.001
Major adverse cardiac event at 9 mo	1676/13,967 (12.0)	467/4508 (10.4)	1.64 (0.77 to 2.51)	0.42	

* Major adverse cardiac events included death, target-vessel revascularization (TVR), and Q-wave myocardial infarction. BMS denotes bare-metal stent, and DES drug-eluting stent.

out and those with on-site cardiac surgery were 11.9% and 10.5%, respectively. In per-protocol analyses (excluding participants who crossed over), the death rates at 6 weeks were 0.9% and 0.8%, respectively, and the rates of major adverse cardiac events at 9 months were 12.0% and 10.4%, respectively.

CABG was performed more frequently among trial participants at hospitals with on-site cardiac surgery than among participants at hospitals without such access (Table 4). The incidence of unplanned catheterization at 6 weeks and 9 months and the incidence of any subsequent revascularization at 9 months were higher among participants at hospitals without on-site cardiac surgery (Table 4).

DISCUSSION

We compared clinical outcomes between trial participants undergoing PCI at a hospital with on-site access to cardiac surgery and participants undergoing PCI at a hospital without such access. We found that outcomes at hospitals without on-site cardiac surgery were noninferior to those at hospitals with cardiac surgery on site, with respect to all-cause mortality at 6 weeks and major adverse cardiac events at 9 months. There were no significant differences between the two study groups at 9 months with respect to rates of death or Q-wave myocardial infarction, but trial participants treated at hospitals without on-site cardiac surgery more frequently required target-vessel revascularization.

The short-term results from this trial are concordant with the findings in previous registry studies and meta-analyses.[17,18] The longer-term outcomes are similar to those in a small randomized trial of low-risk PCI at two hospitals,[19] which showed equivalent safety at the hospitals with and those without on-site cardiac surgery but more frequent target-vessel revascularization at 6 months among participants treated at the sites without cardiac surgery.

The definition of target-vessel revascularization used in the CPORT-E trial included any revascularization (PCI or CABG) after the index PCI. In addition, for randomly assigned participants who did not undergo an index PCI, any subsequent revascularization of the target vessel, whether by PCI or CABG, was considered a target-vessel revascularization. The inclusion of initial CABG as a target-vessel revascularization is consistent with the intention-to-treat approach, which is based on randomized treatment assignments, regardless of the treatment received. When CABG was not counted as a target-vessel revascularization in these trial participants, hospitals without on-site cardiac surgery were inferior to those with on-site access with respect to the rate of major adverse cardiac events at 9 months (Table 3). The per-protocol analysis also showed a higher rate of major adverse cardiac events in hospitals without on-site cardiac surgery. These differences are small and within the range of noninferiority margins used in recent comparative trials of stent types, from 1.5 percentage points (relative difference, 19%)[20] to 3.5 percentage points (relative difference, 43%).[21]

In all analyses, the rate of target-vessel revascularization was higher among participants who underwent PCI at a hospital without cardiac surgery on-site, regardless of the definition of target-vessel revascularization and regardless of stent type. The reason for this is not clear from the current study but may reflect a lower initial success rate and a more conservative approach by interventionalists practicing at relatively inexperienced centers that began PCI programs only as part of the CPORT-E trial.

There are a number of important limitations arising from the design and conduct of the CPORT-E trial. Participants were carefully selected and were excluded if they were deemed to be at high risk. It is possible that the population studied is different from the general population requiring PCI, although a comparison of baseline characteristics with those reported in the National Cardiovascular Data Registry[17] suggests that this is not the case (Table S4 in the Supplementary Appendix). For outcomes of PCI at hospitals without on-site cardiac surgery to be similar to those at hospitals with on-site cardiac surgery, it may be necessary for such centers to participate in a formal PCI development program and for interventionalists who perform the procedures to meet the criteria for competency developed by the ACC, AHA, and SCAI.

In summary, the CPORT-E trial compared the clinical outcomes of PCI performed at hospitals with access to on-site cardiac surgery with outcomes of PCI performed at hospitals without such access. Outcomes at hospitals without on-site cardiac surgery were noninferior to those at hospi-

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Table 4. Adverse Events.

Event	6 Wk			9 Mo		
	No On-Site Cardiac Surgery (N=14,149)	On-Site Cardiac Surgery (N=4718)	P Value	No On-Site Cardiac Surgery (N=14,149)	On-Site Cardiac Surgery (N=4718)	P Value
	no. (%)			*no. (%)*		
CABG						
All	88 (0.6)	69 (1.5)	<0.001	216 (1.5)	107 (2.3)	<0.001
Emergency	15 (0.1)	10 (0.2)		18 (0.1)	11 (0.2)	
Bleeding	486 (3.4)	150 (3.2)		754 (5.3)	247 (5.2)	
Vascular repair	52 (0.4)	20 (0.4)		151 (1.1)	55 (1.2)	
Stroke	40 (0.3)	8 (0.2)		87 (0.6)	23 (0.5)	
Renal insufficiency	72 (0.5)	20 (0.4)		131 (0.9)	37 (0.8)	
Unplanned catheterization	613 (4.3)	150 (3.2)	<0.001	2102 (14.9)	566 (12.0)	<0.001
Any subsequent revascularization	378 (2.7)	127 (2.7)		1200 (8.5)	329 (7.0)	0.001

tals with cardiac surgery on site, with respect to all-cause mortality at 6 weeks and major adverse cardiac events at 9 months.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

We thank Lynnet Tirabassi for helping to take CPORT from initial concept to reality, William Weintraub for his thoughtful advice during the preparation of this manuscript, and Marjorie Aversano and Kenneth L. Baughman for their selfless and constant support, which made this and other CPORT projects possible.

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Attachment IV

Greenwich Hospital-Yale-New Haven Hospital Transfer Protocol and Agreement

Yale-New Haven Hospital, Inc.
TRANSFER PROTOCOL AND AGREEMENT

Yale-New Haven Hospital, Inc., ("YNHH"), a non-stock non-profit corporation organized and existing under the laws of the State of Connecticut, whose principle office is located at 20 York Street, New Haven, Connecticut 06504, hereby contracts with Greenwich Hospital, whose principle office is located at 5 Pennyridge Road, Greenwich, Connecticut, to provide the transfer of patients from Greenwich Hospital to YNHH.

WHEREAS, YNHH is a tertiary care hospital that is available as a statewide resource to other hospitals and their patients; and

WHEREAS, in order to provide optimal care to its community, Greenwich Hospital from time to time desires to transfer patients to YNHH; and

WHEREAS, to the best of its ability, YNHH desires to accept such patients in order to provide them with optimal care:

NOW, THEREFORE, in the consideration of the mutual undertakings set forth below, YNHH and Greenwich Hospital, the "parties" to this transfer protocol and Agreement ("Agreement") hereby agreed as follows:

A. The Decision

1. Greenwich Hospital's transferring physician shall be responsible for evaluating the patient's condition and needs to determine the appropriateness or advisability of transfer. In any such case where Greenwich Hospital's physician determines that a transfer to YNHH is medically necessary and/or appropriate in accordance with state and federal statutes and regulations, Greenwich Hospital's physician shall call YNHH to request transfer of the patient to YNHH.

2. Subject to availability of beds, staff and resources necessary for the care and treatment of the patient, the YNHH receiving physician shall call to accept or decline transfer of the patient. After YNHH has accepted the patient and the patient is en route, YNHH may not subsequently cancel orders to accept the patient unless YNHH arranges for another tertiary care hospital or Level 1 trauma center (or other appropriate facility) to accept the patient.

3. Greenwich Hospital's transferring physician shall provide necessary medical treatment within the capabilities of the staff and facilities available at Greenwich Hospital in order to minimize the risks of transfer to the patient's health, and in consultation with YNHH's receiving physician, shall determine the selection of appropriate transportation and the level of care required for appropriate management of the patient *en route* to YNHH.

4. Greenwich Hospital's transferring physician shall be responsible for the oversight of *en route* patient management. Upon arrival at YNHH the receiving physician or Emergency Department agrees to assume medical control and direction, all in accordance with applicable protocols and operating procedures.

5. All transfers shall be subject to each party's admission and discharge policies as well as their usual rules, regulations and other policies.

6. Each party will maintain required medical care and transfer documentation in accordance with state and federal statutes and regulations.

B. Patient Information

1. At the time of transfer, Greenwich Hospital shall provide YNHH with all the available information required by federal and state statutes and regulations, including but not limited to the reason for transfer, information about the patient's condition, the treatment given, the patient's status at the time of transfer, and any other available, relevant information, such as test results, x-ray films, and imaging studies. In addition, Greenwich Hospital should provide an initial diagnostic impression as well as whatever available patient information (the patient's name, address, hospital number, and the name, address, and the next of kin or other person responsible for the patient) that Greenwich Hospital may have.

2. In the event full patient information is not provided at the time of transfer and subsequently becomes available, Greenwich Hospital shall promptly transmit to YNHH.

3. Greenwich Hospital shall provide YNHH with all available information required for patient charges, including but not limited to demographic and financial data, in order to facilitate proper and efficient billing at YNHH for the services it renders. If YNHH obtains such information from another source, upon request from Greenwich Hospital, YNHH shall provide the information to Greenwich Hospital to assist it to properly bill for Greenwich Hospital's services.

4. If the patient is to be transferred back to Greenwich Hospital subsequent to treatment at YNHH, YNHH shall promptly provide Greenwich Hospital with summaries of medical records and other pertinent information.

C. Compliance with Applicable Federal and State Statutes and Regulations and Other Standards

1. The parties recognize that the Agreement and any patient transfers made in accordance with the Agreement are subject to applicable state and federal statutes and regulations, as well as any applicable accreditation and trauma center verification requirements. The parties agree to confirm their respective obligations under this Agreement in accordance with the applicable requirements.

D. Quality Assurance, Education and Research

1. Upon request, Greenwich Hospital shall cooperate with YNHH in the development and implementation of any patient trauma transfer quality assurance or research program (s).

2. Whenever possible, YNHH shall include Greenwich Hospital in trauma-related programs such as public education for injury prevention, outreach programs, and continuing education programs for trauma center staff, community nurses, physicians, and allied health personnel.

3. Periodically, the parties shall jointly participate in trauma review conferences and morbidity and mortality conferences relating to trauma care.

E. Insurance

At all times, each party shall maintain a full force and effect policies of professional and general liability insurance (or equivalent self-insurance mechanisms) insuring itself and its employees. Each party shall ensure that members of its medical staff who may not be employees are appropriately and adequately insured for professional liability. This insurance or equivalent self-insurance mechanism provides tail coverage for period of this Agreement.

F. Terms of Agreement and Termination

This Agreement shall commence on October 1, 2008, its "effective date", and shall run for a period of two years. This Agreement shall automatically renew itself for successive two year periods, unless terminated by either party by written notice given at least 90 days prior to the expiration of the then running period. Additionally, either party may terminate this Agreement at any time without cause by providing the other party with at least ninety (90) days advance written notice. This Agreement will terminate automatically should either party fail to maintain its license or accreditation.

G. Other Terms and Conditions

1. If any change in law or regulation would cause any provision of the Agreement to jeopardize either party's tax exempt status under section 501 (C)(3) of the Internal Revenue Code, the party at its option may terminate this Agreement. However, prior to such termination, the parties agree to use their best efforts to amend this Agreement, so as to confirm its intent to such applicable laws and/or regulations and to preserve their respective tax-exempt status without terminating this Agreement.

2. If any provision of this Agreement is determined by final decision of any administrative agency or court (after exhaustion of appeals or appeal rights) to be invalid or in violation of any law or regulation, such provision shall be severed from this Agreement and the remainder of this Agreement shall be given effect by the parties as if such provision never had been part of this Agreement.

3. This Agreement is not intended and shall not be construed to create any agency relationship between the parties. Furthermore, this Agreement is not intended and shall not be construed to create an exclusive transfer relationship between parties.

4. Each party shall directly bill any patient transferred hereunder (or the patient's payer) for its respective services rendered to the patient, and neither party shall be responsible to the other for payment for services rendered by the other.

5. Nothing contained in this Agreement is intended to nor shall be construed to create any third party rights for a patient or any other person or entity not a party to this Agreement.

6. This Agreement shall be construed and all of the rights, powers and liabilities of the parties shall be determined in accordance with the laws of the State of Connecticut.

7. This Agreement contains the whole understanding of the parties and supersedes all prior oral or written representations and agreements between the parties or between the parties and any of their representatives or staff as to the subject matter of this Agreement, and may not be varied except in a writing executed by the parties.

8. This Agreement may not be assigned by either party without prior written consent of the other party, except that upon advance written notice to the other party either party may assign this Agreement to a successor corporation that carries on all or substantially all of its business. Subject to the foregoing limitation upon assignment, this Agreement shall be binding upon and insure to the benefit of the successors and assigns of the parties.

9. To the extent that any of the services provided in accordance with this Agreement are deemed by the Secretary of the Federal Department of Health and Human Services of the U.S. Comptroller General, or the Secretary's or Comptroller's delegate, to be subject to the provisions of Section 952 of Public Law 96-499, the parties, until the expiration of four (4) years subsequent to the furnishing of services, shall make available upon written request of the Secretary or of the Comptroller, or any of their duly authorized representatives, this Agreement, and the books, documents and records of the parties that are necessary to certify the nature and extent of the charges to patients for service provided under this Agreement.

10. If either party carries out any of the duties of this Agreement through a Subcontract, with a value or cost of $10,000 or more over a twelve-month period, with a related organization (as that term is defined with regard to a provider in 42 C.F.R. Section 405.427(b), such subcontract shall contain a clause to the effect that until the expiration of four (4) years subsequent to the furnishing of services pursuant to such subcontract, the related organization upon written request shall make available to the Secretary or the Comptroller, or any of their duly authorized representatives, the subcontract, the books, documents and records of such organization that are necessary to verify the nature and extent of such costs.

11. To the extent that any of the provisions of Section G-9 and G-10 of this Agreement vary from any provision required by final regulations issued under the authority of Section 952 of Public Law 96-499, the provision required by the final regulation shall be deemed by the parties to supersede these sections and be made a part of this Agreement by reference.

12. If either party is requested to disclose any books, documents or records relevant to this Agreement for the purpose of an audit or investigation relating directly to the provision of services under this Agreement (e.g., a governmental investigation of billing practices or trauma services provided to patients), such party shall notify the other party of the nature and scope of the request and, to the extent permitted, shall make available to the other party, upon written request, relevant books, documents or records.

13. The headings, titles and captions used in this Agreement are merely for the convenience of the parties and are not intended to add to, subtract from, or in any other manner modify or affect the construction of the substantive terms of this Agreement.

14. This Agreement shall be executed in a least two counterparts, each of which shall be deemed an original, but all such counterparts shall together constitute one and the same instrument. It shall not be necessary in making proof of this Agreement to produce or account for more than one counterpart.

In witness hereof, the authorized representatives of YNHH and Greenwich Hospital do hereby execute this Transfer Protocol and Agreement.

Greenwich Hospital

_____ Date 10/8/08
Name: Frank Corvino
Title: CEO

_____ Date 10/7/08
Name: Brian J. Doran, MD
Title: Director, Emergency Medicine

Yale New-Haven Hospital

_____ Date 9/22/08
Name: Tucker Leary
Title: Vice President Administration

_____ Date 9/23/08
Name: Carla Carusone
Title: Manager, Section of Trauma, Surgical Critical Care & Surgical Emergencies

YALE NEW HAVEN HEALTH

May 14, 2012

RECEIVED
MAY 14 2012

Ms. Kimberly Martone, Director of Operations
Office of Health Care Access
410 Capital Avenue, MS #13HCA
P. O. Box 340308
Hartford, CT 06106

RE: Certificate of Need Application; Docket Number: 12-31748-CON
Yale-New Haven Hospital and Greenwich Hospital
Proposal to Establish and Operate an Elective Angioplasty
Program without Onsite Surgical Backup at Greenwich Hospital

Dear Director Martone,

Enclosed please find Greenwich and Yale-New Haven Hospitals' responses to the completeness questions posed by the Office of Health Care Access (OHCA) on March 15, 2012.

Please do not hesitate to contact me at (203) 688-2609 with any questions.

Thank you for your time and consideration of this project.

Sincerely,

Jean Ahn
System Director, Planning & Business Development

Enclosures

cc: William Aseltyne, Esq.

789 Howard Avenue
New Haven, CT 06519

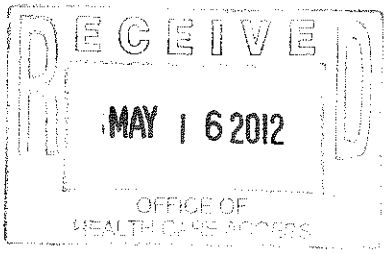
Huber, Jack

From: Bahner, Louise <Louise.Bahner@ynhh.org>
Sent: Wednesday, May 16, 2012 12:04 PM
To: Huber, Jack
Subject: DN 12-31748-CON
Attachments: DN 12-31748 Page 585.pdf

Hi, Mr. Huber. When the responses for the above captioned DN were delivered on Monday, some of the page numbers on the Table of Contents (Page 585) were incorrect. Would it be possible to substitute the attached page for the one that was delivered on Monday? Thanks. Louise

Louise Bahner
Assistant Planner
Planning and Business Development
Yale-New Haven Hospital
20 York Street
New Haven, CT 06504
Phone: 203-688-7545
Fax: 203-688-5013

This message originates from the Yale New Haven Health System. The information contained in this message may be privileged and confidential. If you are the intended recipient you must maintain this message in a secure and confidential manner. If you are not the intended recipient, please notify the sender immediately and destroy this message. Thank you.



Greenwich Hospital
Yale-New Haven Hospital

Certificate of Need Application: Proposal to Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital
Docket Number: 12-31748-CON

Responses to Completeness Questions
Table of Contents

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II	Draft Greenwich Hospital Protocols related to Elective Angioplasty without Cardiac Surgery Backup	604-610
III	*New England Journal of Medicine* Article: "Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery"	611-622
IV	Greenwich Hospital-Yale-New Haven Hospital Transfer Protocol and Agreement	623-626

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Greenwich Hospital
Yale-New Haven Hospital

Certificate of Need Application: Proposal to Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital
Docket Number: 12-31748-CON

Responses to Completeness Questions

Clear Public Need – pages 15 through 29

1. With respect to the state map presented on page 18 of the CON application, please provide a map legend and notes of a legible size as the applicant's presentation is difficult to discern.
   Response
   A large size map along with a legend and notes has been provided in Attachment I.

2. With respect to the table entitled "Number of Patients Discharged Directly from GH to Another Institution for Elective Angioplasty" on page 19 of the CON application, please address the following:
   a. Identify the distance in miles and travel time between Greenwich Hospital and each of the other six hospitals to which Greenwich Hospital transferred patients requiring elective angioplasty over the last four and a quarter fiscal year period.
   Response
   The table below summarizes the distance in miles and travel time between Greenwich Hospital and each of the other six hospitals to which Greenwich Hospital transferred patients requiring elective angioplasty.

Hospital	Address	Distance from GH (Miles)	Travel Time from GH (Minutes)
CT Hospitals:			
Stamford Hospital	**30 Shelburne Road, Stamford, CT**	**6 miles**	**13 minutes**
West Haven VA	**950 Campbell Avenue, West Haven, CT**	**44 miles**	**56 minutes**
Yale-New Haven Hospital	**20 York Street, New Haven, CT**	**46 miles**	**60 minutes**
NY Hospitals:			
Westchester Medical Center	**100 Woods Road, Valhalla, NY**	**15 miles**	**24 minutes**
NY Presbyterian –	**525 E. 68th**	**30 miles**	**45 minutes**

Hospital	Address	Distance from GH (Miles)	Travel Time from GH (Minutes)
Weill Cornell	**Street, New York, NY**		
NY Presbyterian – Columbia	**630 West 168th Street, New York, NY**	**27 miles**	**39 minutes**

Source: MapQuest

b. Describe the existing referral patterns that have resulted in 232 patients needing elective angioplasty, not being able to access this service and being transferred to other Connecticut hospitals; 235 to Yale-New Haven Hospital and 2 to Stamford Hospital over four and a quarter fiscal year period.

Response

Greenwich Hospital is a member of the Yale New Haven Health System and has been for more than twelve years. The medical staff at Greenwich Hospital has developed long-standing referral relationships with the physician specialists at the Yale School of Medicine (YSM), who practice at Yale-New Haven Hospital. In the area of cardiology, Yale School of Medicine faculty physicians have been providing clinical oversight and coverage at Greenwich Hospital since the primary angioplasty service began in February 2005. Dr. Christopher Howes and Dr. John Setaro, both Yale School of Medicine physicians, have practices at Greenwich Hospital. Each physician is at Greenwich Hospital for three, 12-hour days each week. Drs. Howes and Setaro are interventional cardiologists and perform the majority of emergency angioplasty procedures at Greenwich Hospital. Drs. Howes and Setaro and their colleagues from YSM have strong referral relationships with internists and medical cardiologists in the Greenwich Hospital service area.

In regard to the two cases transferred to Stamford Hospital, the two patients were transferred due to patient/family and physician preference reasons.

3. The Applicants point out that "…transferring patients to another facility creates an unnecessary stressful and uncomfortable situation for patients and family." Further "transferring to another facility is an increased stress for the patients and their families with regard to transportation. For some, in Greenwich Hospital's greater service area, transportation outside the service area is problematic." This being the case, why is Yale-New Haven Hospital the institution of choice when transferring a patient requiring elective angioplasty, as Stamford Hospital presents a much closer Connecticut alternative hospital site?

Response

As described in response to question 2, Yale School of Medicine physicians are providing the emergency angioplasty services at Greenwich Hospital and have strong referral relationships with internists and medical cardiologists in the

Greenwich Hospital service area. In cases where a patient must be transferred, the decision regarding which hospital is based on a number of factors including the reasons for transfer, the Greenwich Hospital physician's suggested referral, the patient's preferred choice, and the patient's clinical condition. In the overwhelming majority of cases, patients prefer transfer to Yale-New Haven Hospital so that their care may continue to be provided by YSM interventional cardiologists. YNHH's cardiac catheterization laboratory has excellent outcomes and a proven track record of quality. The familiarity, trust and respect that exist between GH and the YSM physicians are the foundation of the existing referral patterns. In addition, because both hospitals are part of the same health system and share information technology systems, angiograms done at GH can immediately be viewed at YNHH which aids in the preparation and initiation of treatment for the patient being transferred.

In addition to the close collaboration between cardiologists at YNHH and Greenwich Hospital, a similar relationship exists between the cardiologists and the cardiac surgeons at YNHH. YNHH's cardiac surgery program offers the latest surgical techniques and equipment and routinely performs many complex surgeries such as Transplants, Left Ventricular Assistive Devices (LVAD), Hypothermic Circulatory Arrest, and Transcatheter Aortic Valve Implantation (TAVI). The YNHH cardiac surgery program capabilities are often preferred by patients and referring physicians and these requests are pursued in cases where transport to YNHH can be done safely. If transport cannot be completed safely, patients would be transported to the closest appropriate facility.

The cardiac care offered by both Greenwich Hospital and YNHH provides a comprehensive cardiac network of services for Greenwich Hospital's service area population. The lack of elective angioplasty at Greenwich Hospital results in disruptive care for patients. Under the current arrangement, Greenwich Hospital patients have to be transferred to other hospitals for elective angioplasty procedures even though experienced YSM interventional cardiologists and catheterization lab support staff are onsite and available 24 hours every day to provide the needed care at Greenwich Hospital. The vast majority of patients are transferred to Yale-New Haven Hospital, where they are treated by the same physicians from whom they would have received the same care at Greenwich Hospital if Greenwich Hospital was approved to provide elective angioplasty.

The physicians at Stamford Hospital are not members of YSM and generally do not have existing referral relationships with most of the Greenwich Hospital physicians. The medical staffs at the two hospitals are quite distinct and there are only a handful of physicians who treat patients at both locations. Patient town of origin data also differs between Stamford and Greenwich Hospitals. According to the CHIME data, the majority (~73%) of patients treated at Stamford Hospital's cardiac catheterization laboratory live in the cities of Stamford and Norwalk and the town of Darien, whereas, Greenwich Hospital's patient population is primarily from Greenwich and Westchester County towns.

It is important to note that the stress and in some cases, transportation difficulties, result due to the transfer itself, not necessarily the distance or time in an ambulance or the distance between Greenwich Hospital and the referral hospital. It is disruptive for patients to be admitted to one institution and then have to be transferred. Of course, there are times when this cannot be avoided, but in the case of elective angioplasty, there are approximately 50 patients each year who would not have to be transferred to another hospital if Greenwich Hospital could perform elective angioplasty. In addition to the patients who are transferred for PCI, there is another subset of patients (approximately 10-20) who do not receive a PCI but who are transferred for an invasive Fractional Flow Reserve (FFR) or Intravascular Ultrasound (IVUS) to further clarify their anatomy. The Hospital has the latest equipment, experienced staff, expert physicians and modern infrastructure to perform emergency angioplasty and these resources are underutilized. The costs, stress and disruptions to care that result in having to transfer these patients now can be avoided.

4. With respect to the table entitled Population Projections – Greenwich Hospital Service Area on page 27 of the CON application, please provide two tables in the same format, the first depicting the population projections for the state of Connecticut and the second depicting the population projections for the state of New York

Response

Two tables are provided below depicting population projections for Connecticut and New York service area towns as requested.

The Applicants wish to emphasize that as a hospital located on the border of Connecticut and New York (Westchester County), a significant portion of the Hospital's volume (>40%) comes from residents of Westchester County, New York. The Hospital's service area is inclusive of the Connecticut and New York towns as outlined in the CON application on page 24. Greenwich Hospital's unique location on the border and its significant role in providing health care services to many Westchester County residents provides a significant benefit to the State of Connecticut in terms of attracting New York residents and health care revenues to the State.

Population to Be Served - CT					
				% Change	
Area & Age Cohort	2000	2011	2016	2000 - 2011	2011 - 2016
CT Service Area Towns					
0-44	220,400	212,035	206,731	-3.8%	-2.5%
45-54	50,513	61,303	57,366	21.4%	-6.4%
55-64	34,245	45,513	52,234	32.9%	14.8%
65-74	25,419	27,515	32,866	8.2%	19.4%
75-84	16,806	16,619	16,574	-1.1%	-0.3%
85+	6,346	7,863	8,590	23.9%	9.2%
Total	**353,729**	**370,848**	**374,361**	**4.8%**	**0.9%**
% 45+	37.7%	42.8%	44.8%		
% 65+	13.7%	14.0%	15.5%		

Population to Be Served - NY					
NY Service Area Towns					
0-44	265,678	251,755	247,369	-5.2%	-1.7%
45-54	60,434	70,382	66,305	16.5%	-5.8%
55-64	41,106	55,530	63,165	35.1%	13.7%
65-74	30,793	32,697	39,550	6.2%	21.0%
75-84	20,403	20,685	20,512	1.4%	-0.8%
85+	8,295	10,311	11,293	24.3%	9.5%
Total	**426,709**	**441,360**	**448,194**	**3.4%**	**1.5%**
% 45+	37.7%	43.0%	44.8%		
% 65+	13.9%	14.4%	15.9%		

5. Please address the following questions regarding existing providers of elective angioplasty closest to the Hospital and its service area:
   a. Please identify all providers that currently offer Elective Angioplasty.

      Response

      The following providers currently offer elective angioplasty in GH's service area:

      Connecticut service area towns:
      Stamford Hospital
      Stamford, CT

      New York service area towns:
      White Plains Hospital
      White Plains, NY

   b. Identify the existing providers that currently offer elective angioplasty with on-site surgical backup.

Response
The following providers offer elective angioplasty with on-site surgical backup in GH's service area:

Connecticut service area towns:
Stamford Hospital
Stamford, CT

New York service area towns:
None

c. What impact will this proposal have on these existing providers financially and on their elective PCI utilization?
Response
As stated in the Applicants' original CON submission on page 28, the vast majority of patients who must be transferred from Greenwich Hospital to another hospital for elective angioplasty are transferred to Yale-New Haven Hospital. The absence of GH's transfer cases at YNHH will not negatively impact YNHH since its cardiac catheterization laboratories perform a large number of procedures and the volume from GH is a small percentage of YNHH's overall volume.

The additional volume proposed is expected to result from physicians who currently bypass GH and send patients to New York hospitals. Greenwich Hospital physicians interviewed indicated they generally do not refer patients to Stamford Hospital and therefore the proposed program is not expected to have a negative impact on Stamford Hospital elective angioplasty volume.

6. Provide a copy of the Hospital's protocols related to the proposed elective angioplasty without cardiac surgery backup. Additionally, explain any protocols that will be specific to this program.
Response
A copy of the draft protocols related to the proposed elective angioplasty without cardiac surgery backup is included as Attachment II.

2011 ACCF/AHA/SCAI Guidelines for Percutaneous

Coronary Intervention-pages 140-230

7. In regard to the Attachment VI: 2011 ACCF/AHA/SCAI Guidelines for Percutaneous Coronary Intervention, please address the following questions:

a. How does the Hospital meet each of the criteria listed in Class IIa, IIb, III and tables 5 & 6?

Response

In regard to Class III, as stated in response to question 7.c. below, since elective angioplasty without cardiac surgery back-up is classified as a Class IIb recommendation in the Guidelines, the Class III references are not applicable. Please refer to page 144 of the original CON application for a summary table of Classification of Recommendations and Level of Evidence, as included in the 2011 ACCF/AHA/SCAI Guidelines for PCI.

With regard to the 2011 PCI Guidelines, section 4.8, PCI in Hospital Without On-Site Surgical backup: Primary PCI for MI has a Class IIa recommendation, and this program has been in place at GH since 2005 and has worked well with an excellent record in all respects. However, the proposed elective PCI program without cardiac surgery backup is a Class IIb recommendation and therefore the Class IIa recommendation does not apply. In addition, the majority of available literature supports this recommendation, including a recent publication in the March 2012 issue of the *New England Journal of Medicine* entitled "Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery" by Aversano, Lemmon & Liu (please see Attachment III).

Through its emergency PCI program, GH provides highly experienced operators (10 participating YSM Senior Interventional Cardiologists with 156 years combined experience as Attending Operators, performing nearly 50,000 PCIs at a high volume tertiary academic medical center since the inception of the YSM program in 1985). Success and complication rates of the YSM interventional cardiologists are equal or superior to those of national registries.

The relevant criteria for the proposed program are listed in Tables 5 and 6 and represent recommendations from an expert consensus document from the Society for Cardiovascular Angiography and Interventions (2007). These recommendations have been incorporated into the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention.

The table below summarizes each of the items listed in Tables 5 and 6 and Greenwich Hospital's status.

Table 5.	
SCAI Expert Consensus Document Personnel and Facility Requirements for PCI Programs Without On-Site Surgical Backup	**Description of Greenwich Hospital's Compliance**

Table 5.	
SCAI Expert Consensus Document Personnel and Facility Requirements for PCI Programs Without On-Site Surgical Backup	**Description of Greenwich Hospital's Compliance**
Experienced nursing and technical laboratory staff with training in interventional laboratories. Personnel must be comfortable treating acutely ill patients with hemodynamic and electrical instability.	Greenwich Hospital's Cath Lab staff consists of highly trained and experienced nurses and technologists. They are dedicated to the cath lab and cardiology department and are skilled and comfortable treating acutely ill patients with hemodynamic and electrical instability. Greenwich Hospital already cares for the most acutely ill of these patients through its established PAMI program. Nurses and technicians are on a rotation to spend time at Yale-New Haven Hospital's Cath Lab where they receive further training, education and experience.
On-call schedule with operation of laboratory 24 hours per day, 365 days per year.	Greenwich Hospital has an agreement with the Yale School of Medicine (YSM) to provide 24/7, 365 coverage. Greenwich has 2 YSM physicians who primarily practice and cover call at Greenwich Hospital. They are covered by additional YSM Interventional Cardiologists. There will be no need to add staff to this on-call schedule.
Experienced coronary care unit nursing staff comfortable with invasive hemodynamic monitoring, operation of temporary pacemaker, and management of IABP. Personnel capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.	Greenwich Hospital has experienced intensive care unit nursing staff that already cares for PAMI patients. Greenwich Hospital has on-site personnel capable of endotracheal intubation and ventilator management. If patients require transfer, ALS paramedics who are capable of endotracheal intubation and ventilator management provide care during transport.
Full support from hospital administration in fulfilling the institutional requirements, including appropriate support services (e.g.	Greenwich Hospital's Administration is in full support of the program. The needed resources are in place, including 24 hour

Table 5.	
SCAI Expert Consensus Document Personnel and Facility Requirements for PCI Programs Without On-Site Surgical Backup	**Description of Greenwich Hospital's Compliance**
respiratory care, blood bank).	respiratory care and a full service blood bank.
Written agreements for emergency transfer of patients to a facility with cardiac surgery. Transport protocols should be developed and tested a minimum of 2 times per year.	Please see Attachment IV for written transfer agreement between Yale-New Haven and Greenwich Hospitals.
Well-equipped and maintained cardiac catheterization laboratory with high resolution digital imaging capability and IABP equipment compatible with transport vehicles. The capability for real-time transfer of images and hemodynamic data (via T-1 transmission line) as well as audio and video images to review terminals for consultation at the facility providing surgical backup is ideal.	Greenwich Hospital has a state-of-the-art Cath Lab which has all of the equipment and capabilities mentioned including the ability to directly transfer images to tertiary care centers.
Appropriate inventory of interventional equipment, including guide catheters, balloons, and stents in multiple sizes; thrombectomy and distal protection devices; covered stents, temporary pacemakers; and pericardiocentesis trays. Pressure wire device and IVUS equipment are optimal but not mandatory. Rotational or other artherectomy devices should be used cautiously in these facilities because of the greater risk of perforation.	Greenwich Hospital currently has a complete inventory of all of these items. Greenwich Hospitals does not use and does not plan to use at this time, rotational or other atherectomy devices due to the risk of perforation.
Meticulous clinical and angiographic selection criteria for PCI (Tables 6 and 7)	Greenwich Hospital would plan to operate an Elective Angioplasty program with the appropriate level of conservative case selection. The program would adhere to all standards in table 6 & 7.
Performance of primary PCI as the treatment of first choice for STEMI to ensure streamlined care paths and increased case volumes. Door to	Each of these items is already in place through Greenwich Hospital's established PAMI program. Door to balloon times are

Table 5.	
SCAI Expert Consensus Document Personnel and Facility Requirements for PCI Programs Without On-Site Surgical Backup	**Description of Greenwich Hospital's Compliance**
balloon times should be tracked, and <90 min outlier cases should be carefully reviewed for process improvement opportunities. On-site rigorous data collection, outcomes analysis, benchmarking, quality improvement, and formalized periodic case review.	tracked and all cases are reviewed via a PCI report card (including outlier and non-outlier cases). Onsite data collection exists and GH examines benchmarks and outcomes via the ACC NCDR Cath PCI registry. Formalized case review is conducted via a regularly scheduled Cath Conference session.
Participation in a national data registry where available, such as the ACC NCDR in the United States.	Greenwich Hospital participates in the Cath PCI registry through ACC NCDR.

Table 6. Interventional cardiologists establish a working relationship with cardiac surgeons at the receiving facility	
SCAI Expert Consensus Document Requirements for Off-Site Surgical Backup	**Description of Greenwich Hospital's Compliance**
1. Cardiac Surgeon must have privileges at the referring facility to allow review of treatment options as time allows.	Currently there are 3 cardiac surgeons with privileges @ Greenwich Hospital. All of these surgeons are from YNHH where the majority of surgical candidates are transferred. GH will approach cardiac surgeons from other cardiac surgery facilities in order to provide them with privileges in the event of transfer.
2. Cardiac Surgeon and receiving hospital agree to provide cardiac surgical backup for urgent cases at all hours and for elective cases at mutually agreed hours.	YNHH currently provides cardiac surgical backup services for urgent cases from Greenwich Hospital's established PAMI program. These services are available 24 hours per day, 7 days per week and 52 weeks per year.

Table 6. Interventional cardiologists establish a working relationship with cardiac surgeons at the receiving facility	
SCAI Expert Consensus Document Requirements for Off-Site Surgical Backup	**Description of Greenwich Hospital's Compliance**
3. Surgeon and receiving facility ensure that patients will be accepted based on medical condition, capacity of surgeon to provide services at the time of request, and availability of resources. If this cannot be ensured before the start of an elective procedure, the case should be done at this time.	The current agreement with YNHH and Greenwich Hospital (PAMI program) ensures that any patient in need of urgent cardiac surgery will be accepted. Agreements with Westchester Medical Center and Stamford Hospital are being pursued.
4. Interventional cardiologists must review with surgeons the immediate needs and status of any patient transferred for urgent surgery.	This process already occurs in Greenwich Hospital's established PAMI program.
5. Hospital administrations from both facilities endorse transfer agreement.	As evidenced by the agreement between YNHH and Greenwich Hospital (included in Attachment IV), administration from both facilities endorse the agreement.
6. Transferring and receiving facilities establish a rigorous protocol for rapid transfer of patients, including the proper personnel, with appropriate experience.	These protocols are in place between YNHH and Greenwich Hospital for its established PAMI program.
7. A transport provider is available to begin transport within 20 minutes of the request and provide vehicle/helicopter with necessary life sustaining equipment, including IABP and monitoring capability.	Access Ambulance has committed to transport within 20 minutes.
8. Transferring physician obtains consent for surgery from patient or appropriate surrogate.	If given approval to perform Elective Angioplasty, GH will fully comply with this standard.

Table 6. Interventional cardiologists establish a working relationship with cardiac surgeons at the receiving facility	
SCAI Expert Consensus Document Requirements for Off-Site Surgical Backup	**Description of Greenwich Hospital's Compliance**
9. Initial informed consent for PCI discloses that the procedure is being done without on-site surgical backup and acknowledges the possibility of risks related to transfer. The consent process should include the risk of urgent surgery (approximately 0.3%) and state that a written plan for transfer exists.	If given approval to perform Elective Angioplasty, GH will fully comply with this standard. Greenwich Hospital will provide informed consent which discloses the procedure is done without onsite surgical backup and the possibility of risks related to transfer. The consent process will also include the risk of urgent surgery (~0.3%) and state that a written plan for transfer exists.
10. As part of the continuous quality improvement program, a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of any improvement opportunities.	If given approval to perform Elective Angioplasty, GH will fully comply with this standard.

b. How does the Hospital plan to meet the guidelines regarding the rapid transport to a cardiac surgery operating room in a nearby hospital and without hemodynamic support to transfer?

Response

Greenwich Hospital has been successfully transferring critically ill patients for the past five years. The institution has the ability to utilize Intra-Aortic Balloon Pumps and has successfully utilized them when appropriate. The Hospital has an agreement with Access Ambulance to rapidly transport patients within 20 minutes who are in need of additional care. The process used is efficient and safe and there has not been a fatality to date during transport.

c. How do ACCF/AHA/SCAI guidelines define "nearby" hospital/operating room?

Response

The guidelines do not define "nearby". The use of the term "nearby" pertains to Class III recommendations. Elective angioplasty without cardiac

surgery back-up is classified as a Class IIb recommendation in these guidelines and therefore the Class III references are not applicable.

d. How does the Hospital's transport agreement with YNHH (where majority of the patients have been transferred in the past) relate to or meet the guidelines?
Response
Agreement (see Attachment IV) indicates that patients requiring transport can go to the nearest cardiac surgery facility or to YNHH or Bridgeport Hospital. As previously noted, Greenwich Hospital will transfer patients to other cardiac surgery programs, such as Westchester Medical Center and Stamford Hospital if requested by a patient or family member or if there is an imminent crisis and the patient must be sent to the closest cardiac surgery facility.

e. The Hospital's median time to immediate PCI for STEMI patients is 67.0 minutes. As reported in the ACC-NCDR report (Attachment XI of the CON application) all hospitals in the 90th percentile have a median time to immediate PCI for STEMI patients of 50.4 minutes. How does Hospital's median time relate to the ACCF/AHA/SCAI guidelines published in November 2011?
Response
Greenwich Hospital's median time of 67 minutes to immediate PCI for STEMI patients meets the ACCF/AHA/SCAI guidelines which specify that for primary PCI in patients with STEMI who present to a hospital with PCI capability, the PCI should be performed within 90 minutes of first medical contact (also referred to as door-to-balloon time).

8. The Applicants state on page 15, that the Hospital "must address the cost-effectiveness of angioplasty services." Please address how this goal of the Applicants is consistent with the statement in Class III, which states that desires for personal or institutional financial gain…are not appropriate consideration(s) for initiation of a PCI program without on-site cardiac surgery.
Response
As noted previously, elective angioplasty without cardiac surgery back-up has received a Class IIb recommendation in the 2011 ACCF/AHA/SCAI guidelines. Therefore, the discussion included above under Class III is not relevant. However, it should be stressed that Greenwich Hospital's financial considerations for the proposed program address cost-effectiveness and not institutional financial gain. The current primary angioplasty program is extremely costly to operate. GH has been committed to providing this life-saving program to the community despite the associated cost and operating losses. However, as hospitals continue to see reimbursement cuts and rising costs, the primary angioplasty program may be at risk for continued operation. By offering an elective angioplasty program along with the primary program, the additional case volume and associated revenues will help to offset the significant fixed costs which exist for the primary program alone and would help to fortify the primary PCI program and ensure its continued

survival for this necessary service needed by the community served by Greenwich Hospital.

Although financial viability is always of concern, the motivation of the elective program is not to establish the proposed program for reasons of institutional financial gain, prestige, market share, or to intensify competition for patients with respect to other institutions (as noted in Class III in the guidelines). The impetus of the program is to provide superior care to the Greenwich community patients by maximizing continuity of care and lessening fear, and anxiety to patients and their families inherent with a transfer process whether the patients are transferred 5 miles or 500 miles as the transfer is disruptive to care and traumatic to patients. The current population served through Greenwich Hospital's primary angioplasty program is limited to patients that present on an emergent basis with ST segment elevation MI or new onset left bundle branch block. This proposal would provide local access to patients requiring interventional cardiology services on an elective and urgent basis as well as the emergent patients who currently have access to these services. The facility, physicians, staff and equipment required to provide elective angioplasty services are already in place at Greenwich Hospital. The current practice of transferring patients who require elective angioplasty has potential negative implications to patient care quality and safety. As well, the majority of these patients are transferred to Yale-New Haven Hospital, where they are treated by the same physicians from whom they would have received the same care at Greenwich Hospital if Greenwich Hospital was approved to provide elective angioplasty.

It is also important to note the financial (as well as emotional) cost to the patients and their families, as well as the added costs to the overall healthcare system by requiring transfer to another facility. As stated above, the Hospital already has the latest equipment, experienced staff, expert physicians and modern infrastructure to perform emergency angioplasty, and therefore, there would be no additional costs for the proposed program. On the other hand, patient transfer requires patients to undergo two procedures rather than one, which increases the cost of care, which could be avoided with the proposed program. Specifically, service area residents who obtain a cardiac catheterization at Greenwich Hospital and require a subsequent angioplasty procedure must undergo two invasive procedures at two institutions. This practice increases the costs of care to patients and payers and ultimately to the health care system as a whole. Patients have to incur the additional out of pocket costs for the second procedure as well as additional transportation costs for themselves and possibly also family members. As an example, the cost of a helicopter ride, if one is needed, is approximately $6,500 plus $100 per mile. An ambulance ride costs $1,177. Additionally there are staff costs related to arranging the patient transfer. With patients receiving two procedures at two separate institutions, payers have increased expenses for the care provided to patients. On average, the hospital facility fee (non-inclusive of the physician fee) is approximately $7,000 per procedure. Aversano, Lemmon & Liu (2012) in their recent NEJM publication on the results of the CPORT-E trial showed that the number of catheterization visits required to complete PCI is 1.73 for programs with on-site

surgery vs. 1.28 for programs without. The study states this higher number is probably due to the impact of cases that had to be transferred to a site with cardiac surgery and thus required an additional cardiac catheterization. Eliminating a second invasive cardiac procedure would improve the cost-effectiveness of angioplasty services for service area residents. In addition, through the fuller use of its existing angioplasty infrastructure at Greenwich Hospital, including physicians and staff, more efficient care and enhanced patient quality and safety will result.

9. The guidelines state that "competition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interests of the community." Please address your proposal in relation to this statement while taking into consideration the existing providers of elective angioplasty in the Hospital's service area (and geographic) (in CT and NY).

Response

As noted in the response to question 8, elective angioplasty without cardiac surgery back-up has received a Class IIb recommendation in the 2011 ACCF/AHA/SCAI guidelines. The reference noted above is contained under Class III and therefore is not relevant. The only programs in the same geographic area are Stamford Hospital and White Plains Hospital. As has been already discussed, GH's referring physician base differs from Stamford Hospital and projected elective angioplasty volume will come from cases now sent to Yale-New Haven Hospital or to New York hospitals.

The motivation of the program is to provide superior care to the Greenwich community patients by maximizing continuity of care and lessening fear and anxiety to patients and their families inherent with a transfer process whether they are transferred 5 miles or 500 miles as the transfer is disruptive to care and traumatic to patients. The clinical and operational infrastructure to provide a high quality full-service cardiac program already exists at Greenwich Hospital, and will be enhanced by the ability to offer elective angioplasties. Greenwich Hospital is already performing angioplasty on more acutely ill patients through its primary angioplasty program and the staff and physicians are well prepared to perform elective angioplasty for less acute patients.

10. Considering that the Hospital does not have access to a helicopter, explain how it expects to meet the protocols related to emergency transportation to a cardiac facility with a cardiac surgery program. In particular, discuss the Hospital's transfer agreement with its affiliate YNHH in this matter.

Response

Greenwich Hospital currently has a land and air transport systems in place for any of its patients requiring emergency transport to another hospital. GH does have access to a medical helicopter located at Westchester Airport which is approximately 7 miles (15 minutes) from GH. Patients are transported via ambulance to the medical helicopter when required. In cases where air transport is not possible, such as inclement weather, land transportation is provided by a local ambulance service that offers advanced life support and IABP capabilities. This

existing land and air transport system will also apply to the elective angioplasty population in need of transport.

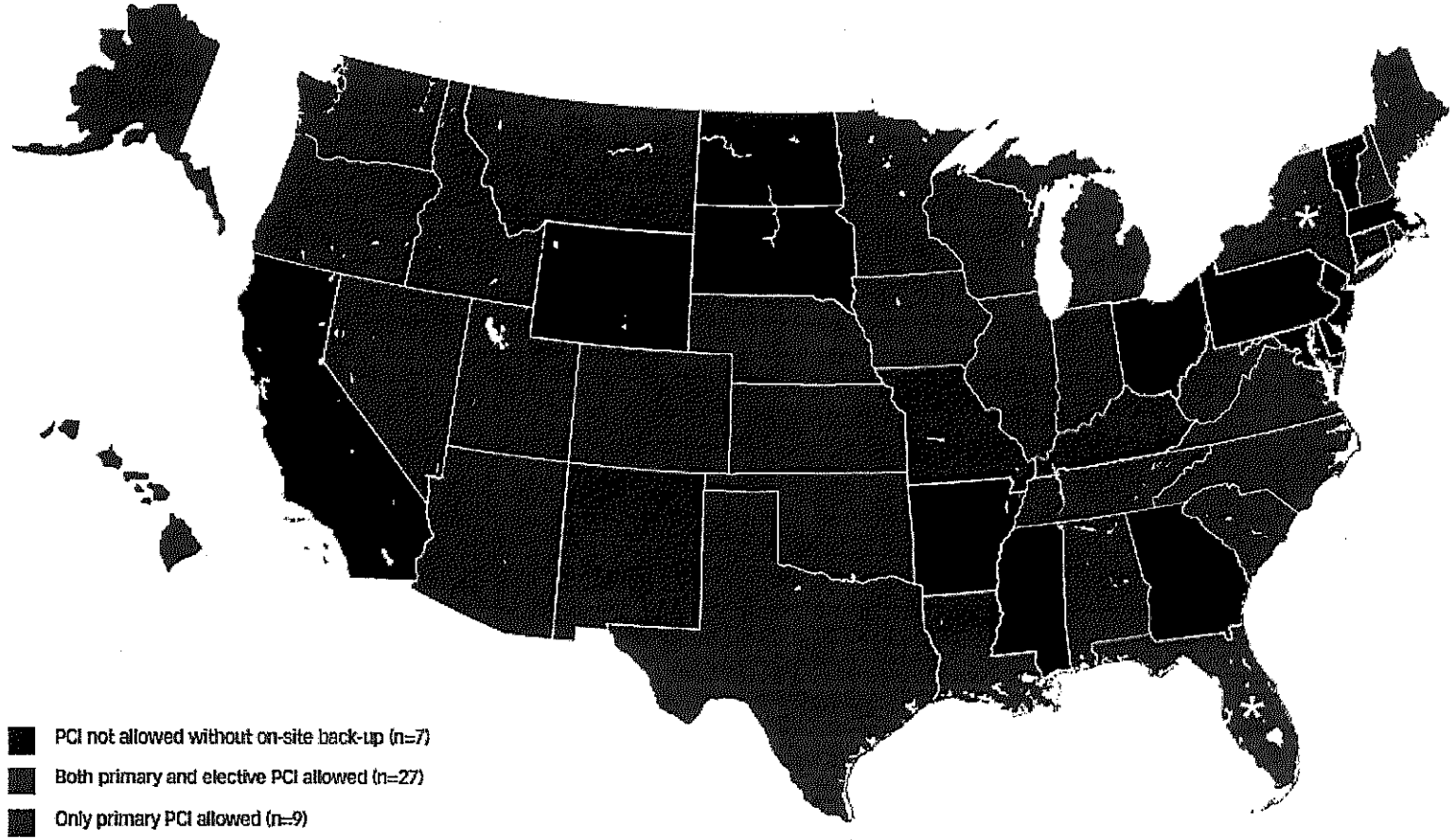
Section A. 3. of the transfer agreement with YNHH is copied below (see Attachment IV), which states that Greenwich Hospital physicians in consultation with YNHH's receiving physician, shall determine selection of the most appropriate transportation:

Greenwich Hospital's transferring physician shall provide necessary medical treatment within the capabilities of the staff and facilities available at Greenwich Hospital in order to minimize the risks of transfer to the patient's health, and in consultation with YNHH's receiving physician, shall determine the selection of appropriate transportation and the level of care required for appropriate management of the patient *en route* to YNHH.

Attachment I

Large Map (from page 18 of CON Application DN 12-31748-CON)

Figure 1: Status of Percutaneous Coronary Intervention without On-site Cardiac Surgical Back-up in the US



There are now only seven states (Arkansas, Delaware, Mississippi, North Dakota, South Dakota, Vermont, and Wyoming) where neither primary nor elective percutaneous coronary intervention (PCI) is allowed without on-site surgery. Legislation is pending in California to allow a carefully monitored demonstration project of elective PCI without on-site back-up. Primary PCI without on-site surgery is allowed in Washington, but not elective PCI. However, Washington has a liberal definition of emergency PCI such that patients with acute coronary syndromes and non-ST-segment elevation myocardial infarction who have stabilized are allowed to undergo PCI at facilities without on-site surgery. Florida and New York both have rule changes pending to allow both primary and elective PCI at selected facilities without on-site surgery. Modified from Dehmer et al., 2007.[19]

Attachment II

Draft Greenwich Hospital Protocols related to Elective Angioplasty without Cardiac Surgery Backup

Greenwich Hospital Greenwich, Connecticut 06830	PATIENT CARE SERVICES POLICY AND PROCEDURE		
Title: **PERCUTANEOUS CORONARY INTERVENTION (ANGIOPLASTY)**			Policy #: CC-13
Date Issued: : 8/2004	Date Reviewed/Revised: :06/2010, 10/2011, 4/2012	Approved By: Medical Director, Interventional Cardiology Senior VP, Patient Care Services	Page 1 of 5
Contact: Clinical Coordinator, Cardiology			

PURPOSE: Balloon angioplasty of the coronary artery and stents (percutaneous coronary intervention, PCI) is a non-surgical procedure that relieves narrowing or obstruction of the arteries to the muscle of the heart. PCI can relieve chest pain (angina), minimize or stop a heart attack, or improve the prognosis of patients with unstable angina. The risk of a failed PCI, requiring emergent surgical intervention is rare, but a recognized risk of the procedure. An emergent transfer procedure is in place and has been used effectively.

POLICY: Coronary angioplasty is performed at Greenwich Hospital by authorized personnel.

PROCEDURE:

RN: **A. Equipment/Supplies:**

1. Complete Emergency Equipment Checklist
   a. Defibrillator
   b. Code cart
   c. Oxygen
   d. Suction Equipment
   e. I – Stat machine and cartridges
   f. Temporary Pacemaker Pulse Generator
   g. 4 or 5 French Pacing Catheter
2. Prepare/Obtain Medications
   a. Lidocaine 1% - 1 vial
   b. Sodium Bicarbonate 8.4% - 1 vial
   c. Heparin flush (1000cc 0.9% NS with 2000 units Heparin) premixed - 2 bags
   d. Medications for Sedation - Fentanyl and Versed

B. **Preparation of Patient on arrival to Cardiac Catheterization Lab:**

1. Use two patient identifiers: Name and date of birth or medical record number to verify patient identification
2. Explain pre-, intra- and post-procedure expectations to patient and/or family
3. Check patient allergies, respiratory and neuro status

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4. Obtain height and weight
5. Check NPO status
6. Check bilateral distal pulses – dorsal pedis and posterior tibial and/or radial pulses
7. Check patency of intravenous line
8. Connect NS 0.9% 500cc at KVO to IV if not already in place
9. Check lab values, if available
    a. CBC
    b. BUN, Creatinine
    c. Lytes
    d. Coagulation Studies (if relevant)
    e. Cardiac Enzymes
    f. Calculate creatinine clearance
10. Check for signed consent
11. History and physical in chart
12. Transfer patient to procedure table
13. Attach patient to monitoring equipment
14. Obtain a set of baseline vital signs and attach patient to O2 – per Physician order
15. Universal Procedure Verification performed by all team members of the procedural team per protocol
16. Administer pre-medications sedation, Fentanyl and Versed, per Physician order and Moderate Sedation/Analgesia for Diagnostic and Therapeutic Procedures
17. Continuously monitor patient's vital signs and patient's response to sedation

Radiology Technician:

1. Turn on Radiology equipment
2. Run fluoroscopy during procedure
3. Assist with Transducer and Procedure table set up
4. Obtain equipment and supplies for angiogram/angioplasty and hand off during procedure
5. Monitor contrast during procedure

6. Assist the physician/scrub tech with attaching lines to flush and pressure transducers

Monitor Technician:

1. Turn on GE Marquette MAC Lab monitoring equipment
2. Enter patient information - labs, height, weight, allergies, current meds, pulses and NPO status in MAC Lab
3. Record Risk Factors/Medical History in MAC Lab (Neuro/Resp/Cardiac/GU/GI).
4. Zero transducers
5. Assist with patient transfer to procedure table
6. Assist with connecting patient to monitoring equipment – NIBP, O2 sat and EKG

Scrub Technician:

1. Patient Preparation
    a. Sterile table set up as indicated by physician
    b. Using clippers prep and clip both groins
    c. Prep and drape patient in sterile fashion
    d. Assist physician with attaching lines to flush and pressure transducers

RESPONSIBILITIES DURING ANGIOPLASTY:

Nurse:

1. Observe patient's response to procedure/medications
2. Follow Moderate Sedation/Analgesia for Diagnostic and Therapeutic Procedures Policy
3. Notify physician with any of the following symptoms:
    Chest, neck, jaw and/or arm discomfort
    Shortness of breath
    Change in vision
    Change in patient's color
    Hives and/or itching
    Change in Vital Signs- EKG, Blood pressure or O2 saturation

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Perform ACT during procedure, if necessary

Radiology Technician:

1. Monitor contrast during procedure
2. Run fluoroscopy equipment during procedure
3. Obtain equipment and supplies for angiogram and angioplasty as ordered by physician.
4. Turn off fluoroscopy at end of procedure

Monitor Technician:

1. Observe EKG and notify MD of arrhythmias, EKG changes, and changes in vital signs
2. Monitor pressure waveforms and notify physician and nurse of abnormalities
3. Record pressure tracings, vital signs, EKG rhythm, LOC, Pain Assessment, per CCL policy
4. Record medication administration throughout procedure
5. Record fluoroscopy time
6. Record amount of IVF and contrast given during procedure
7. Record supplies used during procedure
8. Monitor and record ACTs during procedure

Scrub Technician:

1. Prep and drape patient in sterile fashion
2. Scrub and assist physician
3. Assist with catheter exchange when directed by Physician

RESPONSIBILITIES AFTER ANGIOPLASTY:

Nurse:

1. Instruct patient on post angioplasty orders:
2. Explain post angioplasty instructions
    a. Increase PO fluid intake
    b. Care of catheterization site
    c. Immobilization of limb where angiogram/angioplasty was performed
    d. Bedrest
    e. NPO status

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3. Assist physician with arterial repair, when indicated (RN or Scrub tech)
4. Check pulse(s) distal to angiogram/angioplasty site
5. Evaluate patient's condition after angioplasty (i.e. Neuro, Cardiac, Respiratory, Pain Assessment)
6. Assist patient off table to stretcher/bed
7. Give report to RN on receiving unit using SBAR method.
8. Patient transferred to receiving unit by bed with Physician (if indicated), Technician and RN.

Radiology Technician:

1. Assist patient off table to stretcher or bed
2. Return any unopened equipment
3. Check all radiology equipment is in proper place and turn off fluoroscopy.

Monitor Technician:

1. Monitor patient's vital signs throughout procedure and report any abnormal findings to RN and MD
2. Record procedure in Mac Lab
3. Document in MacLab report
    a. Total Fluoroscopy Time
    b. Total contrast used
4. Print Report at end of procedure and have it signed by Physician, RN and Monitor Technician
5. Scan copy of MacLab report into Epic chart under appropriate Encounter
6. Put signed copy of MacLab report in Cardiology case folder

Scrub Technician:

1. Remove and discard table
2. Discard of sharps and fluid in appropriate receptacles

REFERENCES:

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RELATED POLICIES:

Prevention Wrong Site/Side Protocol - Universal PCIII-56
Medication Reconciliation – PCIII
Patient Identification – PCIII55
Consent – PCI – 5
Moderate Sedation / Analgesia for Diagnostic and Therapeutic Procedures – PC111 - 31

Attachment III

New England Journal of Medicine Article:
"Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery"

ORIGINAL ARTICLE

Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery

Thomas Aversano, M.D., Cynthia C. Lemmon, R.N., B.S.N., M.S., and Li Liu, M.D., for the Atlantic CPORT Investigators

ABSTRACT

BACKGROUND

Performance of percutaneous coronary intervention (PCI) is usually restricted to hospitals with cardiac surgery on site. We conducted a noninferiority trial to compare the outcomes of PCI performed at hospitals without and those with on-site cardiac surgery.

METHODS

We randomly assigned participants to undergo PCI at a hospital with or without on-site cardiac surgery. Patients requiring primary PCI were excluded. The trial had two primary end points: 6-week mortality and 9-month incidence of major adverse cardiac events (the composite of death, Q-wave myocardial infarction, or target-vessel revascularization). Noninferiority margins for the risk difference were 0.4 percentage points for mortality at 6 weeks and 1.8 percentage points for major adverse cardiac events at 9 months.

RESULTS

A total of 18,867 patients were randomly assigned in a 3:1 ratio to undergo PCI at a hospital without on-site cardiac surgery (14,149 patients) or with on-site cardiac surgery (4718 patients). The 6-week mortality rate was 0.9% at hospitals without on-site surgery versus 1.0% at those with on-site surgery (difference, −0.04 percentage points; 95% confidence interval [CI], −0.31 to 0.23; P=0.004 for noninferiority). The 9-month rates of major adverse cardiac events were 12.1% and 11.2% at hospitals without and those with on-site surgery, respectively (difference, 0.92 percentage points; 95% CI, 0.04 to 1.80; P=0.05 for noninferiority). The rate of target-vessel revascularization was higher in hospitals without on-site surgery (6.5% vs. 5.4%, P=0.01).

CONCLUSIONS

We found that PCI performed at hospitals without on-site cardiac surgery was noninferior to PCI performed at hospitals with on-site cardiac surgery with respect to mortality at 6 weeks and major adverse cardiac events at 9 months. (Funded by the Cardiovascular Patient Outcomes Research Team [C-PORT] participating sites; ClinicalTrials.gov number, NCT00549796.)

From Johns Hopkins University, Baltimore (T.A., C.C.L.); and Clinical Trials and Surveys, Owings Mills, MD (L.L.). Address reprint requests to Dr. Aversano at Johns Hopkins Cardiology at the Greater Baltimore Medical Center, Suite 5104, 6701 N. Charles St., Baltimore, MD 21204, or at taversan@jhmi.edu.

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THE POTENTIAL NEED FOR EMERGENCY cardiac surgery to treat complications related to percutaneous coronary intervention (PCI) suggests that performance of PCI may be best limited to hospitals with on-site cardiac surgery. Among Grüntzig's first 50 PCI procedures, 10% of patients required emergency coronary-artery bypass grafting (CABG).[1] Although the need for emergency surgery subsequently diminished dramatically (by 2002, the incidence was 0.15%[2]), concern about the safety and quality of PCI performed without the availability of on-site cardiac surgery has persisted. Hospitals in which PCI is performed but that do not have cardiac surgery programs could have more adverse events and poorer outcomes for a number of reasons (including low institutional volume of PCI procedures and inexperienced staff), in addition to the need for emergency CABG.

Despite these concerns, many hospitals without on-site cardiac surgery developed stand-alone programs for the performance of primary PCI after studies showed that primary PCI was associated with better outcomes than medical therapy in the treatment of myocardial infarction with ST-segment elevation[3] and could be performed safely and effectively at such hospitals.[4] Door-to-balloon times may be shorter, and outcomes consequently better, if primary PCI is widely available. It has further been suggested that, given the relatively low volume of primary PCI procedures at some hospitals, the addition of other PCI procedures (including elective PCI and PCI for acute coronary syndromes without ST-segment elevation) could help sustain and improve these programs.

In addition, previous studies have shown that, for patients with acute coronary syndromes presenting to centers without any revascularization capability, appropriate use of PCI and CABG is limited and outcomes are suboptimal.[5-7] Extension of PCI capability to such hospitals could improve access to appropriate care, particularly in areas where recruitment and retention of cardiologists may be difficult[8] and treatment options for patients are limited.

The Cardiovascular Patient Outcomes Research Team (CPORT) Non-Primary PCI (CPORT-E) trial was designed to help address these issues. CPORT-E was a randomized noninferiority trial that compared outcomes of PCI procedures (excluding primary PCI) at hospitals with and those without on-site cardiac surgery.

METHODS

STUDY DESIGN AND OVERSIGHT

The CPORT-E trial was designed by the study chairman and the protocol-development committee and was funded through financial support provided by participating sites to the Johns Hopkins University and through in-kind support that included the provision of local study coordinators at each site. There was no support from the makers of equipment used in catheterization laboratories or of that used for PCI. The protocol was approved by each participating hospital's institutional review board and the Johns Hopkins institutional review board. Data were gathered by local research coordinators, reviewed for accuracy by central study coordinators at Johns Hopkins, and analyzed by the authors. The authors vouch for the accuracy and completeness of the data and the analysis and for the fidelity of this report to the trial protocol, which is available with the full text of this article at NEJM.org.

TRIAL PARTICIPANTS

Patients were eligible for participation in the trial if they presented for diagnostic cardiac catheterization at 1 of 60 participating hospitals without on-site cardiac surgery located in 10 U.S. states (Maryland, New Jersey, Pennsylvania, Ohio, Georgia, Texas, North Carolina, Illinois, Oregon, and Alabama). During the trial period, patients who did not undergo randomization, whether or not they met the inclusion criteria for the trial, were included in a registry that recorded a limited set of data that excluded identifying private information.

Patients 18 years of age or older with stable coronary artery disease or an acute coronary syndrome were included in the trial. Patients with an acute myocardial infarction with ST-segment elevation were excluded, as were those with an ejection fraction of less than 20% and those who required PCI of an unprotected lesion in the left main coronary artery. In addition, interventionalists could exclude any patient whom they deemed to be at too high a risk for PCI. For each trial participant, all lesions requiring PCI had to be considered treatable at the hospital without on-site cardiac surgery before randomization. Patients who had previously participated in the trial were excluded. Full inclusion and exclusion criteria are available in Table S1 in the Supplementary Appendix, available at NEJM.org.

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PARTICIPATING HOSPITALS AND INTERVENTIONALISTS

Interventionalists were required to meet criteria for competency developed by the American College of Cardiology (ACC), the American Heart Association (AHA), and the Society for Cardiac Angiography and Interventions (SCAI).[9] Participating centers were required to have primary PCI programs available 24 hours per day, 7 days per week, and to be capable of performing 200 PCI procedures annually. Most sites required a waiver from the state department of health to participate. All such waivers allowed for a first-year PCI volume of 100 procedures, increasing to 200 in the second year.

Each site had a formal agreement with a tertiary-care hospital partner specifying that the tertiary-care institution would accept emergency transfers from the enrolling site. However, participants in the trial who were randomly assigned to undergo PCI at a hospital with on-site surgery could have the PCI procedure at any tertiary-care hospital. A formal agreement with an advanced cardiac life-support service capable of transporting patients requiring intraaortic balloon counterpulsation was also required, with an anticipated response time of 30 minutes or less.

Before commencing recruitment, all participating sites were required to complete a formal PCI development program. This program included the development of detailed care plans and pathways, order sets, and logistics and the training of staff in the care of patients undergoing PCI. Details of this program are available in the Supplementary Appendix.

TRIAL PROCEDURES

Before undergoing diagnostic catheterization, study participants provided written informed consent. After catheterization, if PCI was required and all lesions were considered to be treatable at the hospital without on-site cardiac surgery, the participant was randomly assigned in a 3:1 ratio to undergo PCI at either the enrolling site (without on-site cardiac surgery) or another facility with on-site cardiac surgery. Randomization was performed with the use of an automated telephone-response system on a per-site basis in random permuted blocks (of 4, 8, or 12). Patients who were considered to be at too high a risk according to the study-exclusion criteria or in the judgment of the treating physician did not undergo randomization but instead underwent PCI, CABG, or other therapy as clinically indicated.

After randomization, all trial participants were to undergo PCI according to their randomized assignment. The timing of the index PCI procedure depended on individual case acuity, the need to perform PCI on a different day than the visit to the catheterization laboratory to minimize procedural risk (i.e., staged procedure), and scheduling and transportation constraints, but the procedure was to be performed as soon as possible for each participant. All treatments, devices, and drugs were administered and laboratory studies carried out according to routine practice; no specific PCI protocol was prescribed. However, the use of cutting balloons was limited to in-stent restenosis and atherectomy devices were not permitted at hospitals without on-site cardiac surgery.

Participants were contacted by telephone (or mail, if necessary) at 6 weeks and 3, 6, and 9 months after study entry to identify adverse events. Medical records required to document identified events were obtained as needed.

TRIAL OUTCOMES

Two coprimary outcomes were identified: all-cause mortality 6 weeks after the index PCI and the composite rate of major adverse cardiac events, including death from all causes, Q-wave myocardial infarction, and target-vessel revascularization, 9 months after the index PCI. Additional outcomes included the PCI success rate and the incidence of cardiac surgery, bleeding, stroke, renal failure, and any subsequent revascularization.

Except as noted, definitions of data elements followed those in the American College of Cardiology National Cardiovascular Data Registry module on cardiac catheterization, version 3.02.[10] Q-wave myocardial infarction was defined as the development of new Q waves in any two contiguous leads. Target-vessel revascularization was defined as any revascularization intervention (PCI or CABG) occurring in a treated vessel at any time after the index intervention. In randomly assigned participants who did not undergo an index PCI, any revascularization was considered a target-vessel revascularization. Bleeding was defined as any bleeding that required blood transfusion, except for transfusions associated with cardiac surgery. Vascular repair included thrombin injection, ultrasound-guided compression, and surgical repair. Further details of study definitions are available in the Supplementary Appendix.

All events were reported by the enrolling site to the central coordinating center and were con-

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firmed by coordinating-center staff with the source medical records submitted. Occasionally, a review of source documents resulted in the identification of unreported events or the withdrawal of submitted events. A central review committee reviewed electrocardiographic findings without knowledge of the participant's randomized assignment.

STATISTICAL ANALYSIS

The CPORT-E trial was designed as a noninferiority trial. On the basis of previous studies, the 6-week all-cause mortality rate was estimated at 0.8%[11,12] and the rate of major adverse cardiac events at 9 months was estimated at 12.0%.[13-16] Noninferiority margins for the difference in event rates were set at 0.4 percentage points for the 6-week end point and 1.8 percentage points for the 9-month end point. With dual primary end points, the required number of participants for a one-sided test for noninferiority with an alpha level of 0.05 and a beta level of 0.80 was determined to be 18,360.

The primary outcome analysis was performed on data from the intention-to-treat population. Asymptotic normal approximations to the sample proportions were used to generate confidence intervals and P values for noninferiority. Categorical variables were compared with the use of Fisher's exact test or a chi-square test. A per-protocol analysis was also performed, which included only participants who underwent PCI at the site to which they were assigned. All statistical analyses were performed with the use of SAS software, version 9.2.

States that required a waiver from the department of health for trial participation typically specified that the participating hospitals should stop performing PCI when trial enrollment was completed. To allow the creation of a follow-up registry in these states, enrollment continued after the recruitment goal of 18,360 participants was reached. Ultimately, 18,867 participants underwent randomization.

RESULTS

STUDY POPULATION

Enrollment began on April 7, 2006, and ended on March 31, 2011. During that period, there were 99,479 patient visits for diagnostic catheterization at the participating hospitals. Among the 76.1% of patients who provided consent to participate, 21,165 were judged to require PCI after catheterization, and 18,867 underwent randomization (Fig. 1). Excluded were 2298 patients (10.9%) who required PCI but were judged to be at too high a risk for study participation. Reasons for the judgment that the risk was too high are shown in Figure S1 in the Supplementary Appendix. Overall, patients in the registry had fewer risk factors and less severe coronary disease than randomly assigned trial participants (Table S2 in the Supplementary Appendix).

Of the patients who underwent randomization, 319 did not undergo an index PCI. The proportion of patients who did not undergo an index PCI was higher among participants assigned to hospitals with on-site cardiac surgery than among those assigned to hospitals without on-site surgery. Reasons included referral for surgical or medical therapy and lesion resolution (Table S3 in the Supplementary Appendix). Crossovers between study groups were infrequent but were more frequent among participants randomly assigned to hospitals with on-site cardiac surgery (Fig. 1).

The baseline characteristics of the participants are shown in Table 1. There was a higher incidence of prior PCI in participants randomly assigned to hospitals without cardiac surgery on site. In addition, the rate of emergency catheterization was higher, and the rate of urgent catheterizations lower, among participants assigned to hospitals with on-site cardiac surgery.

The median annual volume of catheterizations per hospital was 150 procedures (interquartile range, 99 to 216). The median annual volume of primary PCIs was 51 procedures (interquartile range, 35 to 74). The participation of 12 hospitals was terminated during the trial because of low volume. Data from these sites were included in the data analysis.

PROCEDURE CHARACTERISTICS

A higher percentage of PCIs were staged among participants assigned to hospitals with on-site cardiac surgery than among those assigned to hospitals without on-site surgery, probably because of the need for transfer (Table 2). As a result, the number of visits to the catheterization laboratory that were needed to complete PCI was higher among participants assigned to hospitals with on-

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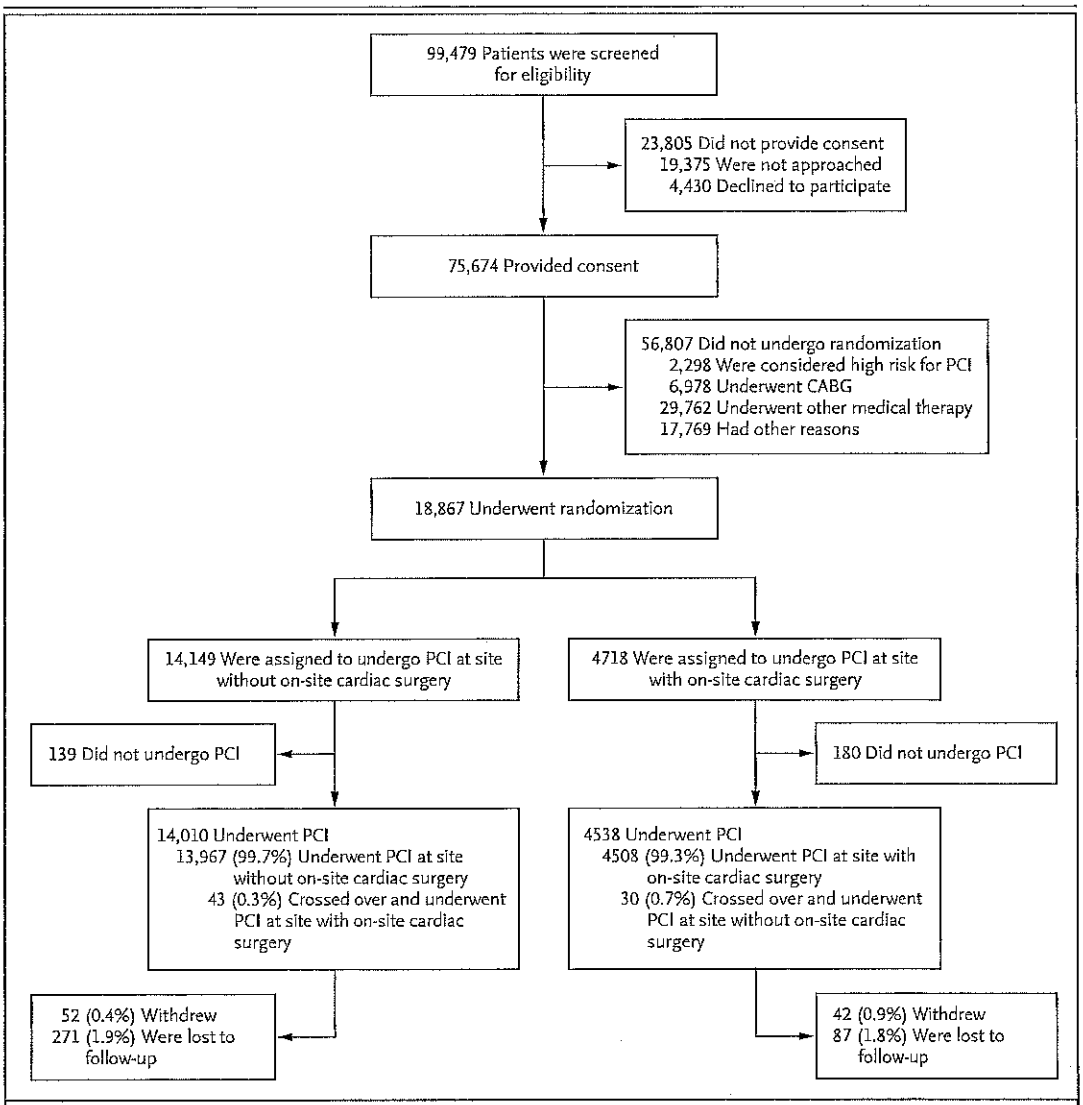

Figure 1. Enrollment and Randomization of the Study Patients.

The percentages for the patients who withdrew or were lost to follow-up are based on the patients assigned to undergo percutaneous coronary intervention (PCI). CABG denotes coronary-artery bypass grafting.

site cardiac surgery. In addition, drug-eluting stents were used more frequently in hospitals with on-site cardiac surgery.

The rate of PCI failure was lower among participants treated at hospitals with on-site cardiac surgery (Table 2). Emergency CABG was associated with high mortality but was rarely performed; it was performed more frequently among participants assigned to hospitals with on-site cardiac surgery. The incidence of unplanned re-catheterization and PCI before discharge was greater at hospitals without on-site cardiac surgery.

OUTCOMES

At 6 weeks after the index PCI, 132 participants assigned to hospitals without on-site cardiac surgery had died and 46 participants assigned to hospitals with on-site cardiac surgery had died. The event rates in the two groups were 0.9% and 1.0%, respectively (difference in event rates, −0.04 percentage points; 95% confidence interval [CI], −0.31 to 0.23; P=0.004 for noninferiority) (Table 3).

At 9 months, there were 1716 major adverse cardiac events in participants at hospitals without on-site cardiac surgery and 529 such events in

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Table 1. Baseline Characteristics of the Study Patients.*

Characteristic	No On-Site Cardiac Surgery (N=14,149)	On-Site Cardiac Surgery (N=4718)
Age — yr	63.9±11.9	64.0±12.0
Male sex — no. (%)	9046 (63.9)	2970 (63.0)
White race — no. (%)†	11,185 (79.1)	3778 (80.1)
Medical history — no. (%)		
Hypertension	11,950 (84.5)	4024 (85.3)
Hypercholesterolemia	11,567 (81.8)	3865 (81.9)
Smoking (current or former)	8,719 (61.6)	2964 (62.8)
Diabetes	5,485 (38.8)	1868 (39.6)
Family history of CAD	7,730 (54.6)	2623 (55.6)
Heart failure	1,531 (10.8)	518 (11.0)
Prior myocardial infarction	6,011 (42.5)	2030 (43.0)
Prior PCI‡	4,506 (31.8)	1430 (30.3)
Prior CABG	1,852 (13.1)	632 (13.4)
Prior stroke or PVD	2,447 (17.3)	868 (18.4)
Angiographic findings at baseline		
One-vessel CAD — no. (%)	5,097 (36.0)	1645 (34.9)
Two-vessel CAD — no. (%)	5,087 (36.0)	1741 (36.9)
Three-vessel CAD — no. (%)	3,959 (28.0)	1326 (28.1)
Left main CAD — no. (%)	465 (3.3)	178 (3.8)
Graft disease — no. (%)	1,323 (9.4)	456 (9.7)
Left ventricular ejection fraction — %	54.2±10.6	54.3±10.7
Procedure status at time of catheterization — no. (%)§		
Elective	10,350 (73.2)	3414 (72.4)
Urgent¶	3,291 (23.3)	1127 (23.9)
Emergency‡	493 (3.5)	175 (3.7)
Clinical status at time of catheterization — no. (%)‖		
STEMI	390 (2.8)	147 (3.1)
NSTEMI	3,471 (24.5)	1210 (25.7)
Unstable angina	5,196 (36.7)	1665 (35.3)
Stable angina	2,011 (14.2)	636 (13.5)
Atypical chest pain	723 (5.1)	268 (5.7)
Other	2,356 (16.7)	790 (16.8)

* Plus–minus values are means ±SD. CABG denotes coronary-artery bypass grafting, CAD coronary artery disease, NSTEMI non–ST-segment elevation myocardial infarction, PCI percutaneous coronary intervention, PVD peripheral vascular disease, and STEMI ST-segment elevation myocardial infarction.

† Race was self-reported.

‡ P<0.05 for the comparison between groups.

§ For procedure status at time of catheterization, data were missing for 15 patients treated at hospitals without on-site cardiac surgery and 2 patients treated at hospitals with on-site cardiac surgery. The definitions for "urgent" and "emergency" were those used in the American College of Cardiology National Cardiovascular Data Registry module on cardiac catheterization, version 3.02.[10]

¶ P<0.01 for the comparison between groups.

‖ For clinical status at time of catheterization, data were missing for 2 patients in each study group. "Other" includes patients presenting with heart failure, arrhythmia, positive stress tests, syncope, and other non–chest-pain syndromes and patients undergoing cardiovascular risk assessment before a noncardiac surgical procedure.

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Table 2. Characteristics of the Index Procedure.*

Characteristic	No On-Site Cardiac Surgery	On-Site Cardiac Surgery	P Value
PCI staged — no./total no. (%)†	3652/14,010 (26.1)	3084/4538 (68.0)	<0.001
Single-vessel PCI — no./total no. (%)	11,212/14,010 (80.0)	3716/4538 (81.9)	
Multivessel PCI — no./total no. (%)	2937/14,010 (21.0)	1002/4538 (22.1)	
No. of catheterization laboratory visits needed to complete index PCI	1.28	1.73	<0.001
No. of days from randomization to index PCI — median (IQR)	0 (0–3)	1 (0–3)	<0.001
Stent use — no./total no. (%)			0.03
DES only	10,074/14,010 (71.9)	3343/4538 (73.7)	
BMS only	2790/14,010 (19.9)	877/4538 (19.3)	
Both DES and BMS	596/14,010 (4.3)	156/4538 (3.4)	
Balloon only	550/14,010 (3.9)	162/4538 (3.6)	
PCI success — no./total no. (%)			
By patient‡			0.007
Complete success	12,714/14,010 (90.7)	4148/4538 (91.4)	
Partial success	808/14,010 (5.8)	253/4538 (5.6)	
Failure	482/14,010 (3.4)	113/4538 (2.5)	
By lesion§			0.04
Success	19,886/21,292 (93.4)	6499/6907 (94.1)	
Failure	1406/21,292 (6.6)	408/6907 (5.9)	
Emergency procedures			
Emergency PCI — no./total no. (%)	23/14,010 (0.2)	6/4538 (0.1)	
Death associated with emergency PCI — no. of deaths/total no. of emergency PCI procedures (%)	1/23 (4.3)	0	
Emergency CABG — no./total no. (%)	13/14,010 (0.1)	10/4538 (0.2)	0.11
Death associated with emergency CABG — no. of deaths/total no. of emergency CABG procedures (%)	2/13 (15.4)	2/10 (20.0)	

* Data are for all randomly assigned patients who underwent PCI. BMS denotes bare-metal stent, DES drug-eluting stent, and IQR interquartile range.

† Staged PCI indicates that PCI was performed on a different day than the visit to the catheterization laboratory to minimize procedural risk.

‡ Thirty patients (6 in hospitals without on-site cardiac surgery and 24 in hospitals with on-site cardiac surgery) did not have valid postprocedure data available on coronary-artery flow (according to the Thrombolysis in Myocardial Infarction [TIMI] scale, which ranges from 0 to 3, with 0 indicating no flow and 3 normal flow) or percentage of residual stenosis. These 30 patients were excluded from the analysis of PCI success by patient. Complete success was defined as a postprocedure TIMI flow grade of 3 and residual stenosis not exceeding 20% in all treated lesions. Partial success was defined as a postprocedure TIMI flow grade of 3 and residual stenosis not exceeding 20% in at least one (but not all) treated lesions. Failure was defined as no treated lesions with a postprocedure TIMI flow grade of 3 and residual stenosis of more than 20%.

§ Success by lesion was defined as a postprocedure TIMI flow grade of 3 and residual stenosis not exceeding 20%. Failure was defined as a postprocedure TIMI flow grade of less than 3 or residual stenosis of more than 20%.

patients at hospitals with on-site cardiac surgery (12.1% vs. 11.2%; difference in event rates, 0.92 percentage points; 95% CI, 0.04 to 1.80; P=0.05 for noninferiority) (Table 3). There were no significant differences in all-cause mortality or Q-wave myocardial infarction between the two groups, but there was a significant difference in the rate of target-vessel revascularization — 6.5% among participants at hospitals without on-site cardiac surgery versus 5.4% among those at hospitals with on-site cardiac surgery (P=0.01).

Several exploratory analyses were conducted (Table 3). If CABG was not considered to qualify as target-vessel revascularization when it was performed as an initial procedure (i.e., for participants who did not undergo the intended index PCI), the rates of major adverse cardiac events at 9 months among participants at hospitals with-

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Table 3. Trial Outcomes.*

Outcome	No On-Site Cardiac Surgery	On-Site Cardiac Surgery	Difference in Rate (Asymptotic One-Sided 95% CI)	P Value	
				Noninferiority	Superiority
	no./total no. (%)		*percentage points*		
Primary end point (intention-to-treat population)					
Death at 6 wk	132/14,149 (0.9)	46/4718 (1.0)	−0.04 (−0.31 to 0.23)	0.004	
9-mo outcomes					
Death	454/14,149 (3.2)	150/4718 (3.2)			
TVR	915/14,149 (6.5)	255/4718 (5.4)			0.01
Q-wave myocardial infarction	434/14,149 (3.1)	144/4718 (3.1)			
Major adverse cardiac event	1716/14,149 (12.1)	529/4718 (11.2)	0.92 (0.04 to 1.80)	0.05	
Exploratory analyses (intention-to-treat population)					
Major adverse cardiac event, including withdrawal and loss to follow-up	2026/14,149 (14.3)	653/4718 (13.8)	0.48 (−0.48 to 1.44)	0.01	
CABG as initial procedure not included in TVR definition					
TVR	873/14,149 (6.2)	218/4718 (4.6)			<0.001
Major adverse cardiac event	1678/14,149 (11.9)	495/4718 (10.5)	1.37 (0.51 to 2.23)	0.21	
TVR according to stent type					
DES only	484/10,074 (4.8)	120/3343 (3.6)			0.005
BMS only	223/2790 (8.0)	53/877 (6.0)			
Both DES and BMS	39/596 (6.5)	8/156 (5.1)			
Balloon only	138/550 (25.1)	34/162 (21.0)			
Per-protocol analyses					
Death at 6 wk	129/13,967 (0.9)	38/4508 (0.8)	0.08 (−0.18 to 0.34)	0.03	
TVR	860/13,967 (6.2)	202/4508 (4.5)			<0.001
Major adverse cardiac event at 9 mo	1676/13,967 (12.0)	467/4508 (10.4)	1.64 (0.77 to 2.51)	0.42	

* Major adverse cardiac events included death, target-vessel revascularization (TVR), and Q-wave myocardial infarction. BMS denotes bare-metal stent, and DES drug-eluting stent.

out and those with on-site cardiac surgery were 11.9% and 10.5%, respectively. In per-protocol analyses (excluding participants who crossed over), the death rates at 6 weeks were 0.9% and 0.8%, respectively, and the rates of major adverse cardiac events at 9 months were 12.0% and 10.4%, respectively.

CABG was performed more frequently among trial participants at hospitals with on-site cardiac surgery than among participants at hospitals without such access (Table 4). The incidence of unplanned catheterization at 6 weeks and 9 months and the incidence of any subsequent revascularization at 9 months were higher among participants at hospitals without on-site cardiac surgery (Table 4).

DISCUSSION

We compared clinical outcomes between trial participants undergoing PCI at a hospital with on-site access to cardiac surgery and participants undergoing PCI at a hospital without such access. We found that outcomes at hospitals without on-site cardiac surgery were noninferior to those at hospitals with cardiac surgery on site, with respect to all-cause mortality at 6 weeks and major adverse cardiac events at 9 months. There were no significant differences between the two study groups at 9 months with respect to rates of death or Q-wave myocardial infarction, but trial participants treated at hospitals without on-site cardiac surgery more frequently required target-vessel revascularization.

The short-term results from this trial are concordant with the findings in previous registry studies and meta-analyses.[17,18] The longer-term outcomes are similar to those in a small randomized trial of low-risk PCI at two hospitals,[19] which showed equivalent safety at the hospitals with and those without on-site cardiac surgery but more frequent target-vessel revascularization at 6 months among participants treated at the sites without cardiac surgery.

The definition of target-vessel revascularization used in the CPORT-E trial included any revascularization (PCI or CABG) after the index PCI. In addition, for randomly assigned participants who did not undergo an index PCI, any subsequent revascularization of the target vessel, whether by PCI or CABG, was considered a target-vessel revascularization. The inclusion of initial CABG as a target-vessel revascularization is consistent with the intention-to-treat approach, which is based on randomized treatment assignments, regardless of the treatment received. When CABG was not counted as a target-vessel revascularization in these trial participants, hospitals without on-site cardiac surgery were inferior to those with on-site access with respect to the rate of major adverse cardiac events at 9 months (Table 3). The per-protocol analysis also showed a higher rate of major adverse cardiac events in hospitals without on-site cardiac surgery. These differences are small and within the range of noninferiority margins used in recent comparative trials of stent types, from 1.5 percentage points (relative difference, 19%)[20] to 3.5 percentage points (relative difference, 43%).[21]

In all analyses, the rate of target-vessel revascularization was higher among participants who underwent PCI at a hospital without cardiac surgery on-site, regardless of the definition of target-vessel revascularization and regardless of stent type. The reason for this is not clear from the current study but may reflect a lower initial success rate and a more conservative approach by interventionalists practicing at relatively inexperienced centers that began PCI programs only as part of the CPORT-E trial.

There are a number of important limitations arising from the design and conduct of the CPORT-E trial. Participants were carefully selected and were excluded if they were deemed to be at high risk. It is possible that the population studied is different from the general population requiring PCI, although a comparison of baseline characteristics with those reported in the National Cardiovascular Data Registry[17] suggests that this is not the case (Table S4 in the Supplementary Appendix). For outcomes of PCI at hospitals without on-site cardiac surgery to be similar to those at hospitals with on-site cardiac surgery, it may be necessary for such centers to participate in a formal PCI development program and for interventionalists who perform the procedures to meet the criteria for competency developed by the ACC, AHA, and SCAI.

In summary, the CPORT-E trial compared the clinical outcomes of PCI performed at hospitals with access to on-site cardiac surgery with outcomes of PCI performed at hospitals without such access. Outcomes at hospitals without on-site cardiac surgery were noninferior to those at hospi-

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Table 4. Adverse Events.

Event	6 Wk			9 Mo		
	No On-Site Cardiac Surgery (N=14,149)	On-Site Cardiac Surgery (N=4718)	P Value	No On-Site Cardiac Surgery (N=14,149)	On-Site Cardiac Surgery (N=4718)	P Value
	no. (%)			*no. (%)*		
CABG						
All	88 (0.6)	69 (1.5)	<0.001	216 (1.5)	107 (2.3)	<0.001
Emergency	15 (0.1)	10 (0.2)		18 (0.1)	11 (0.2)	
Bleeding	486 (3.4)	150 (3.2)		754 (5.3)	247 (5.2)	
Vascular repair	52 (0.4)	20 (0.4)		151 (1.1)	55 (1.2)	
Stroke	40 (0.3)	8 (0.2)		87 (0.6)	23 (0.5)	
Renal insufficiency	72 (0.5)	20 (0.4)		131 (0.9)	37 (0.8)	
Unplanned catheterization	613 (4.3)	150 (3.2)	<0.001	2102 (14.9)	566 (12.0)	<0.001
Any subsequent revascularization	378 (2.7)	127 (2.7)		1200 (8.5)	329 (7.0)	0.001

tals with cardiac surgery on site, with respect to all-cause mortality at 6 weeks and major adverse cardiac events at 9 months.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

We thank Lynnet Tirabassi for helping to take CPORT from initial concept to reality, William Weintraub for his thoughtful advice during the preparation of this manuscript, and Marjorie Aversano and Kenneth L. Baughman for their selfless and constant support, which made this and other CPORT projects possible.

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Attachment IV

Greenwich Hospital-Yale-New Haven Hospital Transfer Protocol and Agreement

Yale-New Haven Hospital, Inc.
TRANSFER PROTOCOL AND AGREEMENT

Yale-New Haven Hospital, Inc., ("YNHH"), a non-stock non-profit corporation organized and existing under the laws of the State of Connecticut, whose principle office is located at 20 York Street, New Haven, Connecticut 06504, hereby contracts with Greenwich Hospital, whose principle office is located at 5 Pennyridge Road, Greenwich, Connecticut, to provide the transfer of patients from Greenwich Hospital to YNHH.

WHEREAS, YNHH is a tertiary care hospital that is available as a statewide resource to other hospitals and their patients; and

WHEREAS, in order to provide optimal care to its community, Greenwich Hospital from time to time desires to transfer patients to YNHH; and

WHEREAS, to the best of its ability, YNHH desires to accept such patients in order to provide them with optimal care:

NOW, THEREFORE, in the consideration of the mutual undertakings set forth below, YNHH and Greenwich Hospital, the "parties" to this transfer protocol and Agreement ("Agreement") hereby agreed as follows:

A. The Decision

1. Greenwich Hospital's transferring physician shall be responsible for evaluating the patient's condition and needs to determine the appropriateness or advisability of transfer. In any such case where Greenwich Hospital's physician determines that a transfer to YNHH is medically necessary and/or appropriate in accordance with state and federal statutes and regulations, Greenwich Hospital's physician shall call YNHH to request transfer of the patient to YNHH.

2. Subject to availability of beds, staff and resources necessary for the care and treatment of the patient, the YNHH receiving physician shall call to accept or decline transfer of the patient. After YNHH has accepted the patient and the patient is en route, YNHH may not subsequently cancel orders to accept the patient unless YNHH arranges for another tertiary care hospital or Level 1 trauma center (or other appropriate facility) to accept the patient.

3. Greenwich Hospital's transferring physician shall provide necessary medical treatment within the capabilities of the staff and facilities available at Greenwich Hospital in order to minimize the risks of transfer to the patient's health, and in consultation with YNHH's receiving physician, shall determine the selection of appropriate transportation and the level of care required for appropriate management of the patient *en route* to YNHH.

4. Greenwich Hospital's transferring physician shall be responsible for the oversight of *en route* patient management. Upon arrival at YNHH the receiving physician or Emergency Department agrees to assume medical control and direction, all in accordance with applicable protocols and operating procedures.

5. All transfers shall be subject to each party's admission and discharge policies as well as their usual rules, regulations and other policies.

6. Each party will maintain required medical care and transfer documentation in accordance with state and federal statutes and regulations.

B. Patient Information

1. At the time of transfer, Greenwich Hospital shall provide YNHH with all the available information required by federal and state statutes and regulations, including but not limited to the reason for transfer, information about the patient's condition, the treatment given, the patient's status at the time of transfer, and any other available, relevant information, such as test results, x-ray films, and imaging studies. In addition, Greenwich Hospital should provide an initial diagnostic impression as well as whatever available patient information (the patient's name, address, hospital number, and the name, address, and the next of kin or other person responsible for the patient) that Greenwich Hospital may have.

2. In the event full patient information is not provided at the time of transfer and subsequently becomes available, Greenwich Hospital shall promptly transmit to YNHH.

3. Greenwich Hospital shall provide YNHH with all available information required for patient charges, including but not limited to demographic and financial data, in order to facilitate proper and efficient billing at YNHH for the services it renders. If YNHH obtains such information from another source, upon request from Greenwich Hospital, YNHH shall provide the information to Greenwich Hospital to assist it to properly bill for Greenwich Hospital's services.

4. If the patient is to be transferred back to Greenwich Hospital subsequent to treatment at YNHH, YNHH shall promptly provide Greenwich Hospital with summaries of medical records and other pertinent information.

C. Compliance with Applicable Federal and State Statutes and Regulations and Other Standards

1. The parties recognize that the Agreement and any patient transfers made in accordance with the Agreement are subject to applicable state and federal statutes and regulations, as well as any applicable accreditation and trauma center verification requirements. The parties agree to confirm their respective obligations under this Agreement in accordance with the applicable requirements.

D. Quality Assurance, Education and Research

1. Upon request, Greenwich Hospital shall cooperate with YNHH in the development and implementation of any patient trauma transfer quality assurance or research program (s).

2. Whenever possible, YNHH shall include Greenwich Hospital in trauma-related programs such as public education for injury prevention, outreach programs, and continuing education programs for trauma center staff, community nurses, physicians, and allied health personnel.

3. Periodically, the parties shall jointly participate in trauma review conferences and morbidity and mortality conferences relating to trauma care.

E. Insurance

At all times, each party shall maintain a full force and effect policies of professional and general liability insurance (or equivalent self-insurance mechanisms) insuring itself and its employees. Each party shall ensure that members of its medical staff who may not be employees are appropriately and adequately insured for professional liability. This insurance or equivalent self-insurance mechanism provides tail coverage for period of this Agreement.

F. Terms of Agreement and Termination

This Agreement shall commence on October 1, 2008, its "effective date", and shall run for a period of two years. This Agreement shall automatically renew itself for successive two year periods, unless terminated by either party by written notice given at least 90 days prior to the expiration of the then running period. Additionally, either party may terminate this Agreement at any time without cause by providing the other party with at least ninety (90) days advance written notice. This Agreement will terminate automatically should either party fail to maintain its license or accreditation.

G. Other Terms and Conditions

1. If any change in law or regulation would cause any provision of the Agreement to jeopardize either party's tax exempt status under section 501 (C)(3) of the Internal Revenue Code, the party at its option may terminate this Agreement. However, prior to such termination, the parties agree to use their best efforts to amend this Agreement, so as to confirm its intent to such applicable laws and/or regulations and to preserve their respective tax-exempt status without terminating this Agreement.

2. If any provision of this Agreement is determined by final decision of any administrative agency or court (after exhaustion of appeals or appeal rights) to be invalid or in violation of any law or regulation, such provision shall be severed from this Agreement and the remainder of this Agreement shall be given effect by the parties as if such provision never had been part of this Agreement.

3. This Agreement is not intended and shall not be construed to create any agency relationship between the parties. Furthermore, this Agreement is not intended and shall not be construed to create an exclusive transfer relationship between parties.

4. Each party shall directly bill any patient transferred hereunder (or the patient's payer) for its respective services rendered to the patient, and neither party shall be responsible to the other for payment for services rendered by the other.

5. Nothing contained in this Agreement is intended to nor shall be construed to create any third party rights for a patient or any other person or entity not a party to this Agreement.

6. This Agreement shall be construed and all of the rights, powers and liabilities of the parties shall be determined in accordance with the laws of the State of Connecticut.

7. This Agreement contains the whole understanding of the parties and supersedes all prior oral or written representations and agreements between the parties or between the parties and any of their representatives or staff as to the subject matter of this Agreement, and may not be varied except in a writing executed by the parties.

8. This Agreement may not be assigned by either party without prior written consent of the other party, except that upon advance written notice to the other party either party may assign this Agreement to a successor corporation that carries on all or substantially all of its business. Subject to the foregoing limitation upon assignment, this Agreement shall be binding upon and insure to the benefit of the successors and assigns of the parties.

9. To the extent that any of the services provided in accordance with this Agreement are deemed by the Secretary of the Federal Department of Health and Human Services of the U.S. Comptroller General, or the Secretary's or Comptroller's delegate, to be subject to the provisions of Section 952 of Public Law 96-499, the parties, until the expiration of four (4) years subsequent to the furnishing of services, shall make available upon written request of the Secretary or of the Comptroller, or any of their duly authorized representatives, this Agreement, and the books, documents and records of the parties that are necessary to certify the nature and extent of the charges to patients for service provided under this Agreement.

10. If either party carries out any of the duties of this Agreement through a Subcontract, with a value or cost of $10,000 or more over a twelve-month period, with a related organization (as that term is defined with regard to a provider in 42 C.F.R. Section 405.427(b), such subcontract shall contain a clause to the effect that until the expiration of four (4) years subsequent to the furnishing of services pursuant to such subcontract, the related organization upon written request shall make available to the Secretary or the Comptroller, or any of their duly authorized representatives, the subcontract, the books, documents and records of such organization that are necessary to verify the nature and extent of such costs.

11. To the extent that any of the provisions of Section G-9 and G-10 of this Agreement vary from any provision required by final regulations issued under the authority of Section 952 of Public Law 96-499, the provision required by the final regulation shall be deemed by the parties to supersede these sections and be made a part of this Agreement by reference.

12. If either party is requested to disclose any books, documents or records relevant to this Agreement for the purpose of an audit or investigation relating directly to the provision of services under this Agreement (e.g., a governmental investigation of billing practices or trauma services provided to patients), such party shall notify the other party of the nature and scope of the request and, to the extent permitted, shall make available to the other party, upon written request, relevant books, documents or records.

13. The headings, titles and captions used in this Agreement are merely for the convenience of the parties and are not intended to add to, subtract from, or in any other manner modify or affect the construction of the substantive terms of this Agreement.

14. This Agreement shall be executed in a least two counterparts, each of which shall be deemed an original, but all such counterparts shall together constitute one and the same instrument. It shall not be necessary in making proof of this Agreement to produce or account for more than one counterpart.

In witness hereof, the authorized representatives of YNHH and Greenwich Hospital do hereby execute this Transfer Protocol and Agreement.

Greenwich Hospital

_____ Date 10/8/08
Name: Frank Corvino
Title: CEO

_____ Date 10/7/08
Name: Brian J. Doran, MD
Title: Director, Emergency Medicine

Yale New-Haven Hospital

_____ Date 9/22/08
Name: Tucker Leary
Title: Vice President Administration

_____ Date 9/23/08
Name: Carla Carusone
Title: Manager, Section of Trauma, Surgical Critical Care & Surgical Emergencies

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

June 20, 2012

Ms. Jean Ahn
System Director
Yale-New Haven Hospital
Planning & Business Development Office
20 York Street (Howe 3)
New Haven, CT 06504

RE: Certificate of Need Application; Docket Number: 12-31748-CON
Yale-New Haven Hospital and Greenwich Hospital
Proposal to Establish and Operate an Elective Angioplasty
Program without Onsite Surgical Backup at Greenwich Hospital
Notification of Application Deemed Complete

Dear Ms. Ahn:

Pursuant to section 19a-639a(d) of the Connecticut General Statutes, the Office of Health Care Access ("OHCA") has determined that the above-referenced application has been deemed complete as of June 12, 2012 . The date of June12. 2012, also begins the ninety-day review period of the application.

If you have any questions regarding this matter, please feel free to contact me at (860) 418-7012.

Sincerely,

Steven W. Lazarus
Associate Health Care Analyst

****
*** TX REPORT ***
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STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: Jean Ahn

FAX: (203) 685-5013

AGENCY:

FROM: Steven Lazarus

DATE: 6/20/12 **TIME:** 2:05 p-

NUMBER OF PAGES:
(including transmittal sheet

Comments: Letter re: DN: 12-31748-CON
Enclosed: [Dean Complete notice]

PLEASE PHONE IF THERE ARE ANY TRANSMISSION PROBLEMS.

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
Office of Health Care Access

July 2, 2012

Ms. Jean Ahn
System Director
Yale-New Haven Hospital
20 York Street (Howe 3)
New Haven, CT 06504

RE: Certificate of Need Application; Docket Number: 12-31748-CON
Proposal to Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital
Notice of Public Hearing

Dear Ms. Ahn:

With the receipt of the completed Certificate of Need ("CON") application information submitted by Yale-New Haven Hospital ("Applicant") on June 12, 2012, the Office of Health Care Access ("OHCA") has initiated its review of the CON application identified above.

Pursuant to General Statutes § 19a-638a (f), OHCA may hold a hearing with respect to any Certificate of Need application.

This hearing notice is being issued pursuant to General Statutes § 19a-639a (f)

Applicant:	Yale New Haven Hospital
Docket Number:	12-31748-CON
Proposal:	Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital

Notice is hereby given of a public hearing to be held in this matter to commence on:

Date: July 17, 2012

Time: 9:00 a.m.

Place: Department of Public Health, Office of Health Care Access
Third Floor Hearing Room
410 Capitol Avenue, Hartford, Connecticut

The Applicants are designated as party in this proceeding. Enclosed for your information is a copy of the hearing notice for the public hearing that will be published in *The Greenwich Times* pursuant to General Statutes § 19a-639a (f).

Sincerely,

Kimberly R. Martone
Director of Operations

Enclosure

cc: Henry Salton, Esq., Office of the Attorney General
Marianne Horn, Department of Public Health
Joanne Yandow, Department of Public Health
Wendy Furniss, Department of Public Health
Marielle Daniels, Connecticut Hospital Association

KRM:SWL:AV:lmg

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH
Office of Health Care Access

July 2, 2012 Requisition # 12345

Greenwich Times
20 East Elm Street
Greenwich, CT 06830

Gentlemen/Ladies:

Please make an insertion of the attached copy, in a single column space, set solid under legal notices, in the issue of your newspaper by no later than **Tuesday, July 3, 2012.** Please provide the following **within 30 days** of publication:

- Proof of publication (copy of legal ad. acceptable) showing published date along with the invoice.

If there are any questions regarding this legal notice, please contact Steven Lazarus or Alla Veyberman at (860) 418-7001.

KINDLY RENDER BILL IN DUPLICATE ATTACHED TO THE TEAR SHEET.

Sincerely,

Kimberly R. Martone
Director of Operations

Attachment

cc: Danielle Pare, DPH
Marielle Daniels, Connecticut Hospital Association

KRM:SWL:AV:lmg

Greenwich Times **July 2, 2012**
Notice of Public Hearing, Docket Number 12-31748-CON

PLEASE INSERT THE FOLLOWING:

Office of Health Care Access Public Hearing

Statute Reference:	19a-639
Applicant:	Yale New Haven Hospital
Town:	Greenwich
Docket Number:	12-31748-CON
Proposal:	Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital
Date:	July 17, 2012
Time:	9:00 a.m.
Place:	Department of Public Health, Office of Health Care Access Third Floor Hearing Room 410 Capitol Avenue, Hartford, Connecticut

Any person who wishes to request status in the above listed public hearing may file a written petition no later than May 31, 2012 (5 calendar days before the date of the hearing) pursuant to the Regulations of Connecticut State Agencies §§ 19a-9-26 and 19a-9-27. If the request for status is granted, such person shall be designated as a Party, an Intervenor or an Informal Participant in the above proceeding. Please check OHCA's website at **www.ct.gov/ohca** for more information or call OHCA directly at (860) 418-7001.

****
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STATE OF CONNECTICUT
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OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: JEAN AHN

FAX: (203) 688-5013

AGENCY: YALE-NEW HAVEN HOSPITAL

FROM: ALLA VEYBERMAN

DATE: 7/2/12 **TIME:**

NUMBER OF PAGES: 5
(including transmittal sheet

Comments: Docket 12-31748-CON Notice of Public Hearing

PLEASE PHONE IF THERE ARE ANY TRANSMISSION PROBLEMS.

Phone: (860) 418-7001 Fax: (860) 418-7053

Greer, Leslie

From: ADS <ADS@graystoneadv.com>
Sent: Monday, July 02, 2012 1:05 PM
To: Greer, Leslie
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We will be in touch shortly and look forward to serving you.

If you have any questions or concerns, please don't hesitate to contact us at the number below.

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Date: Monday, July 2, 2012 1:03 PM
To: ads <ads@graystoneadv.com>
Subject: Public Hearing Notice 12-31748-CON

To Whom It May Concern,
Please run the attached public hearing notice in tomorrow's edition of the Greenwich Times. For billing purposes, refer to requisition #12345. If you have any questions feel free to call me.

Thank you,
Leslie M. Greer
CT Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
Hartford, CT 06134
Phone: (860) 418-7013
Fax: (860) 418-7053
Website: www.ct.gov/ohca
Please consider the environment before printing this message

Greer, Leslie

From: Laurie <Laurie@graystoneadv.com>
Sent: Monday, July 02, 2012 4:56 PM
To: Greer, Leslie
Subject: FW: Public Hearing Notice 12-31748-CON
Attachments: 12-31748np Greenwich Times.doc

Importance: High

Your legal notice is all set to run as follows:

Greenwich Times, 7/3 issue - $87.13

Thanks,
Laurie Miller

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From: <Greer>, Leslie <Leslie.Greer@ct.gov>
Date: Monday, July 2, 2012 1:03 PM
To: ads <ads@graystoneadv.com>
Subject: Public Hearing Notice 12-31748-CON

To Whom It May Concern,
Please run the attached public hearing notice in tomorrow's edition of the Greenwich Times. For billing purposes, refer to requisition #12345. If you have any questions feel free to call me.

Thank you,
Leslie M. Greer
CT Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
Hartford, CT 06134
Phone: (860) 418-7013
Fax: (860) 418-7053
Website: www.ct.gov/ohca

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Jewel Mullen, M.D., M.P.H., M.P.A.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

TO: Joanne V. Yandow, Hearing Officer

FROM: Jewel Mullen, M.D., M.P.H., M.P.A., Commissioner

DATE: July 3, 2012

RE: Certificate of Need Application; Docket Number: 12-31748-CON
Yale-New Haven Hospital and Greenwich Hospital
Proposal to Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital

---

I hereby designate you to sit as a hearing officer in the above-captioned matter to rule on all motions and recommend findings of fact and conclusions of law upon completion of the hearing.

Connecticut Department of Public Health

Phone: (860) 509-8000 • Fax: (860) 509-7184 • VP: (860) 899-1611
410 Capitol Avenue, P.O. Box 340308
Hartford, Connecticut 06134-0308
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STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

July 10, 2012

Ms. Jean Ahn
System Director
Yale-New Haven Hospital
Planning & Business Development Office
20 York Street (Howe 3)
New Haven, CT 06504

RE: Certificate of Need Application; Docket Number: 12-31748-CON
Yale-New Haven Hospital and Greenwich Hospital
Proposal to Establish and Operate an Elective Angioplasty
Program without Onsite Surgical Backup at Greenwich Hospital
Request for Prefile Testimony and Interrogatories

Dear Ms. Ahn:

The Office of Health Care Access ("OHCA") will hold a public hearing on Tuesday, July17, 2012, at 9:00 a.m. in the Department of Public Health's third floor hearing room, 410 Capitol Avenue, Hartford, regarding the Certificate of Need ("CON") application identified above. Pursuant to the Regulations of Connecticut State Agencies § 19a-9-29 (e), any party or other participant is required to prefile in written form all substantive, technical, or expert testimony that it proposes to offer at the hearing. Yale-New Haven Hospital and Greenwich Hospital (together herein known as "Applicants") must submit prefiled testimony to OHCA no later than **12:00 p.m.** on **Thursday, July 12, 2012**.

All persons providing prefiled testimony must be present at the public hearing to adopt their written testimony under oath and must be available for cross-examination for the entire duration of the hearing. If you are unable to meet the specified time for filing the prefiled testimony you must request a time extension in writing, detailing the reasons for not being able to meet the specified deadline.

Additionally, please find attached OHCA's interrogatories outlining the topics that will be discussed at the hearing.

Please contact Steven W. Lazarus at (860) 418-7012, if you have any questions concerning this request.

Sincerely,

Joanne V. Yandow, Esq.
Hearing Officer

Attachment

KRM:swl

Issues

Certificate of Need Application, Docket Number: 12-31748-CON

Yale-New Haven Hospital and Greenwich Hospital Proposal to Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital

Applicants should be prepared to present evidence and argument on the above referenced matter indicating but not limited to, the following issues:

1. Need for Greenwich Hospital to establish its own elective angioplasty program without onsite open heart surgery program (including what has changed in terms of the need for this proposal since OHCA's last decision regarding Greenwich Hospital's need for elective angioplasty program under Docket No.: 08-3120).
2. Access to elective angioplasty for population residing in the service area of Greenwich Hospital.
3. Existing providers in Greenwich Hospital's service area (in the states of Connecticut and New York).

****
*** TX REPORT ***
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STATE OF CONNECTICUT
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OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: Jean Ahn

FAX: (203) 688- ~~2669~~ 5013

AGENCY:

FROM: Steven Lazarus

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Comments: Pre-File Testimony Request and Issues related the DN: 12-31748-CSC enclosed

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From: Lazarus, Steven
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To: Greer, Leslie
Cc: Yandow, Joanne; Hansted, Kevin; Martone, Kim; Riggott, Kaila; Veyberman, Alla
Subject: FW: 12-31748-CON Greenwich Hospital/Yale-New HavenHospital Prefile testimony
Attachments: DN 12 31748 GH and YNHH Elective PCI Pre File Testimony.pdf

Leslie,

Please add the email below to the original record and we should be receiving the hard copies soon.

Steve

Steven W. Lazarus
Associate Health Care Analyst
Office of Heaalth Care Access
A Division of Department of Public Health
410 Capitol Avenue
Hartford, CT 06134
Phone (Direct): 860.418.7012
Fax (Main): 860.418.7053

From: Banoff, Karen [mailto:Karen.Banoff@YNHH.ORG]
Sent: Thursday, July 12, 2012 9:38 AM
To: Lazarus, Steven
Cc: Ahn, Jean
Subject: DN: 12-31748-CON Greenwich Hospital/Yale-New HavenHospital Prefile testimony

Hi Steve-
Hard copies are being delivered today before noon. I'm emailing the pdf file for your convenience. Please let me know if you have any questions.

How quickly can we obtain copies of any Intervenor requests/prefile?

Thanks so much and see you Tuesday. Karen

Karen M. Banoff
(203) 459-1601

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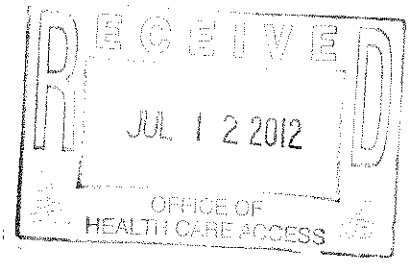
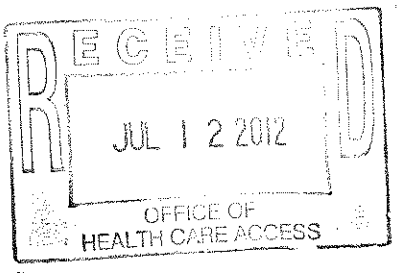
Certificate of Need Application
CON Docket Number 12-31748



Proposal to Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital

YALE-NEW HAVEN HOSPITAL



July 12, 2012

Joanne V. Yandow
Hearing Officer
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P. O. Box 340308
Hartford, CT 06134

Re: Certificate of Need Application (CON); Docket Number 12-31748
Proposal to Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital

Dear Hearing Officer Yandow:

Please find enclosed an original and six (6) copies of our prefile testimony for the upcoming public hearing on July 17, 2012.

Thank you in advance for your time and effort on this critically important CON application.

Sincerely,

Gayle Capozzalo

Gayle L. Capozzalo
Executive Vice President, Strategy and System Development

Enclosures

20 York Street
New Haven, CT 06504

STATE OF CONNECTICUT
OFFICE OF HEALTH CARE ACCESS

IN RE: ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM AT GREENWICH HOSPITAL	DOCKET NO. 12-31748-CON
	JULY 12, 2012

NOTICE OF APPEARANCE

In accordance with Section 19a-9-28 of the Regulations of Connecticut State Agencies, please enter the appearance of Updike, Kelly & Spellacy, P.C. ("Firm") in the above-captioned proceeding on behalf of Greenwich Hospital ("Greenwich") and Yale-New Haven Hospital ("YNHH"). The Firm will appear and represent Greenwich and YNHH at the public hearing on this matter, scheduled for July 17, 2012.

Respectfully Submitted,

GREENWICH HOSPITAL &
YALE-NEW HAVEN HOSPITAL

By: _____

JENNIFER L. GROVES, ESQ.
Updike, Kelly & Spellacy, P.C.
265 Church Street
One Century Tower
New Haven, CT 06510
Tel: (203) 786-8300
Fax (203) 772-2037

Testimony of

Marna Borgstrom

Yale-New Haven Heart and Vascular Center at Greenwich Hospital

Docket Number: 12-31748

Introduction

Hearing Officer Yandow and members of the OHCA staff, thank you for the opportunity to speak about this critically important Certificate of Need (CON) application before you. My name is Marna Borgstrom and I am the Chief Executive Officer (CEO) of Yale-New Haven Hospital (YNHH) and President and CEO of the Yale New Haven Health System (YNHHS). The Yale-New Haven Heart and Vascular Center (YNHHVC) is proposing the development of a satellite elective angioplasty program at Greenwich Hospital. Although we have proposed this program before and were not granted approval, there have been some new developments surrounding elective angioplasty programs without cardiac surgery back-up which have led us to pursue the proposed program again. We continue to believe there is sufficient need for the proposed program and its availability in Greenwich will enhance patient care and access.

I have the distinct privilege of introducing my colleagues who will speak to you in more detail about these developments and summarize our proposal. Here with me today are: Dr. Henry Cabin, Clinical Chief of Cardiology, a Professor at the Yale University School of Medicine, and Medical Director of the Yale-New Haven Heart and Vascular Center; Dr. Christopher Howes, Assistant Professor at the Yale University School of Medicine, Chief of Cardiology and Medical Director of the primary angioplasty program at Greenwich Hospital, and a practicing interventional cardiologist; and Mr. Frank Corvino, President and Chief Executive Officer of Greenwich Hospital and an Executive Vice President of Yale New Haven Health System.

YNHHVC Overview

YNHHVC is one of the leading providers of heart and vascular care. YNHH has been named as one of the top hospitals in the United States according to U.S. News & World Report's annual hospital ranking and among the very best in the nation in many medical specialties including cardiology and heart surgery.

We are proud of the following significant milestones which span from our early days as a cardiac leader to the present:

- 1949: William Glenn, MD, and William Sewell, MD created the first working heart-lung machine.
- 1956: Surgeons at YNHH performed the first open heart surgery in Connecticut.
- 1957: Obstetricians at YNHH were the first to monitor fetal heartbeats.
- 1984: Surgeons at YNHH performed the first heart transplant operation in Connecticut.
- 1985: The world's first fetal cardiovascular center opened at YNHH.
- 1988: Surgeons at YNHH performed the first heart-lung transplant operation in New England.
- 1992: The first successful heart transplant from an unmatched donor was performed at YNHH.
- 1996: The first Battista Heart Reduction surgery in Connecticut was performed at YNHH.
- 1995 & 1997: The first documented heart transplants of adult twins were performed at YNHH, one in 1995 and one in 1997.
- 2004: Surgeons at YNHH are the first in New England to implant an artificial heart device, a Jarvik 2000.
- 2005: YNHH becomes the first U.S. hospital to successfully remove both left and right cardiac assist devices after recovery of native heart function in a patient awaiting heart transplant.
- 2009: The Hospital's fetoscopy program is one of only three in New England.
- 2011: YNHH received certification from The Joint Commission to implant left ventricular assist devices (LVADs) into patients with end-stage heart failure as a permanent or destination therapy
- 2011: YNHH's cardiac electrophysiology and arrhythmia service is the first in Connecticut to begin offering a novel non-surgical approach to treating a life-threatening heart rhythm disorder called ventricular tachycardia (VT or V-TACH).
- 2011: YNHH received certification from the Society of Chest Pain Centers (SCPC) as a Chest Pain Center with PCI, and is the first and only hospital in Connecticut to received Cycle III accreditation - the highest designation given by the SCPC.
- 2012: YNHH is the only program in Connecticut performing percutaneous pulmonary and aortic valve procedures.

YNHHVC has recruited an impressive list of pioneering cardiology specialists, leading the way in developing cardiac diagnostic tools and treatments to help both adults and children with heart

disease. We treat more heart and vascular patients than any other facility in Connecticut and can perform virtually all cardiac and vascular procedures that are offered anywhere in the world.

Signature programs include:

- Center for Advanced Heart Failure (Joint Commission certification for LVAD destination therapy);
- Cardiovascular medicine, including comprehensive cardiovascular medical care, cardiovascular imaging, and nuclear cardiology;
- Interventional cardiology, including diagnostic and interventional cardiac procedures and electrophysiology;
- Cardiothoracic surgery, including the coronary artery bypass, valve repair and replacement, minimally invasive cardiac surgery, and mechanical heart and heart transplant;
- Vascular surgery and endovascular interventions; and
- Chest Pain Center with PCI accreditation by Joint Commission.

In additional to sophisticated tertiary and quaternary cardiac services, the YNHHVC also offers a wide array of programs focused on prevention, education and patient support. Some of these include:

- Cardiac rehabilitation;
- Heart disease health library;
- Women's heart program which educates women to assess their risk of heart attack and recognize signs and symptoms;
- Peer support offered by former cardiac patients and caregivers to current cardiac patients;
- Heart transplant support group which meets monthly to connect patients and families who are waiting for a heart or recently had transplant surgery; and
- Community and corporate events such as health walks, health fairs and civic engagements.

Our physicians are diagnosing and treating heart disease, and at the same time many are also conducting ground-breaking research and educating the next generation of cardiovascular specialists. YNHHVC also offers a number of cardiac clinical trials with several underway focusing on peripheral vascular devices and CORE valves.

YNHHVC Satellite Programs

YNHHVC has established satellite emergency angioplasty programs at Greenwich and Lawrence & Memorial Hospitals. Our position on the appropriateness and safety of free standing interventional cardiac programs has evolved as cardiac care and research have demonstrated the effectiveness of these programs over the last few years. It is clear that smaller volume programs can deliver high quality and safe care assuming the proper infrastructure and clinical expertise.

Our vision for the YNHHVC is to develop cost effective services in certain geographic locations which ensure the delivery of high quality of patient care, enhance access, and improve the patient experience and satisfaction. Consistent with our objective to provide accountable, cost effective and high quality care, we want to bring the appropriate care closer to patients and eliminate the need for repeat procedures and hospitalizations, travel and unnecessary stress. This especially makes sense in our satellite emergency angioplasty programs where infrastructure is already in place. We believe the thoughtful expansion of satellite primary angioplasty programs to include elective angioplasty without onsite cardiac surgery is now firmly accepted by the cardiovascular medical community and health care regulators throughout the United States.

Our CON application offered evidence that elective angioplasty programs without onsite cardiac surgery now exist throughout the United States and recent research (e.g. CPORT-E study) and revisions to relevant clinical guidelines address the appropriateness of such development. Angioplasty has become a fairly routine procedure, often performed in the outpatient setting and at much lower risk than used to exist. The ability to offer elective angioplasty locally at qualified institutions allows patients and their families to remain close to home while they receive and recover from these procedures. It eliminates the need for two invasive procedures which adds hospital costs, clinical risk and expensive medical transportation costs.

Yale University School of Medicine cardiovascular physicians have been actively involved in the primary angioplasty program at Greenwich Hospital since its inception and will continue to provide clinical oversight, direct patient care, and staff and physician education at the proposed program. These physicians are highly skilled in cardiac catheter-based procedures and provide Greenwich Hospital cardiac patients with an exceptional level of expertise and experience. The role of the YNHHVC will ensure that the proposed program at Greenwich Hospital meets or

exceeds all of the program requirements identified by professional organizations. All of the physicians, staff, facilities, and equipment are already in place to treat the higher acuity emergency angioplasty patients.

We believe the time has come for patients to be offered elective angioplasty at Greenwich Hospital and encourage you to approve this CON application. I would like to introduce Dr. Henry Cabin who will discuss recent medical research and changes to Clinical Practice guidelines and the relevance to our proposal. Thank you.

The foregoing is my sworn testimony.

Marna Borgstrom
Chief Executive Officer
Yale-New Haven Hospital

Testimony of
Henry Cabin MD
Yale-New Haven Heart and Vascular Center at Greenwich Hospital
Docket Number: 12-31748

Introduction

Good morning Hearing Officer Yandow and OHCA staff. My name is Dr. Henry Cabin and I am the Clinical Chief of Cardiology and a Professor at the Yale University School of Medicine, Medical Director of the Yale-New Haven Heart and Vascular Center, and a practicing interventional cardiologist. My testimony will address the following two areas:

- Recent research and changes to Clinical Practice Guidelines which offer clinical evidence in support of this proposal; and
- YNHHVC's expertise and support of the proposed satellite program.

Recent Research Findings (CPORT-E) and Clinical Practice Guidelines Supporting Proposal

As discussed in our CON application, the CPORT-E study has been completed and results of the study published in 2012 in the New England Journal of Medicine (see Attachment I for a copy of the publication). This multi-center study included more than 18,000 patients that were randomly assigned in a 3:1 ratio to one of two groups. One group received elective angioplasty at a hospital with onsite cardiac surgery (n= 4,718) and the second group received elective angioplasty at a hospital without onsite cardiac surgery (n=14,149). The study measured mortality at 6-weeks and the incidence of major adverse cardiac events at 9-months post procedure. The study found that there were no significant differences between 6- week mortality and adverse cardiac events at 9 months between the two groups. The results of this study are consistent with some other studies and meta-analyses previously performed by Kutcher et al (2009) and Singh et al (2011). Copies of these other studies are also provided in Attachment I.

The research on elective angioplasty without onsite cardiac surgery led to a significant change to the 2011 ACCF/AHA/SCAI Clinical Practice Guidelines for Angioplasty, specifically the modification of elective angioplasty without onsite cardiac surgery from a Class III (not recommended, no benefit) to a Class IIb (benefit is either equal or greater than the risk) recommendation. This change reflects the growing body of research which has demonstrated

that patient outcomes are essentially the same in hospitals with or without onsite cardiac surgery. However, I want to stress that although the guidelines made this modification they also emphasize that such programs adhere to rigorous clinical, programmatic requirements and strict angiographic criteria for proper patient selection. The guidelines refer to the 2007 SCAI Consensus Document which provides clear facility and personnel requirements for angioplasty programs without onsite cardiac surgery.

Not all hospitals are equipped to offer safe, high quality elective angioplasty services. YNHHVC is uniquely positioned in Connecticut to support the careful expansion of elective angioplasty without onsite cardiac surgery. Although we addressed each of the 2007 SCAI specific facility and personnel requirements in our completeness responses to OHCA, I want to reiterate that the proposed program will adhere to these requirements and it is because of this proposed program's status as a satellite of the YNHHVC that it has the clinical expertise, resources and experience to do so and in fact is already staffed and equipped to handle the higher acuity emergency angioplasty patients. Not all primary angioplasty programs will be able to meet these stringent program and facility requirements.

YNHHVC's Expertise and Support of Proposed Program

The YNHHVC's medical staff encompasses physician experts in the areas of medical cardiology, interventional cardiology, electrophysiology, cardiac surgery, transplant surgery and vascular surgery. As noted by Ms. Borgstrom, we treat more heart and vascular patients than any other provider in Connecticut. In particular, our highly skilled board-certified interventional cardiologists collectively perform thousands of procedures each year. Each cardiologist is required to perform a minimum of 75 angioplasty procedures per year, with most performing significantly more. All of our interventional cardiologists, including the current Greenwich Hospital physicians, meet the SCAI annual volume recommendations (>75 procedures) and they all perform procedures at YNHH which is a very high volume catheterization laboratory and among the busiest in the State (performing in excess of 1,300 angioplasty procedures per year).

Our other clinical staff both in New Haven and Greenwich consist of experienced nurses, physician assistants, technicians and other support staff who have received comprehensive training in our interventional laboratory and are very comfortable treating the most acutely ill patients. Nursing and other technical staff at our satellite program at Greenwich Hospital receive the same education, training and clinical oversight as the staff at YNHH. They work and train

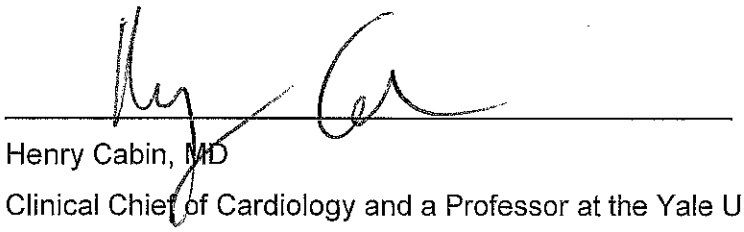
side by side on a rotational basis with the New Haven clinical staff. All of the nurses who rotate at YNHH are required to complete a competency based orientation program in heart and vascular care. In addition, all of the nurses that work in the catheterization laboratory at Greenwich Hospital are intensive care trained and all are certified in advanced cardiac life support (ACLS). Nursing staff at Greenwich Hospital who now care for emergency angioplasty patients and would provide care to elective angioplasty patients have had the benefit of receiving training and clinical experiences by YNHHVC physicians. Clinical cardiology staff at Greenwich Hospital rotate through similar clinical areas at YNHH to gain added experience and exposure.

The current emergency angioplasty program at Greenwich Hospital operates according to the same policies, procedures and protocols as our programs at YNHH. This will continue to be the case with an elective angioplasty program. This consistency of care is very important for both physicians and patients alike and results in an optimal experience. The high caliber and experience of the clinical staff assigned to the program has been a major factor in the emergency angioplasty program's very positive clinical results.

Conclusion

The proposed satellite elective angioplasty program at Greenwich Hospital offers the residents of the Greenwich Hospital service area the opportunity to receive high quality interventional cardiac care in their local community by one of the nation's leading cardiac providers. I strongly encourage OHCA to approve this CON application. I would like to introduce Dr. Christopher Howes who will discuss the need for the proposed program and provide additional information about the Greenwich Hospital catheterization laboratory.

The foregoing is my sworn testimony.



Henry Cabin, MD
Clinical Chief of Cardiology and a Professor at the Yale University School of Medicine
Medical Director of the Yale-New Haven Heart and Vascular Center
Director of the Cardiac Intensive Care Unit at Yale-New Haven

ATTACHMENT I

ORIGINAL ARTICLE

Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery

Thomas Aversano, M.D., Cynthia C. Lemmon, R.N., B.S.N., M.S., and Li Liu, M.D., for the Atlantic CPORT Investigators

ABSTRACT

BACKGROUND

Performance of percutaneous coronary intervention (PCI) is usually restricted to hospitals with cardiac surgery on site. We conducted a noninferiority trial to compare the outcomes of PCI performed at hospitals without and those with on-site cardiac surgery.

METHODS

We randomly assigned participants to undergo PCI at a hospital with or without on-site cardiac surgery. Patients requiring primary PCI were excluded. The trial had two primary end points: 6-week mortality and 9-month incidence of major adverse cardiac events (the composite of death, Q-wave myocardial infarction, or target-vessel revascularization). Noninferiority margins for the risk difference were 0.4 percentage points for mortality at 6 weeks and 1.8 percentage points for major adverse cardiac events at 9 months.

RESULTS

A total of 18,867 patients were randomly assigned in a 3:1 ratio to undergo PCI at a hospital without on-site cardiac surgery (14,149 patients) or with on-site cardiac surgery (4718 patients). The 6-week mortality rate was 0.9% at hospitals without on-site surgery versus 1.0% at those with on-site surgery (difference, −0.04 percentage points; 95% confidence interval [CI], −0.31 to 0.23; P=0.004 for noninferiority). The 9-month rates of major adverse cardiac events were 12.1% and 11.2% at hospitals without and those with on-site surgery, respectively (difference, 0.92 percentage points; 95% CI, 0.04 to 1.80; P=0.05 for noninferiority). The rate of target-vessel revascularization was higher in hospitals without on-site surgery (6.5% vs. 5.4%, P=0.01).

CONCLUSIONS

We found that PCI performed at hospitals without on-site cardiac surgery was noninferior to PCI performed at hospitals with on-site cardiac surgery with respect to mortality at 6 weeks and major adverse cardiac events at 9 months. (Funded by the Cardiovascular Patient Outcomes Research Team [C-PORT] participating sites; ClinicalTrials.gov number, NCT00549796.)

From Johns Hopkins University, Baltimore (T.A., C.C.L.); and Clinical Trials and Surveys, Owings Mills, MD (L.L.). Address reprint requests to Dr. Aversano at Johns Hopkins Cardiology at the Greater Baltimore Medical Center, Suite 5104, 6701 N. Charles St., Baltimore, MD 21204, or at taversan@jhmi.edu.

This article (10.1056/NEJMoa1114540) was published on March 25, 2012, and updated on March 26, 2012, at NEJM.org.

N Engl J Med 2012.

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THE POTENTIAL NEED FOR EMERGENCY cardiac surgery to treat complications related to percutaneous coronary intervention (PCI) suggests that performance of PCI may be best limited to hospitals with on-site cardiac surgery. Among Grüntzig's first 50 PCI procedures, 10% of patients required emergency coronary-artery bypass grafting (CABG).[1] Although the need for emergency surgery subsequently diminished dramatically (by 2002, the incidence was 0.15%[2]), concern about the safety and quality of PCI performed without the availability of on-site cardiac surgery has persisted. Hospitals in which PCI is performed but that do not have cardiac surgery programs could have more adverse events and poorer outcomes for a number of reasons (including low institutional volume of PCI procedures and inexperienced staff), in addition to the need for emergency CABG.

Despite these concerns, many hospitals without on-site cardiac surgery developed stand-alone programs for the performance of primary PCI after studies showed that primary PCI was associated with better outcomes than medical therapy in the treatment of myocardial infarction with ST-segment elevation[3] and could be performed safely and effectively at such hospitals.[4] Door-to-balloon times may be shorter, and outcomes consequently better, if primary PCI is widely available. It has further been suggested that, given the relatively low volume of primary PCI procedures at some hospitals, the addition of other PCI procedures (including elective PCI and PCI for acute coronary syndromes without ST-segment elevation) could help sustain and improve these programs.

In addition, previous studies have shown that, for patients with acute coronary syndromes presenting to centers without any revascularization capability, appropriate use of PCI and CABG is limited and outcomes are suboptimal.[5-7] Extension of PCI capability to such hospitals could improve access to appropriate care, particularly in areas where recruitment and retention of cardiologists may be difficult[8] and treatment options for patients are limited.

The Cardiovascular Patient Outcomes Research Team (CPORT) Non-Primary PCI (CPORT-E) trial was designed to help address these issues. CPORT-E was a randomized noninferiority trial that compared outcomes of PCI procedures (excluding primary PCI) at hospitals with and those without on-site cardiac surgery.

METHODS

STUDY DESIGN AND OVERSIGHT

The CPORT-E trial was designed by the study chairman and the protocol-development committee and was funded through financial support provided by participating sites to the Johns Hopkins University and through in-kind support that included the provision of local study coordinators at each site. There was no support from the makers of equipment used in catheterization laboratories or of that used for PCI. The protocol was approved by each participating hospital's institutional review board and the Johns Hopkins institutional review board. Data were gathered by local research coordinators, reviewed for accuracy by central study coordinators at Johns Hopkins, and analyzed by the authors. The authors vouch for the accuracy and completeness of the data and the analysis and for the fidelity of this report to the trial protocol, which is available with the full text of this article at NEJM.org.

TRIAL PARTICIPANTS

Patients were eligible for participation in the trial if they presented for diagnostic cardiac catheterization at 1 of 60 participating hospitals without on-site cardiac surgery located in 10 U.S. states (Maryland, New Jersey, Pennsylvania, Ohio, Georgia, Texas, North Carolina, Illinois, Oregon, and Alabama). During the trial period, patients who did not undergo randomization, whether or not they met the inclusion criteria for the trial, were included in a registry that recorded a limited set of data that excluded identifying private information.

Patients 18 years of age or older with stable coronary artery disease or an acute coronary syndrome were included in the trial. Patients with an acute myocardial infarction with ST-segment elevation were excluded, as were those with an ejection fraction of less than 20% and those who required PCI of an unprotected lesion in the left main coronary artery. In addition, interventionalists could exclude any patient whom they deemed to be at too high a risk for PCI. For each trial participant, all lesions requiring PCI had to be considered treatable at the hospital without on-site cardiac surgery before randomization. Patients who had previously participated in the trial were excluded. Full inclusion and exclusion criteria are available in Table S1 in the Supplementary Appendix, available at NEJM.org.

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PARTICIPATING HOSPITALS AND INTERVENTIONALISTS

Interventionalists were required to meet criteria for competency developed by the American College of Cardiology (ACC), the American Heart Association (AHA), and the Society for Cardiac Angiography and Interventions (SCAI).[9] Participating centers were required to have primary PCI programs available 24 hours per day, 7 days per week, and to be capable of performing 200 PCI procedures annually. Most sites required a waiver from the state department of health to participate. All such waivers allowed for a first-year PCI volume of 100 procedures, increasing to 200 in the second year.

Each site had a formal agreement with a tertiary-care hospital partner specifying that the tertiary-care institution would accept emergency transfers from the enrolling site. However, participants in the trial who were randomly assigned to undergo PCI at a hospital with on-site surgery could have the PCI procedure at any tertiary-care hospital. A formal agreement with an advanced cardiac life-support service capable of transporting patients requiring intraaortic balloon counterpulsation was also required, with an anticipated response time of 30 minutes or less.

Before commencing recruitment, all participating sites were required to complete a formal PCI development program. This program included the development of detailed care plans and pathways, order sets, and logistics and the training of staff in the care of patients undergoing PCI. Details of this program are available in the Supplementary Appendix.

TRIAL PROCEDURES

Before undergoing diagnostic catheterization, study participants provided written informed consent. After catheterization, if PCI was required and all lesions were considered to be treatable at the hospital without on-site cardiac surgery, the participant was randomly assigned in a 3:1 ratio to undergo PCI at either the enrolling site (without on-site cardiac surgery) or another facility with on-site cardiac surgery. Randomization was performed with the use of an automated telephone-response system on a per-site basis in random permuted blocks (of 4, 8, or 12). Patients who were considered to be at too high a risk according to the study-exclusion criteria or in the judgment of the treating physician did not undergo randomization but instead underwent PCI, CABG, or other therapy as clinically indicated.

After randomization, all trial participants were to undergo PCI according to their randomized assignment. The timing of the index PCI procedure depended on individual case acuity, the need to perform PCI on a different day than the visit to the catheterization laboratory to minimize procedural risk (i.e., staged procedure), and scheduling and transportation constraints, but the procedure was to be performed as soon as possible for each participant. All treatments, devices, and drugs were administered and laboratory studies carried out according to routine practice; no specific PCI protocol was prescribed. However, the use of cutting balloons was limited to in-stent restenosis and atherectomy devices were not permitted at hospitals without on-site cardiac surgery.

Participants were contacted by telephone (or mail, if necessary) at 6 weeks and 3, 6, and 9 months after study entry to identify adverse events. Medical records required to document identified events were obtained as needed.

TRIAL OUTCOMES

Two coprimary outcomes were identified: all-cause mortality 6 weeks after the index PCI and the composite rate of major adverse cardiac events, including death from all causes, Q-wave myocardial infarction, and target-vessel revascularization, 9 months after the index PCI. Additional outcomes included the PCI success rate and the incidence of cardiac surgery, bleeding, stroke, renal failure, and any subsequent revascularization.

Except as noted, definitions of data elements followed those in the American College of Cardiology National Cardiovascular Data Registry module on cardiac catheterization, version 3.02.[10] Q-wave myocardial infarction was defined as the development of new Q waves in any two contiguous leads. Target-vessel revascularization was defined as any revascularization intervention (PCI or CABG) occurring in a treated vessel at any time after the index intervention. In randomly assigned participants who did not undergo an index PCI, any revascularization was considered a target-vessel revascularization. Bleeding was defined as any bleeding that required blood transfusion, except for transfusions associated with cardiac surgery. Vascular repair included thrombin injection, ultrasound-guided compression, and surgical repair. Further details of study definitions are available in the Supplementary Appendix.

All events were reported by the enrolling site to the central coordinating center and were con-

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firmed by coordinating-center staff with the source medical records submitted. Occasionally, a review of source documents resulted in the identification of unreported events or the withdrawal of submitted events. A central review committee reviewed electrocardiographic findings without knowledge of the participant's randomized assignment.

STATISTICAL ANALYSIS

The CPORT-E trial was designed as a noninferiority trial. On the basis of previous studies, the 6-week all-cause mortality rate was estimated at 0.8%[11,12] and the rate of major adverse cardiac events at 9 months was estimated at 12.0%.[13-16] Noninferiority margins for the difference in event rates were set at 0.4 percentage points for the 6-week end point and 1.8 percentage points for the 9-month end point. With dual primary end points, the required number of participants for a one-sided test for noninferiority with an alpha level of 0.05 and a beta level of 0.80 was determined to be 18,360.

The primary outcome analysis was performed on data from the intention-to-treat population. Asymptotic normal approximations to the sample proportions were used to generate confidence intervals and P values for noninferiority. Categorical variables were compared with the use of Fisher's exact test or a chi-square test. A per-protocol analysis was also performed, which included only participants who underwent PCI at the site to which they were assigned. All statistical analyses were performed with the use of SAS software, version 9.2.

States that required a waiver from the department of health for trial participation typically specified that the participating hospitals should stop performing PCI when trial enrollment was completed. To allow the creation of a follow-up registry in these states, enrollment continued after the recruitment goal of 18,360 participants was reached. Ultimately, 18,867 participants underwent randomization.

RESULTS

STUDY POPULATION

Enrollment began on April 7, 2006, and ended on March 31, 2011. During that period, there were 99,479 patient visits for diagnostic catheterization at the participating hospitals. Among the 76.1% of patients who provided consent to participate, 21,165 were judged to require PCI after catheterization, and 18,867 underwent randomization (Fig. 1). Excluded were 2298 patients (10.9%) who required PCI but were judged to be at too high a risk for study participation. Reasons for the judgment that the risk was too high are shown in Figure S1 in the Supplementary Appendix. Overall, patients in the registry had fewer risk factors and less severe coronary disease than randomly assigned trial participants (Table S2 in the Supplementary Appendix).

Of the patients who underwent randomization, 319 did not undergo an index PCI. The proportion of patients who did not undergo an index PCI was higher among participants assigned to hospitals with on-site cardiac surgery than among those assigned to hospitals without on-site surgery. Reasons included referral for surgical or medical therapy and lesion resolution (Table S3 in the Supplementary Appendix). Crossovers between study groups were infrequent but were more frequent among participants randomly assigned to hospitals with on-site cardiac surgery (Fig. 1).

The baseline characteristics of the participants are shown in Table 1. There was a higher incidence of prior PCI in participants randomly assigned to hospitals without cardiac surgery on site. In addition, the rate of emergency catheterization was higher, and the rate of urgent catheterizations lower, among participants assigned to hospitals with on-site cardiac surgery.

The median annual volume of catheterizations per hospital was 150 procedures (interquartile range, 99 to 216). The median annual volume of primary PCIs was 51 procedures (interquartile range, 35 to 74). The participation of 12 hospitals was terminated during the trial because of low volume. Data from these sites were included in the data analysis.

PROCEDURE CHARACTERISTICS

A higher percentage of PCIs were staged among participants assigned to hospitals with on-site cardiac surgery than among those assigned to hospitals without on-site surgery, probably because of the need for transfer (Table 2). As a result, the number of visits to the catheterization laboratory that were needed to complete PCI was higher among participants assigned to hospitals with on-

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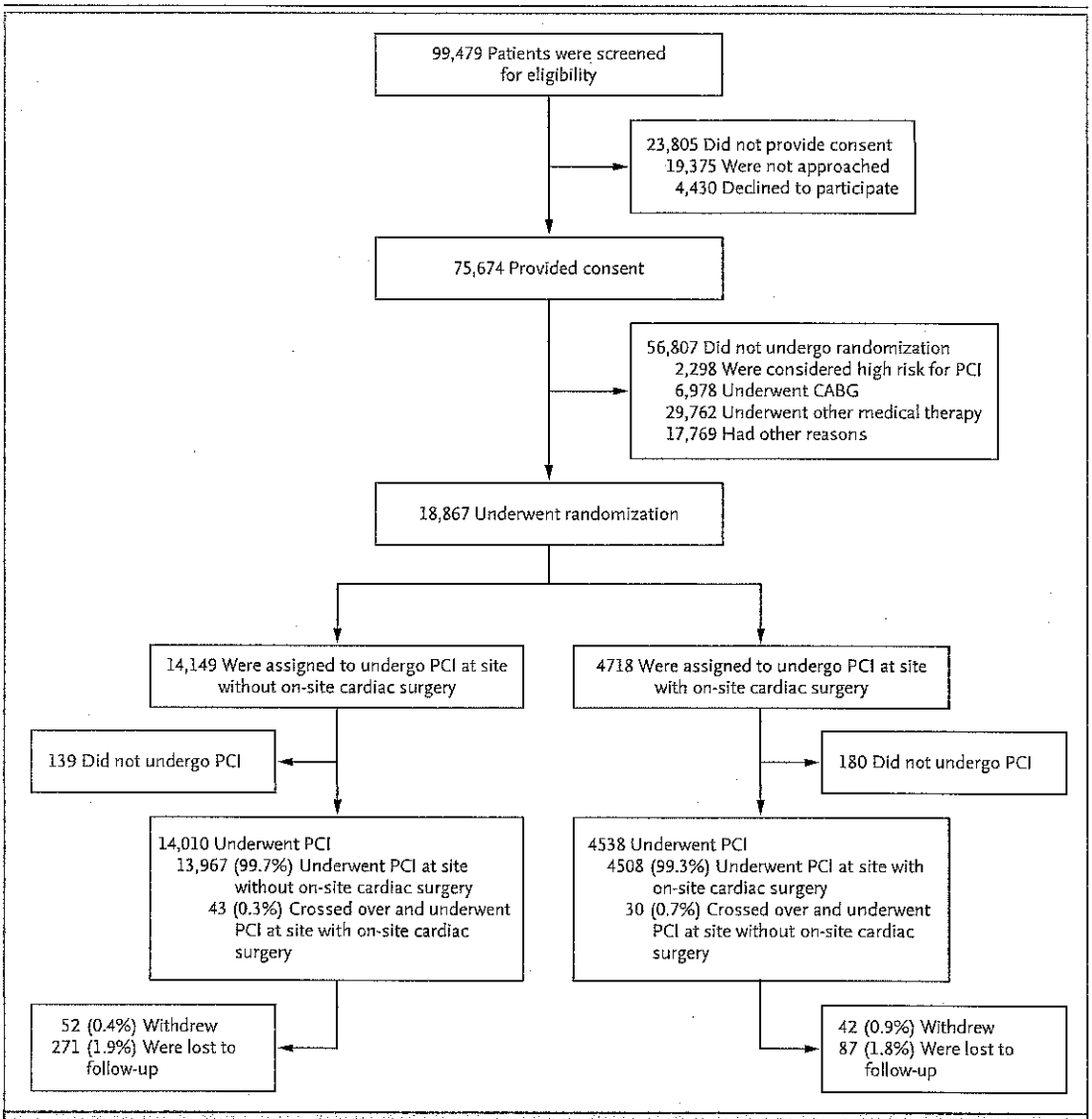

Figure 1. Enrollment and Randomization of the Study Patients.

The percentages for the patients who withdrew or were lost to follow-up are based on the patients assigned to undergo percutaneous coronary intervention (PCI). CABG denotes coronary-artery bypass grafting.

site cardiac surgery. In addition, drug-eluting stents were used more frequently in hospitals with on-site cardiac surgery.

The rate of PCI failure was lower among participants treated at hospitals with on-site cardiac surgery (Table 2). Emergency CABG was associated with high mortality but was rarely performed; it was performed more frequently among participants assigned to hospitals with on-site cardiac surgery. The incidence of unplanned re-catheterization and PCI before discharge was greater at hospitals without on-site cardiac surgery.

OUTCOMES

At 6 weeks after the index PCI, 132 participants assigned to hospitals without on-site cardiac surgery had died and 46 participants assigned to hospitals with on-site cardiac surgery had died. The event rates in the two groups were 0.9% and 1.0%, respectively (difference in event rates, −0.04 percentage points; 95% confidence interval [CI], −0.31 to 0.23; P=0.004 for noninferiority) (Table 3).

At 9 months, there were 1716 major adverse cardiac events in participants at hospitals without on-site cardiac surgery and 529 such events in

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Table 1. Baseline Characteristics of the Study Patients.*

Characteristic	No On-Site Cardiac Surgery (N=14,149)	On-Site Cardiac Surgery (N=4718)
Age — yr	63.9±11.9	64.0±12.0
Male sex — no. (%)	9046 (63.9)	2970 (63.0)
White race — no. (%)†	11,185 (79.1)	3778 (80.1)
Medical history — no. (%)		
Hypertension	11,950 (84.5)	4024 (85.3)
Hypercholesterolemia	11,567 (81.8)	3865 (81.9)
Smoking (current or former)	8,719 (61.6)	2964 (62.8)
Diabetes	5,485 (38.8)	1868 (39.6)
Family history of CAD	7,730 (54.6)	2623 (55.6)
Heart failure	1,531 (10.8)	518 (11.0)
Prior myocardial infarction	6,011 (42.5)	2030 (43.0)
Prior PCI‡	4,506 (31.8)	1430 (30.3)
Prior CABG	1,852 (13.1)	632 (13.4)
Prior stroke or PVD	2,447 (17.3)	868 (18.4)
Angiographic findings at baseline		
One-vessel CAD — no. (%)	5,097 (36.0)	1645 (34.9)
Two-vessel CAD — no. (%)	5,087 (36.0)	1741 (36.9)
Three-vessel CAD — no. (%)	3,959 (28.0)	1326 (28.1)
Left main CAD — no. (%)	465 (3.3)	178 (3.8)
Graft disease — no. (%)	1,323 (9.4)	456 (9.7)
Left ventricular ejection fraction — %	54.2±10.6	54.3±10.7
Procedure status at time of catheterization — no. (%)§		
Elective	10,350 (73.2)	3414 (72.4)
Urgent¶	3,291 (23.3)	1127 (23.9)
Emergency‡	493 (3.5)	175 (3.7)
Clinical status at time of catheterization — no. (%)‖		
STEMI	390 (2.8)	147 (3.1)
NSTEMI	3,471 (24.5)	1210 (25.7)
Unstable angina	5,196 (36.7)	1665 (35.3)
Stable angina	2,011 (14.2)	636 (13.5)
Atypical chest pain	723 (5.1)	268 (5.7)
Other	2,356 (16.7)	790 (16.8)

* Plus–minus values are means ±SD. CABG denotes coronary-artery bypass grafting, CAD coronary artery disease, NSTEMI non–ST-segment elevation myocardial infarction, PCI percutaneous coronary intervention, PVD peripheral vascular disease, and STEMI ST-segment elevation myocardial infarction.

† Race was self-reported.

‡ P<0.05 for the comparison between groups.

§ For procedure status at time of catheterization, data were missing for 15 patients treated at hospitals without on-site cardiac surgery and 2 patients treated at hospitals with on-site cardiac surgery. The definitions for "urgent" and "emergency" were those used in the American College of Cardiology National Cardiovascular Data Registry module on cardiac catheterization, version 3.02.[10]

¶ P<0.01 for the comparison between groups.

‖ For clinical status at time of catheterization, data were missing for 2 patients in each study group. "Other" includes patients presenting with heart failure, arrhythmia, positive stress tests, syncope, and other non–chest-pain syndromes and patients undergoing cardiovascular risk assessment before a noncardiac surgical procedure.

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Table 2. Characteristics of the Index Procedure.*

Characteristic	No On-Site Cardiac Surgery	On-Site Cardiac Surgery	P Value
PCI staged — no./total no. (%)†	3652/14,010 (26.1)	3084/4538 (68.0)	<0.001
Single-vessel PCI — no./total no. (%)	11,212/14,010 (80.0)	3716/4538 (81.9)	
Multivessel PCI — no./total no. (%)	2937/14,010 (21.0)	1002/4538 (22.1)	
No. of catheterization laboratory visits needed to complete index PCI	1.28	1.73	<0.001
No. of days from randomization to index PCI — median (IQR)	0 (0–3)	1 (0–3)	<0.001
Stent use — no./total no. (%)			0.03
DES only	10,074/14,010 (71.9)	3343/4538 (73.7)	
BMS only	2790/14,010 (19.9)	877/4538 (19.3)	
Both DES and BMS	596/14,010 (4.3)	156/4538 (3.4)	
Balloon only	550/14,010 (3.9)	162/4538 (3.6)	
PCI success — no./total no. (%)			
By patient‡			0.007
Complete success	12,714/14,010 (90.7)	4148/4538 (91.4)	
Partial success	808/14,010 (5.8)	253/4538 (5.6)	
Failure	482/14,010 (3.4)	113/4538 (2.5)	
By lesion§			0.04
Success	19,886/21,292 (93.4)	6499/6907 (94.1)	
Failure	1406/21,292 (6.6)	408/6907 (5.9)	
Emergency procedures			
Emergency PCI — no./total no. (%)	23/14,010 (0.2)	6/4538 (0.1)	
Death associated with emergency PCI — no. of deaths/total no. of emergency PCI procedures (%)	1/23 (4.3)	0	
Emergency CABG — no./total no. (%)	13/14,010 (0.1)	10/4538 (0.2)	0.11
Death associated with emergency CABG — no. of deaths/total no. of emergency CABG procedures (%)	2/13 (15.4)	2/10 (20.0)	

* Data are for all randomly assigned patients who underwent PCI. BMS denotes bare-metal stent, DES drug-eluting stent, and IQR interquartile range.

† Staged PCI indicates that PCI was performed on a different day than the visit to the catheterization laboratory to minimize procedural risk.

‡ Thirty patients (6 in hospitals without on-site cardiac surgery and 24 in hospitals with on-site cardiac surgery) did not have valid postprocedure data available on coronary-artery flow (according to the Thrombolysis in Myocardial Infarction [TIMI] scale, which ranges from 0 to 3, with 0 indicating no flow and 3 normal flow) or percentage of residual stenosis. These 30 patients were excluded from the analysis of PCI success by patient. Complete success was defined as a postprocedure TIMI flow grade of 3 and residual stenosis not exceeding 20% in all treated lesions. Partial success was defined as a postprocedure TIMI flow grade of 3 and residual stenosis not exceeding 20% in at least one (but not all) treated lesions. Failure was defined as no treated lesions with a postprocedure TIMI flow grade of 3 and residual stenosis of more than 20%.

§ Success by lesion was defined as a postprocedure TIMI flow grade of 3 and residual stenosis not exceeding 20%. Failure was defined as a postprocedure TIMI flow grade of less than 3 or residual stenosis of more than 20%.

patients at hospitals with on-site cardiac surgery (12.1% vs. 11.2%; difference in event rates, 0.92 percentage points; 95% CI, 0.04 to 1.80; P=0.05 for noninferiority) (Table 3). There were no significant differences in all-cause mortality or Q-wave myocardial infarction between the two groups, but there was a significant difference in the rate of target-vessel revascularization — 6.5% among participants at hospitals without on-site cardiac surgery versus 5.4% among those at hospitals with on-site cardiac surgery (P=0.01).

Several exploratory analyses were conducted (Table 3). If CABG was not considered to qualify as target-vessel revascularization when it was performed as an initial procedure (i.e., for participants who did not undergo the intended index PCI), the rates of major adverse cardiac events at 9 months among participants at hospitals with-

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Table 3. Trial Outcomes.*

Outcome	No On-Site Cardiac Surgery	On-Site Cardiac Surgery	Difference in Rate (Asymptotic One-Sided 95% CI)	P Value	
				Noninferiority	Superiority
	no./total no. (%)		*percentage points*		
Primary end point (intention-to-treat population)					
Death at 6 wk	132/14,149 (0.9)	46/4718 (1.0)	−0.04 (−0.31 to 0.23)	0.004	
9-mo outcomes					
Death	454/14,149 (3.2)	150/4718 (3.2)			
TVR	915/14,149 (6.5)	255/4718 (5.4)			0.01
Q-wave myocardial infarction	434/14,149 (3.1)	144/4718 (3.1)			
Major adverse cardiac event	1716/14,149 (12.1)	529/4718 (11.2)	0.92 (0.04 to 1.80)	0.05	
Exploratory analyses (intention-to-treat population)					
Major adverse cardiac event, including withdrawal and loss to follow-up	2026/14,149 (14.3)	653/4718 (13.8)	0.48 (−0.48 to 1.44)	0.01	
CABG as initial procedure not included in TVR definition					
TVR	873/14,149 (6.2)	218/4718 (4.6)			<0.001
Major adverse cardiac event	1678/14,149 (11.9)	495/4718 (10.5)	1.37 (0.51 to 2.23)	0.21	
TVR according to stent type					
DES only	484/10,074 (4.8)	120/3343 (3.6)			0.005
BMS only	223/2790 (8.0)	53/877 (6.0)			
Both DES and BMS	39/596 (6.5)	8/156 (5.1)			
Balloon only	138/550 (25.1)	34/162 (21.0)			
Per-protocol analyses					
Death at 6 wk	129/13,967 (0.9)	38/4508 (0.8)	0.08 (−0.18 to 0.34)	0.03	
TVR	860/13,967 (6.2)	202/4508 (4.5)			<0.001
Major adverse cardiac event at 9 mo	1676/13,967 (12.0)	467/4508 (10.4)	1.64 (0.77 to 2.51)	0.42	

* Major adverse cardiac events included death, target-vessel revascularization (TVR), and Q-wave myocardial infarction. BMS denotes bare-metal stent, and DES drug-eluting stent.

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out and those with on-site cardiac surgery were 11.9% and 10.5%, respectively. In per-protocol analyses (excluding participants who crossed over), the death rates at 6 weeks were 0.9% and 0.8%, respectively, and the rates of major adverse cardiac events at 9 months were 12.0% and 10.4%, respectively.

CABG was performed more frequently among trial participants at hospitals with on-site cardiac surgery than among participants at hospitals without such access (Table 4). The incidence of unplanned catheterization at 6 weeks and 9 months and the incidence of any subsequent revascularization at 9 months were higher among participants at hospitals without on-site cardiac surgery (Table 4).

DISCUSSION

We compared clinical outcomes between trial participants undergoing PCI at a hospital with on-site access to cardiac surgery and participants undergoing PCI at a hospital without such access. We found that outcomes at hospitals without on-site cardiac surgery were noninferior to those at hospitals with cardiac surgery on site, with respect to all-cause mortality at 6 weeks and major adverse cardiac events at 9 months. There were no significant differences between the two study groups at 9 months with respect to rates of death or Q-wave myocardial infarction, but trial participants treated at hospitals without on-site cardiac surgery more frequently required target-vessel revascularization.

The short-term results from this trial are concordant with the findings in previous registry studies and meta-analyses.[17,18] The longer-term outcomes are similar to those in a small randomized trial of low-risk PCI at two hospitals,[19] which showed equivalent safety at the hospitals with and those without on-site cardiac surgery but more frequent target-vessel revascularization at 6 months among participants treated at the sites without cardiac surgery.

The definition of target-vessel revascularization used in the CPORT-E trial included any revascularization (PCI or CABG) after the index PCI. In addition, for randomly assigned participants who did not undergo an index PCI, any subsequent revascularization of the target vessel, whether by PCI or CABG, was considered a target-vessel revascularization. The inclusion of initial CABG as a target-vessel revascularization is consistent with the intention-to-treat approach, which is based on randomized treatment assignments, regardless of the treatment received. When CABG was not counted as a target-vessel revascularization in these trial participants, hospitals without on-site cardiac surgery were inferior to those with on-site access with respect to the rate of major adverse cardiac events at 9 months (Table 3). The per-protocol analysis also showed a higher rate of major adverse cardiac events in hospitals without on-site cardiac surgery. These differences are small and within the range of noninferiority margins used in recent comparative trials of stent types, from 1.5 percentage points (relative difference, 19%)[20] to 3.5 percentage points (relative difference, 43%).[21]

In all analyses, the rate of target-vessel revascularization was higher among participants who underwent PCI at a hospital without cardiac surgery on-site, regardless of the definition of target-vessel revascularization and regardless of stent type. The reason for this is not clear from the current study but may reflect a lower initial success rate and a more conservative approach by interventionalists practicing at relatively inexperienced centers that began PCI programs only as part of the CPORT-E trial.

There are a number of important limitations arising from the design and conduct of the CPORT-E trial. Participants were carefully selected and were excluded if they were deemed to be at high risk. It is possible that the population studied is different from the general population requiring PCI, although a comparison of baseline characteristics with those reported in the National Cardiovascular Data Registry[17] suggests that this is not the case (Table S4 in the Supplementary Appendix). For outcomes of PCI at hospitals without on-site cardiac surgery to be similar to those at hospitals with on-site cardiac surgery, it may be necessary for such centers to participate in a formal PCI development program and for interventionalists who perform the procedures to meet the criteria for competency developed by the ACC, AHA, and SCAI.

In summary, the CPORT-E trial compared the clinical outcomes of PCI performed at hospitals with access to on-site cardiac surgery with outcomes of PCI performed at hospitals without such access. Outcomes at hospitals without on-site cardiac surgery were noninferior to those at hospi-

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Table 4. Adverse Events.

Event	6 Wk			9 Mo		
	No On-Site Cardiac Surgery (N=14,149)	On-Site Cardiac Surgery (N=4718)	P Value	No On-Site Cardiac Surgery (N=14,149)	On-Site Cardiac Surgery (N=4718)	P Value
	no. (%)			*no. (%)*		
CABG						
All	88 (0.6)	69 (1.5)	<0.001	216 (1.5)	107 (2.3)	<0.001
Emergency	15 (0.1)	10 (0.2)		18 (0.1)	11 (0.2)	
Bleeding	486 (3.4)	150 (3.2)		754 (5.3)	247 (5.2)	
Vascular repair	52 (0.4)	20 (0.4)		151 (1.1)	55 (1.2)	
Stroke	40 (0.3)	8 (0.2)		87 (0.6)	23 (0.5)	
Renal insufficiency	72 (0.5)	20 (0.4)		131 (0.9)	37 (0.8)	
Unplanned catheterization	613 (4.3)	150 (3.2)	<0.001	2102 (14.9)	566 (12.0)	<0.001
Any subsequent revascularization	378 (2.7)	127 (2.7)		1200 (8.5)	329 (7.0)	0.001

tals with cardiac surgery on site, with respect to all-cause mortality at 6 weeks and major adverse cardiac events at 9 months.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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REVIEW

Percutaneous Coronary Intervention at Centers With and Without On-site Surgery

A Meta-analysis

Mandeep Singh, MD, MPH
David R. Holmes Jr, MD
Gregory J. Dehmer, MD
Ryan J. Lennon, MS
Thomas P. Wharton, MD
Michael A. Kutcher, MD
Thomas Aversano, MD
Charanjit S. Rihal, MD

Context Percutaneous coronary interventions are performed at centers without on-site surgery, despite current guidelines discouraging this.

Objective To assess literature comparing rates of in-hospital mortality and emergency coronary artery bypass grafting surgery at centers with and without on-site surgery.

Data Sources A systematic search of studies published between January 1990 and May 2010 was conducted using MEDLINE, EMBASE, and Cochrane Review databases.

Study Selection English-language studies of percutaneous coronary intervention performed at centers with and without on-site surgery providing data on in-hospital mortality and emergency bypass were identified. Two study authors independently reviewed the 1029 articles originally identified and selected 40 for analysis.

Data Extraction Study title, time period, indication for angioplasty, and outcomes were extracted manually from all selected studies, and quality of each study was assessed using the strengthening the reporting of observational studies in epidemiology (STROBE) checklist.

Data Synthesis High-quality studies of percutaneous coronary interventions performed at centers with and without on-site surgery were included. Pooled-effect estimates were calculated with random-effects models. Analyses of primary percutaneous coronary intervention for ST-segment elevation myocardial infarction of 124 074 patients demonstrated no increase in in-hospital mortality (no on-site surgery vs on-site surgery: observed risk, 4.6% vs 7.2%; odds ratio [OR], 0.96; 95% CI, 0.88-1.05; I^2=0%) or emergency bypass (observed risk, 0.22% vs 1.03%; OR, 0.53; 95% CI, 0.35-0.79; I^2=20%) at centers without on-site surgery. For nonprimary percutaneous coronary interventions (elective and urgent, n=914 288), the rates of in-hospital mortality (observed risk, 1.4% vs 2.1%; OR, 1.15; 95% CI, 0.93-1.41; I^2=46%) and emergency bypass (observed risk, 0.17% vs 0.29%; OR, 1.21; 95% CI, 0.52-2.85; I^2=5%) were not significantly different at centers without or with on-site surgery.

Conclusion Percutaneous coronary interventions performed at centers without on-site surgery, compared with centers with on-site surgery, were not associated with a higher incidence of in-hospital mortality or emergency bypass surgery.

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CURRENT GUIDELINES RECOMmend against performing elective percutaneous coronary intervention (PCI) at institutions without on-site cardiac surgery capability (American Heart Association/American Cardiology class III indication).[1] It is considered acceptable to perform PCI at such facilities (class IIb) for patients with ST-segment elevation myocardial infarction (STEMI), but additional requirements must be present at the facility to ensure patient safety.[1] The need for on-site coronary artery bypass grafting (CABG) surgery to back up PCI was considered mandatory during the prior era of angioplasty, when up to 5% of patients required urgent or emergency CABG surgery after failed angioplasty.

Despite the marked decline in the need for emergency CABG surgery after PCI[2,3] and satisfactory outcomes at selected centers,[4] several concerns remain regarding PCI programs without on-site surgical backup. First, favorable results reported from such centers were largely derived from small, single-center observational registries.[4-6]

For editorial comment see p 2507.

Second, 1 large study using administrative data demonstrated worse outcomes for elective PCIs at sites without on-site surgery, especially at centers with low annual angioplasty volumes.[7] Third, since publication of the guidelines,[1] additional studies at institutions without on-site surgery have reported favorable results.[4,8-12]

This unresolved clinical issue has implications for the delivery of clinical care

Author Affiliations: Division of Cardiovascular Diseases (Drs Singh, Holmes, and Rihal) and Division of Biomedical Statistics and Informatics (Mr Lennon), Mayo Clinic, Rochester, Minnesota; Division of Cardiology, Scott & White Healthcare, Temple, Texas (Dr Dehmer); Cardiovascular Medicine, Exeter Hospital, Exeter, New Hampshire (Dr Wharton); Department of Cardiology, Wake Forest University Baptist Medical Center, Winston-Salem, North Carolina (Dr Kutcher); and Department of Cardiology, Johns Hopkins Hospital, Baltimore, Maryland (Dr Aversano).
Corresponding Author: Mandeep Singh, MD, MPH, Division of Cardiovascular Diseases, Mayo Clinic, 200 First St SW, Rochester, MN 55905 (singh.mandeep@mayo.edu).

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and for health care infrastructure. Given the discrepant results among studies and low power of some studies to detect a difference between centers with and without on-site surgery, we performed a meta-analysis of studies to further define the safety and outcomes of PCI at centers without on-site surgery. We aimed to test the hypothesis that outcomes of elective PCI and primary PCI for STEMI at centers without on-site surgery are not different from those for PCI performed at centers with on-site surgery.

METHODS

Search Strategy

Following the meta-analysis of observational studies in epidemiology (MOOSE) guidelines, we conducted a comprehensive literature search of MEDLINE, EMBASE, and Cochrane Library databases for studies published between January 1990 and December 2009.[13] The search was started in 1990 so as to include most studies reporting data at centers without on-site surgery. Keywords related to angioplasty used for searching were *percutaneous transluminal coronary angioplasty* or *PTCA*, *primary angioplasty*, *ST-segment elevation myocardial infarction* or *STEMI*, *PCI*, *angioplasty*, *on-site surgery*, *coronary stents*, *drug-eluting stents*, and *balloon angioplasty*. These terms were cross-referenced to citations pertinent to outcomes (ie, mortality and CABG rates).

Studies that met each of the following criteria were considered eligible for meta-analysis: published in English; PCI results from a center without on-site surgery were available; PCI outcomes were compared with a center with on-site surgery; provided a clear definition of STEMI for studies including patients with STEMI; and had a case-control matching design, with statistical analyses (matching, covariate adjustment, or propensity-based adjustment) to adjust for differences in patient characteristics between centers with and without on-site surgery.[4-12,14-19] Articles were excluded if results were reported only on PCI at centers without on-site surgery without a control population. Unpublished studies and studies that were presented at conferences were not included in the meta-analysis. Reviews were hand-searched for additional references, but yielded no additional articles. Title and abstract review of all articles was completed by 2 of the authors (M.S., M.A.K.). Full reports of 17 potentially relevant articles were independently reviewed by at least 2 investigators (C.S.R., M.S.) to establish eligibility according to the inclusion criteria.

Data Analysis

A standardized, piloted data extraction form was used for recording information. Data extraction was completed by one of the authors (M.S.). For the primary analyses, we obtained the adjusted odds ratio (OR) for available studies, with corresponding 95% confidence intervals, and noted the type of statistical adjustment (ie, variables examined as possible covariates in relation to the outcomes of interest).

Study populations were characterized at centers with or without on-site surgery, and the following information was recorded: primary author; publication year; study design (single-center or multicenter); PCI type (primary PCI for STEMI or nonprimary PCI [elective and non-STEMI]); number of patients; and mortality, emergency CABG rates stratified by the presence or absence of on-site surgery and by the indication for PCI, or both. Patients with STEMI did not include those with facilitated PCI or rescue PCI; such patients were more likely to be included in the non-STEMI subset of the nonprimary PCI group. Information on the need for transfer out of a facility without on-site surgery was not consistently available but was recorded when available. Disagreement between reviewers during the selection process was resolved through consensus.

The quality of the studies was assessed on the basis of elements from the strengthening the reporting of observational studies in epidemiology (STROBE) checklist for cohort studies.[20] We did not assign a threshold for study inclusion. All the studies included in the analyses met at least 15 variables in the checklist. Inconsistencies among studies were found in determination of bias, selection of participants in the study, determination of study size, handling of quantitative variables, and determination of the source of funding.

In-hospital mortality and the need for emergency CABG surgery were examined as separate outcomes. There was no uniform definition of emergency CABG surgery. Wherever reported, the need for emergency CABG surgery was largely due to complications during the PCI procedure, and patients were transferred within 24 hours of PCI. However, some patients were also transferred because of unstable hemodynamics. Each study contributed only 1 effect size per analysis. If data were duplicated between studies, the most recent study was used. When available, ORs reported in the article were used, and adjusted ORs (and their corresponding 95% confidence intervals) were used preferentially over unadjusted ORs. If ORs were not reported, we calculated them using the event and sample size frequencies. If frequencies were not given, they were estimated from percentages and rounded to the nearest integer. If any cell had a 0 count, ORs were calculated by adding 0.5 to all cell counts from the study to avoid division by 0.

Random-effects models were used to estimate pooled ORs. Fixed-effects models were only used in sensitivity analyses that examined whether these models yielded similar results. An OR greater than 1 indicates an increased risk of an outcome among patients undergoing PCI at centers without on-site surgery as compared with controls (patients undergoing PCI at centers with on-site surgery). The I^2 statistic was used to examine the heterogeneity of effect sizes in the overall aggregations: $I^2 \leq 25\%$ indicates low heterogeneity, $I^2 \approx 50\%$ indicates moderate heterogeneity, and $I^2 \geq 75\%$ indicates high heterogeneity.

Publication bias was evaluated with a combination of a funnel plot–based

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method and the trim-and-fill method to estimate the number of missing studies and to calculate a corrected OR as if these studies were present.[13] The effect of potential outliers was examined by comparing the pooled estimate with estimates obtained after iterations using k–1 findings (each study is left out and the effect re-estimated). Studies were treated as statistical outliers if the k–1 estimate produced a 95% confidence interval that did not overlap with the 95% confidence interval of the aggregated estimate.

Statistical analyses were performed using SAS version 9.2 software (SAS Institute Inc). *P* values less than .05 were considered statistically significant.

RESULTS

We identified 1029 articles, of which we selected 40 for further review on the basis of the inclusion and exclusion criteria described in the "Methods" section. Excluded studies did not include PCIs performed at centers without on-site surgery. We then excluded 23 additional studies that were case series of PCIs performed at centers without on-site surgery and that lacked a control group, an abstract that did not provide sufficient details, and a Japanese study that defined myocardial infarction differently.[21,22] Fifteen studies met our inclusion criteria (FIGURE 1). The included studies reported statistically adjusted effect estimates for the outcome of mortality, emergency CABG, or both (TABLE 1).

Mortality

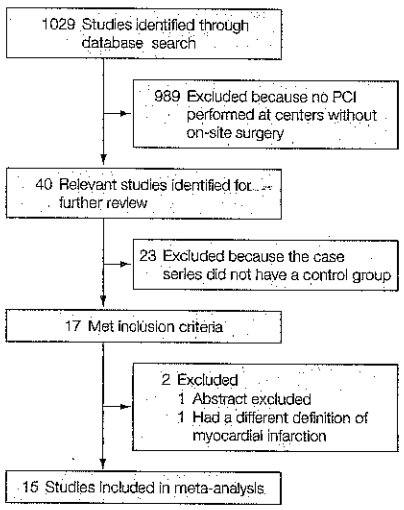
Primary PCI. The pooled OR for in-hospital mortality in patients undergoing primary PCI was derived from 124 074 patients. The average mortality rate across studies was 4.6% (range, 2.1%-11.3%) for sites without on-site surgery and 5.1% (range, 1.0%-12.2%) for sites with on-site surgery. Pooling all patients equally resulted in observed mortality rates of 4.6% and 7.2%, respectively. In-hospital mortality for patients at hospitals without on-site surgery was not different from hospitals having on-site surgery (OR, 0.96; 95% CI, 0.88-1.05) in both fixed-effects and random-effects models, with no observed heterogeneity (I^2=0%; FIGURE 2). The funnel plot was narrow, and the estimated effects are consistent across various studies (FIGURE 3).

Nonprimary PCI. The pooled OR for in-hospital mortality in patients undergoing nonprimary PCI was derived from 914 288 patients. Mortality was not significantly different for patients undergoing nonprimary PCI at facilities with and without on-site surgery (OR, 1.15; 95% CI, 0.93-1.41). The average mortality rate across studies was 0.9% (range, 0%-4.6%) for sites without on-site surgery and 0.8% (range, 0%-2.8%) for sites with on-site surgery. Pooling all patients equally resulted in observed rates of 1.4% and 2.1%, respectively. Moderate heterogeneity (I^2=46%) was identified in this group. After adjustment for publication bias, the mortality rate for nonprimary PCI was 25% higher at centers without on-site surgery compared with centers that had on-site surgery (OR, 1.25; 95% CI, 1.01-1.53; *P*=.04; Figure 2 and TABLE 2).

Emergency CABG

The incidence of emergency CABG for both primary and nonprimary PCI at centers without on-site surgery was low. The highest observed rate of emergency CABG surgery among the studies was 1.2% for primary PCI and 0.3% for nonprimary PCI; these occurred at facilities with on-site surgery. For primary PCI, the observed rate (pooling all patients equally) of emergency CABG surgery was 0.22% at centers without on-site surgery vs 1.03% at centers with on-site surgery; for nonprimary PCI, the rates were 0.17% and 0.29%, respectively. The OR for emergency CABG surgery after primary or nonprimary PCI performed at sites without on-site surgery vs that at centers with on-site surgery was 0.53 (95% CI, 0.35-0.79) for primary PCI and was 1.21 (95% CI, 0.52-2.85) for nonprimary PCI in the random-effects model (FIGURE 4). Estimates of heterogeneity were low for these outcomes (I^2=20% for primary PCI; I^2=5% for nonprimary PCI). After adjustment for publication bias, the ORs were not substantially different. Transfer rates to hospitals with on-site surgery and the outcomes of transferred patients were not consistently reported and, hence, were not included in the analyses.

Figure 1. Study Flow



PCI indicates percutaneous coronary intervention. Abstracts were excluded because they do not provide enough information.

Subset Analysis

We performed a subset analysis of 11 studies in which the study period included no years earlier than 1999. The results of this analysis gave ORs very similar to those in the primary analysis: For patients with STEMI, the OR of death was 0.97 (95% CI, 0.88-1.06); elective PCI, the OR for death was 1.15 (95% CI, 0.93-1.42); with STEMI the OR for emergency CABG surgery was 0.56 (95% CI, 0.37-0.84); and elective PCI, the OR for emergency CABG surgery was 1.32 (95% CI, 0.49-3.59).

COMMENT

Several important clinical findings emerge from our meta-analysis. It demonstrated that mortality and the need

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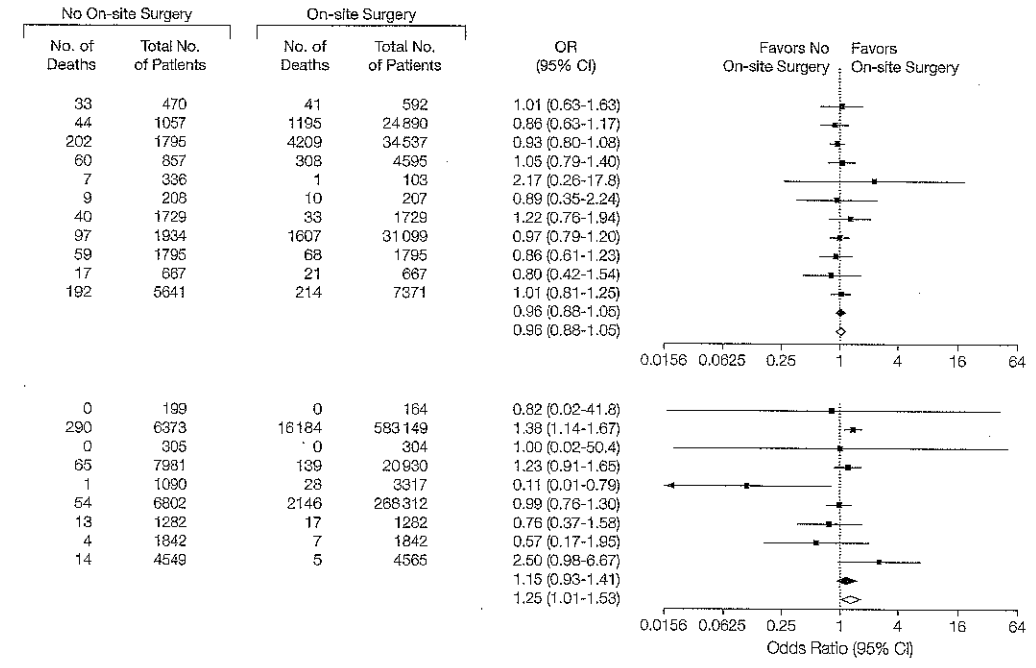
for emergency CABG surgery after primary PCI for STEMI were similar at centers with and without on-site surgical backup. The narrow funnel plot and consistent individual and combined effect estimates for mortality support the safety of performing primary PCI at these centers. No significant publication bias was demonstrated.

Table 1. Studies Included in the Meta-analysis

Source	Study	Study Period	Indication for PCI	Study Center Type	No. of Patients			
					STEMI		Elective or Non-STEMI	
					Without On-site Surgery	With On-site Surgery	Without On-site Surgery	With On-site Surgery
Dellavalle et al,[6] 1995	Dellavalle	1992-1994	Elective	Single			199	164
Weaver et al,[14] 1995	MITI	1988-1994	STEMI	Multi	470	592		
Sanborn et al,[15] 2004	NRMI	1998-2001	STEMI	Multi	1057	24 890		
Wennberg et al,[7] 2004	Medicare	1999-2001	All	Multi	1795	34 537	6373	583 149
Melberg et al,[16] 2006	Norwegian randomized	1997-2001	Elective	Single			305	304
Carlsson et al,[9] 2007	SCAAR	2000-2003	All	Multi	857	4595	7981	20 930
Peels et al,[5] 2007	Alkmaar, the Netherlands	2002-2005	STEMI	Single	336	103		
Frutkin et al,[10] 2008	MAHI	2003-2005	Elective	Single			1090	3317
Giuliani et al,[19] 2008	Italian	2005-2006	STEMI	Multi	208	207		
Hannan et al,[11] 2009	NY State PCIRS	2003-2006	STEMI	Multi	1729	1729		
Kutcher et al,[8] 2009	NCDR	2004-2006	All	Multi	1934	31 099	6802	268 312
Pride et al,[17] 2009	NRMI-STEMI	2004-2006	STEMI	Multi	1795	1795		
Pride et al,[18] 2009	NRMI-non-STEMI	2004-2006	Non-STEMI	Multi			1282	1282
Singh et al,[4] 2009	Mayo Clinic	1999-2007	All	Multi	667	667	1842	1842
Tebbe et al,[12] 2009	German, ALKK	2006	All	Multi	5641	7371	4549	4565

Abbreviations: ALKK, Arbeitsgemeinschaft Leitende Kardiologische Krankenhausärzte; MAHI, Mid America Heart Institute; MITI, Myocardial Infarction Triage and Intervention; NCDR, National Cardiovascular Data Registry; NRMI, National Registry of Myocardial Infarction; PCI, percutaneous coronary intervention; PCIRS, Percutaneous Coronary Intervention Reporting System; SCAAR, Swedish Coronary Angiography and Angioplasty Registry; STEMI, ST-segment elevation myocardial infarction.

Figure 2. Forest Plots Comparing In-hospital Mortality Following Percutaneous Coronary Intervention at Sites With and Without Surgery



Odds ratio (OR) estimates with 95% CIs of all studies for the outcomes of death by indication for percutaneous coronary intervention. In the case of 0 counts, ORs were calculated by adding 0.5 to all cell counts from the study to avoid division by 0. STEMI indicates ST-elevation myocardial infarction.

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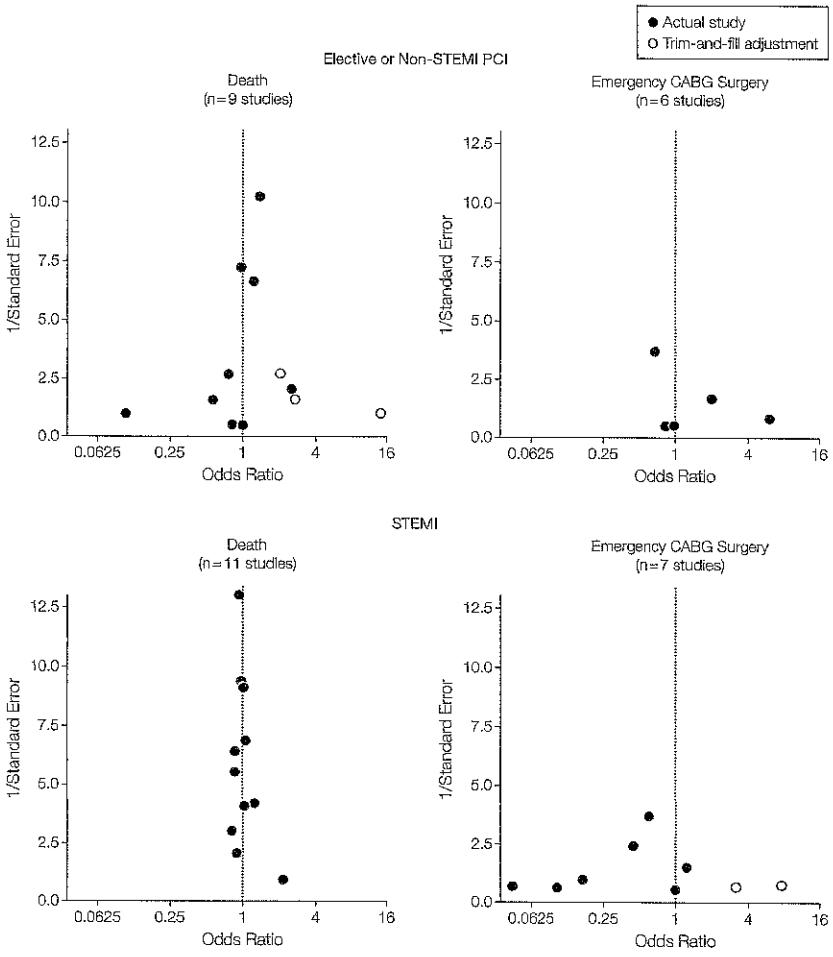
For nonprimary PCI overall, there was no difference in in-hospital mortality or the need for emergency CABG surgery in patients treated at centers with or without on-site surgery. In contrast to primary PCI, we noted moderate heterogeneity in mortality among studies and some evidence of publication bias. For further improvement in the outcomes at hospitals without on-site surgery, additional efforts should not only explore covariates linked to worse outcomes but also identify best practices. Outcome models that are effective for promoting successful outcomes after PCI have used, among other things, exporting of data into a national repository[4,6-10,12,16,18]; linkage of these hospitals to a tertiary care center for consultation, cross-training, and similar processes and structures of care of a patient undergoing PCI[4,6,8,10,16]; expeditious transfer for emergency CABG surgery[4,8,10,16]; and use of risk-adjustment tools for case selection, outcomes analyses and benchmarking of operators' performance, or both.[4,6,10,12,16,18] Studies that have adhered to such processes had more favorable outcomes (eFigure available at http://www.jama.com). Adherence to such standard processes of care has been demonstrated to be a successful strategy for successful outcomes in patients with coronary artery disease.[23] Patients admitted to centers without on-site surgery and angioplasty capabilities are less likely to receive guideline-recommended medications or to receive reperfusion therapy. However, no differences in guideline adherence or adverse outcomes were detected in hospitals with PCI capability.[17,18]

The relationship between outcomes and PCI volume of centers is inconsistent among studies, but Wennberg et al[7] reported worse outcomes for nonprimary PCI at low-volume centers without on-site surgery.[24,25] Because of inconsistent reporting and results, this important relationship was not examined in the present analysis but should be investigated in future studies.

The results of this meta-analysis are relevant to patient care and gain special clinical relevance in light of the recent American College of Cardiology/American Heart Association guidelines that do not recommend PCI for elective indications and give a class IIb indication for primary PCI at centers without on-site surgery.[1] In-hospital mortality was not significantly different for patients undergoing nonprimary PCI at facilities with and without on-site surgery, but after adjustment for publication bias, the mortality rates for nonprimary PCI were approximately 25% higher at centers without on-site surgery. This finding is of concern, despite improved outcomes observed in recent years in studies from national registries in Europe and the United States.[8,9,26] Most studies included in our analysis did not distinguish truly elective and low-risk PCI from treatment of higher-risk patients with unstable angina or non-STEMI or those needing rescue or facilitated PCI. More data for nonprimary PCI are required for definitive conclusions, especially data stratified on the basis of clinical and angiographic risk and operator or institutional PCI volumes, to better optimize the performance of PCI at centers without on-site surgery. Further work should identify processes that

Figure 3. Funnel Plot to Evaluate Publication Bias



Studies comparing in-hospital mortality and emergency coronary artery bypass grafting (CABG) surgery after nonprimary (elective for patients without ST elevation myocardial infarction [STEMI]) and primary (patients with STEMI) percutaneous coronary intervention. Trim-and-based estimates of unpublished studies are also shown.

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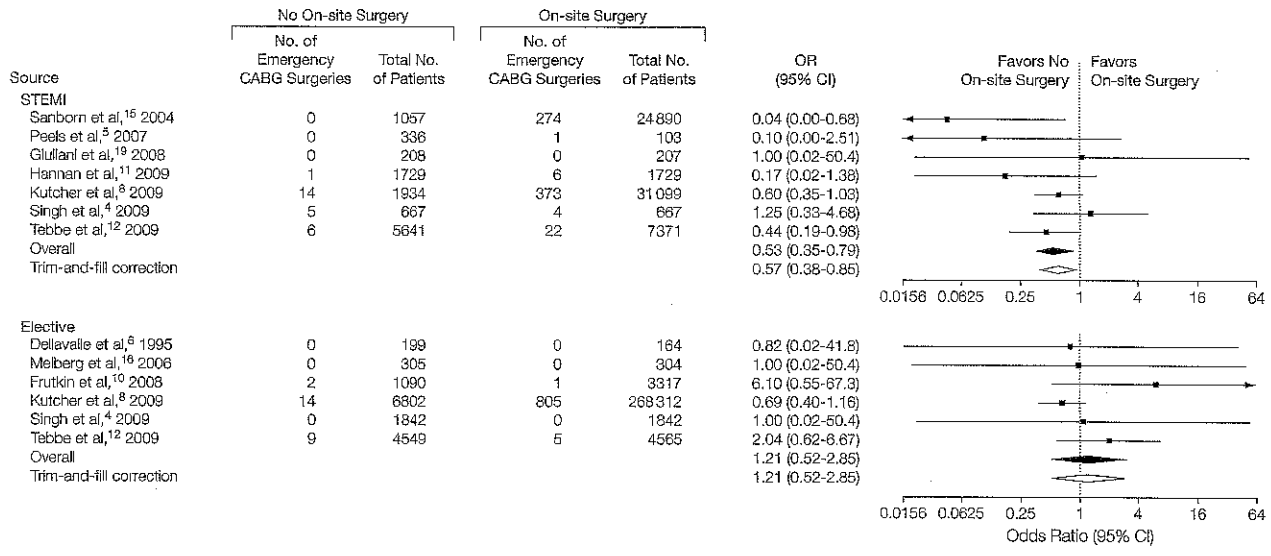
Table 2. Study Results Included in the Meta-Analysis

Study	Death			Emergency-CABG Surgery		
	Incidence, %			Incidence, %		
	Without On-site Surgery	With On-site Surgery	OR (95% CI)	Without On-site Surgery	With On-site Surgery	OR (95% CI)
Primary PCI						
Medicare	11.3	12.2	0.93 (0.80-1.08)			
SCAAR	7.0	6.7	1.05 (0.79-1.40)			
Mayo Clinic	2.5	3.1	0.80 (0.42-1.54)	0.7	0.6	1.25 (0.33-4.68)
NCDR	5.1	5.2	0.97 (0.79-1.20)	0.7	1.2	0.60 (0.35-1.03)
German, ALKK	3.4	2.9	1.01 (0.81-1.25)	0.1	0.3	0.44 (0.19-0.98)
MITI	7.0	7.0	1.01 (0.63-1.63)			
NRMI	4.2	4.8	0.86 (0.63-1.17)	0.0	1.1	0.04 (0.00-0.68)
Alkmaar, the Netherlands	2.1	1.0	2.17 (0.26-17.8)	0.0	1.0	0.10 (0.00-2.51)
Italian	4.3	4.9	0.89 (0.35-2.24)	0.0	0.0	1.00 (0.02-50.4)
NY State PCIRS	2.3	1.9	1.22 (0.76-1.94)	0.06	0.35	0.17 (0.02-1.38)
NRMI-STEMI	3.3	3.8	0.86 (0.61-1.23)			
Nonprimary PCI						
Medicare	4.6	2.8	1.38 (1.14-1.67)			
SCAAR	0.8	0.7	1.23 (0.91-1.65)			
Mayo Clinic	0.2	0.4	0.57 (0.17-1.95)	0.0	0.0	1.00 (0.02-50.4)
NCDR	0.8	0.8	0.99 (0.76-1.30)	0.2	0.3	0.69 (0.40-1.16)
German, ALKK	0.3	0.1	2.50 (0.98-6.67)	0.2	0.1	2.04 (0.62-6.67)
Dellavalle	0.0	0.0	0.82 (0.02-41.8)	0.0	0.0	0.82 (0.02-41.8)
Norwegian randomized	0.0	0.0	1.00 (0.02-50.4)	0.0	0.0	1.00 (0.02-50.4)
MAHI	0.09	0.8	0.11 (0.01-0.79)	0.2	0.03	6.10 (0.55-67.3)
NRMI-non-STEMI	1.0	1.3	0.76 (0.37-1.58)			

Abbreviations: ALKK, Arbeitsgemeinschaft Leitende Kardiologische Krankenhausärzte; CABG, coronary artery bypass grafting; MAHI, Mid America Heart Institute; MITI, Myocardial Infarction Triage and Intervention; NCDR, National Cardiovascular Data Registry; NRMI, National Registry of Myocardial Infarction; OR, odds ratio; PCI, percutaneous coronary intervention; PCIRS, Percutaneous Coronary Intervention Reporting System; SCAAR, Swedish Coronary Angiography and Angioplasty Registry; STEMI, ST-segment elevation myocardial infarction.

Figure 4. Forest Plot Comparing Emergency Coronary Bypass Graft Surgery Rates Following Percutaneous Coronary Intervention at Sites With and Without Surgery



Odds ratio (OR) estimates with 95% CIs of studies for the outcomes of emergency coronary artery bypass grafting (CABG) surgery by indication for percutaneous coronary intervention (PCI). In the case of 0 counts, ORs were calculated by adding 0.5 to all cell counts from the study to avoid division by 0.

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improve the safety and outcomes of nonprimary PCI performed at centers without on-site surgery.

The rates of emergency CABG surgery were very low with wide confidence intervals. For primary PCI, the rates were lower at sites without on-site surgery, raising concern that borderline stable patients with suboptimal procedural results are being kept at their local facility rather than being transferred emergently to an outside surgical center.[8] If patients were being transferred, the in-hospital mortality rate for primary PCI would be expected to be higher at sites without on-site surgery; however, it was similar among sites with and without on-site surgery. Conversely, the higher risk-adjusted incidence of emergency CABG surgery at on-site PCI centers could reflect a lower threshold to opt for emergency surgery if there is any doubt about a suboptimal result. The rates of emergency CABG surgery for nonprimary PCI were higher than those for primary PCI but had wide confidence intervals because of the few patients (0.3%) who needed transfer. A study from Mayo Clinic demonstrated a transfer rate of 0.69%, and no patients undergoing elective PCI were transferred for emergency CABG surgery.[4] Most patients who needed transfer (80%) were patients with hemodynamic compromise, mechanical complications, or STEMI due to significant coronary artery disease requiring CABG surgery. The indications for transfer, transfer rates, and their outcomes were not universally reported and, hence, were not included in our analysis.

To our knowledge, this is the first study to systematically summarize in-hospital outcomes after PCI at centers with and without on-site surgery. We used a comprehensive search strategy and systematic review method, following recommendations from the MOOSE guidelines.[13] In our meta-analysis, we limited heterogeneity and potential sources of bias by including only high-quality studies that compared results of PCI at centers with and without on-site surgery, excluding studies that just reported case series. Furthermore, our approach subdivided outcomes into several categories (primary vs nonprimary PCI; mortality and emergency CABG), thereby avoiding potential heterogeneity that may arise when a single summary estimate is used.

Our study had several methodological limitations. All but 1 study in our meta-analysis was observational; diverse study designs and patient characteristics make interpretation of aggregated estimates challenging, and causality could not be inferred. Additionally, it limits the relevance and reliability of the results. For more definitive conclusions, randomized designs by site (with or without on-site CABG surgery) with inclusion of low-risk, elective PCI is needed. For these analyses, we only had summary estimates, and we may not have adjusted for important patient-level covariates. On-site surgery may be a surrogate for other variables that could have favorable or adverse effects on outcome (eg, trainee operators, case mix, number of operators and their experience, skills of the nonmedical catheter laboratory team, private vs public institutions). However, these variables were not reported in the studies used for this analysis and thus could not be considered. Moreover, heterogeneity was moderate in the mortality analyses of nonprimary PCI. Variation in the definition of acute myocardial infarction and significant overlap in the indications for PCI did not allow us to separately analyze the results of truly low-risk, elective PCI. Hence, we aggregated the results into the nonprimary PCI category, which may not truly reflect the outcomes of elective PCI. Furthermore, very few studies reported a composite end point of death and emergency CABG surgery, precluding the chance to study whether one is being traded for another. We also restricted our search to English-language sources.

Our study method also had several strengths. The magnitude and consistency of the observed effects for primary PCI make the likelihood of bias affecting this observation unlikely. Moreover, we rigorously controlled for publication bias and used random-effects models that are generally better suited when studies are only gathered from the published literature.

In conclusion, this meta-analysis provides evidence that rates of in-hospital mortality and emergency CABG surgery for primary and nonprimary PCI are similar at centers with and without on-site surgery. Additional outcome data are still needed, including rates and indications for urgent or emergency transfers, especially in patients undergoing nonprimary PCI at centers without on-site surgery.

Author Contributions: Dr Singh had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Singh, Holmes, Wharton, Kutcher, Rihal.
Acquisition of data: Holmes, Aversano.
Analysis and interpretation of data: Holmes, Dehmer, Lennon, Wharton, Kutcher, Aversano, Rihal.
Drafting of the manuscript: Singh, Holmes, Wharton, Rihal.
Critical revision of the manuscript for important intellectual content: Singh, Holmes, Dehmer, Lennon, Wharton, Kutcher, Aversano, Rihal.
Statistical analysis: Lennon.
Administrative, technical, or material support: Holmes, Rihal.
Study supervision: Singh, Holmes, Dehmer, Kutcher, Rihal.
Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.
Online-Only Material: The eFigure is available at http://www.jama.com.

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It helps to write down half a dozen things which are worrying me. Two of them, say, disappear; about two nothing can be done, so it's no use worrying; and two perhaps can be settled.

—Winston Churchill (1874-1965)

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News from the NCDR

NCDR™ National Cardiovascular Data Registry

Percutaneous Coronary Interventions in Facilities Without Cardiac Surgery On Site: A Report From the National Cardiovascular Data Registry (NCDR)

Michael A. Kutcher, MD,* Lloyd W. Klein, MD,† Fang-Shu Ou, MS,‡ Thomas P. Wharton, JR, MD,§ Gregory J. Dehmer, MD,‖ Mandeep Singh, MD, MPH,¶ H. Vernon Anderson, MD,# John S. Rumsfeld, MD, PHD,** William S. Weintraub, MD,†† Richard E. Shaw, PHD,‡‡ Matthew T. Sacrinty, MPH,* Albert Woodward, PHD, MBA,§§ Eric D. Peterson, MD, MPH,‡ Ralph G. Brindis, MD, MPH,‖‖ on behalf of the National Cardiovascular Data Registry (NCDR)

Since the introduction of percutaneous coronary intervention (PCI) in 1977 by Andreas Gruntzig (1), the presence of cardiac surgery backup on site has been a recommended practice to treat the potential of life-threatening complications. As a result of major improvements in technology and pharmacology, the need for emergency cardiac surgery is now infrequent (0.3% to 0.6%) (2,3). Moreover, primary PCI has been accepted as superior to fibrinolytic therapy for ST-segment elevation myocardial infarction (STEMI) (4). These developments have provided the justification for some hospitals without cardiac surgery to develop PCI programs based on a strategy to provide more rapid care for STEMI (5,6) and to increase the availability of PCI to patients in geographically underserved areas.

Favorable outcomes for primary PCI performed in facilities without cardiac surgery backup on site have been reported (7–9). In addition, smaller observational studies have extended this concept to both primary and elective PCI (10–14), and even PCI limited to elective cases (15). However, there are few large studies that have directly compared the procedural outcomes of both primary and elective PCI at facilities without cardiac surgery on site with those that have traditional surgery on site (16–18). Because of the conflicting literature on this subject, the American College of Cardiology (ACC), American Heart Association (AHA), and Society for Cardiovascular Angiography and Interventions (SCAI) 2005 PCI guidelines continue to designate primary PCI a Class IIb indication (may be considered), and elective PCI a Class III indication (not recommended) when performed at facilities without surgical backup on site (19). The 2007 PCI guideline focused update did not address or change these designations (20). Despite

From the *Wake Forest University School of Medicine, Winston-Salem, North Carolina; †Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois; ‡Duke Clinical Research Institute, Durham, North Carolina; §Exeter Hospital, Exeter, New Hampshire; ‖Texas A&M University College of Medicine, Scott & White HealthCare, Temple, Texas; ¶Mayo Clinic, Rochester, Minnesota; #University of Texas Health Science Center, Houston, Texas; **Denver VA Medical Center, Denver, Colorado; ††Christiana Health Care System, Newark, Delaware; ‡‡Sutter Pacific Heart Centers, San Francisco, California; §§National Cardiovascular Data Registry, Washington, DC; and ‖‖Northern California Kaiser Permanente, San Francisco, California. Data analysis was performed by the Duke Clinical Research Institute with funding from the National Cardiovascular Data Registry. Drs. Kutcher and Klein perform percutaneous coronary intervention (PCI) at facilities that have on-site cardiac surgery. Dr. Wharton is a consultant to Corazon, The Heart and Vascular Experts, and performs PCI at a facility that does not have on-site cardiac surgery. Dr. Dehmer is Chief, Division of Cardiology, Texas A&M College of Medicine, Scott & White HealthCare, which includes facilities that have on-site cardiac surgery and facilities that do not. Dr. Singh performs PCI at Mayo Clinic facilities that have on-site cardiac surgery and facilities that do not. Dr. Anderson performs PCI at a facility that has on-site cardiac surgery.

these classifications, the number of PCI programs in the U.S. without surgery on site has increased significantly over the past several years (21). Recently, a SCAI expert panel outlined practical consensus principles for PCI performed at facilities without surgery on site, while not specifically encouraging or endorsing this practice (22).

The National Cardiovascular Data Registry (NCDR) was established by the ACC to proactively monitor and assess the clinical practice of cardiology in the U.S. (23). The NCDR CathPCI Registry, cosponsored by the ACC and SCAI, offers its participant institutions data field definitions, uniform data entry, secure transmission requirements, a data quality program, and risk-adjustment algorithms (24–26). Therefore, this registry provides an excellent resource of comparative data, in a relative contemporary clinical setting, to address the controversy over PCI at facilities without surgical backup on site.

Methods

Study population. Clinical characteristics and in-hospital outcomes were assessed in consecutive PCI cases reported to the NCDR CathPCI Registry from January 1, 2004, to March 30, 2006. Standardized NCDR version 3.04 definitions and data fields were used by all participating sites (27). The analysis cohort consisted of 308,161 patients from 465 PCI-capable facilities. Of these, 8,736 patients had PCI performed at 60 institutions in which it was verified there was no surgical backup on site within the buildings or campus that constituted the facility (off-site facility). The remaining 299,425 patients underwent PCI at 405 facilities that had cardiac surgery on site (on-site facility). Off-site PCI facilities comprised 13% of sites and 3% of patients in the NCDR CathPCI Registry during the study period.

Definitions. The primary outcomes for analysis were the incidence of emergency surgery and in-hospital death from all causes after PCI. Emergency surgery was defined as coronary artery bypass graft (CABG) surgery performed after PCI in which there was evidence of active ischemia or mechanical dysfunction (emergency), or if the patient required cardiopulmonary resuscitation en route to the operating room or before anesthesia (emergent/salvage). Secondary outcomes included procedure success, total complications (any general, bleeding, or vascular complications), and reperfusion time in cases of primary PCI for STEMI.

Off-site data clarification. During initial analysis, variations in 2 data fields unique to off-site PCI programs were noted. The field "CABG during this admission" permitted entry of only 1 category. In off-site centers, there was a disproportionately low incidence of "emergency" surgery, but a proportionately large number of patients "transferred for CABG" entered in this field. In addition, "transfer" patients could be counted as "alive" in the data field "discharge status" from an off-site center, but this opened the potential that a subsequent death after emergency surgery at the outside surgical center may not have been captured.

To resolve these issues, we conducted a data clarification project. Off-site centers with specific data points in question were queried to clarify whether a "transfer for CABG" data point was for elective or emergency surgery, and to verify the eventual survival at the off-site surgical center. This effort also provided an opportunity to gather additional information by a Capabilities Survey to reaffirm a true off-site status and to assess organization, staffing, and logistics. All of the off-site programs were invited to fill out the survey form, even those sites in which data clarification was not necessary.

Abbreviations and Acronyms

ACC = American College of Cardiology

AHA = American Heart Association

CABG = coronary artery bypass graft surgery

IABP = intra-aortic balloon pump

MI = myocardial infarction

NSTEMI = non–ST-segment myocardial infarction

PCI = percutaneous coronary intervention

SCAI = Society for Cardiovascular Angiography and Interventions

STEMI = ST-segment elevation myocardial infarction

Of the 8,736 patients undergoing PCI in off-site centers, 172 (2%) patients from 43 sites required data clarification regarding transfer surgery or mortality status. Of these 43 sites, 38 (88%) sites were able to clarify CABG status and/or mortality information for 154 of the 172 (90%) patients. For the 18 patients (0.2% of 8,736) whose transfer or mortality data were not clarified, if CABG status was uncertain, the original record entry was used for the CABG status-related analysis. If the subsequent mortality at the receiving surgery center could not be clarified, these patients were not included in the analysis of observed or risk-adjusted mortality.

Statistical analysis. Data analysis was performed by the Duke Clinical Research Institute. For descriptive analyses, institutional comparisons between off- and on-site PCI centers were made based on hospital characteristics. Comparisons between patients were made based on clinical characteristics, treatment profiles, procedural details, and clinical outcomes. These aggregates were further divided and analysis performed in patients who underwent primary PCI as first-line therapy for reperfusion in the presence of STEMI, and to the remainder of patients who underwent PCI in a nonprimary setting. Continuous variables are presented as mean with SD or as frequencies with percentages in each pre-specified category. Categorical variables are expressed as frequencies with percentages. To test for independence of patients' baseline characteristics, in-hospital care patterns and outcomes with respect to off-site versus on-site centers, the Wilcoxon rank-sum test was used for continuous variables, and the Pearson chi-square test was used for categorical variables.

A multivariable logistic regression model was then used to estimate the risk-adjusted association between on-site versus off-site PCI center surgical status and primary outcomes. Variables adjusted to mortality in-

cluded age, sex, insulin-treated diabetes mellitus, hypercholesterolemia, hypertension, dialysis, cerebrovascular disease, chronic lung disease, peripheral vascular disease, congestive heart failure, prior CABG, prior PCI, prior myocardial infarction (MI), cardiogenic shock at presentation, MI status (STEMI, non–ST-segment myocardial infarction [NSTEMI], and no MI), pre-operative intra-aortic balloon pump (IABP), PCI status (rescue, emergent, urgent, and elective), subacute thrombosis in a major artery, any treated lesion in left main artery, any treated lesion with pre-procedure stenosis 100%, any treated lesion with pre-procedure Thrombolysis In Myocardial Infarction (TIMI) flow grade 0, any treated lesion with high/C risk characteristics (see definition, bottom legend, Table 1), and total number of lesions treated. Variables adjusted to emergency CABG included cardiogenic shock, MI status (STEMI, NSTEMI, and no MI), pre-operative IABP, PCI status (rescue, emergent, urgent, and elective), and any treated left main artery lesion.

The Generalized Estimate Equation method (28) was applied to account for within-hospital clustering, considering patients at the same hospital are more likely to have similar responses relative to patients in other hospitals (i.e., within-center correlation for response). This method produces estimates comparable to those from ordinary logistic regression, but estimated variances are adjusted for the correlation of outcomes within each hospital.

Because not all off-site PCI center patient mortality data could be clarified, a sensitivity analysis was performed. This analysis utilized the same multivariable logistic regression model but imputed data to either of the following: patients with missing mortality data were considered either as all had died (worst scenario) or as all were alive (best scenario) on discharge.

Results

Institutional characteristics. Institutional characteristics are shown in Table 2. Compared with on-site centers, off-site PCI facilities had smaller bed capacity, were more likely to be located in nonurban areas, and had lower annual total PCI and primary PCI volume ($p < 0.001$). Overall, 43 (72%) of the off-site programs performed <200 total PCIs per year, and only 3 sites (5%) had >400 cases, suggesting that it was unlikely the outcomes were preferentially influenced by a few large-volume centers. The recommended volume standard of 36 or more primary PCIs per year (19) was achieved by 42% of the off-site programs compared with 80% of the on-site centers ($p < 0.001$).

Off-site capabilities survey. The survey (Table 3) was completed by 53 of the 60 off-site PCI facilities (88%). Approximately one-quarter of the centers had travel distances >40 miles and transit times (estimated driving or flight) >30 min. This information also reaffirmed that these were true off-site programs and did not have surgery back-up nearby in the next building. Full 24-h, 7-day coverage for PCI was provided by 92% of the sites. Both primary and elective PCI were performed in 79% of the centers, and none of the programs performed only elective PCI. Descriptive demographics regarding the organization of technical staff, interventional cardiologists, and transpor-

Table 1 Clinical Characteristics by PCI Status

	All PCI Patients			Primary PCI Patients			Nonprimary PCI Patients		
Characteristic	Off-Site (n = 8,736)	On-Site (n = 299,425)	p Value	Off-Site (n = 1,934)	On-Site (n = 31,099)	p Value	Off-Site (n = 6,802)	On-Site (n = 268,312)*	p Value
Age, yrs, mean ± SD	63.5 ± 12	64.1 ± 12	<0.001	61.2 ± 13	60.6 ± 13	0.194	64.2 ± 12	64.4 ± 12	0.062
Male	5,817 (67)	198,656 (66)	0.639	1,384 (72)	21,958 (71)	0.371	4,433 (65)	176,688 (66)	0.243
Previous MI >7 days	2,285 (26)	87,521 (29)	<0.001	327 (17)	5,440 (17)	0.509	1,958 (29)	82,077 (31)	0.001
Previous CHF	839 (9.6)	30,953 (10.3)	0.026	80 (4)	1,442 (5)	0.308	759 (11)	29,510 (11)	0.675
Diabetes	2,534 (29)	95,160 (32)	<0.001	361 (19)	6,514 (21)	0.016	2,173 (32)	88,642 (33)	0.058
Previous renal failure	367 (4)	15,868 (5)	<0.001	56 (3)	1,033 (3)	0.308	311 (4.6)	14,835 (5.5)	<0.001
Cerebrovascular disease	817 (9)	33,865 (11)	<0.001	105 (5)	2,165 (7)	0.010	712 (10)	31,700 (12)	<0.001
Peripheral vascular disease	895 (10)	35,519 (12)	<0.001	123 (6)	2,019 (6)	0.818	772 (11)	33,500 (12)	0.005
Hypertension	6,226 (71)	225,404 (75)	<0.001	1,069 (55)	18,275 (59)	0.002	5,157 (76)	207,120 (77)	0.007
Dyslipidemia	5,827 (67)	220,220 (74)	<0.001	974 (50)	17,432 (56)	<0.001	4,853 (71)	202,780 (76)	<0.001
Previous PCI	2,711 (31)	105,133 (35)	<0.001	321 (17)	5,254 (17)	0.735	2,390 (35)	99,875 (37)	<0.001
Previous CABG	1,068 (12)	56,815 (19)	<0.001	99 (5)	1,810 (6)	0.199	969 (14)	55,000 (21)	<0.001
Lesion characteristics									
≥2 lesions in laboratory visit	2,503 (29)	99,309 (33)	<0.001	478 (25)	8,463 (27)	0.048	2,025 (30)	90,843 (34)	<0.001
Segment in SVG	396 (5)	20,644 (7)	<0.001	55 (3)	989 (3)	0.657	341 (5)	19,675 (7)	<0.001
High-risk C lesion†	3,426 (39)	123,207 (41)	<0.001	1,106 (57)	18,933 (61)	0.001	2,320 (34)	104,270 (39)	<0.001

Data are n (%) unless otherwise indicated. *14 patients not included due to missing value for variable "Acute PCI." †High risk C lesion includes any of the following: diffuse (length >20 mm), excessive tortuosity of proximal segment, extremely angulated segments >90 degrees, total occlusions >3 months old and/or bridging collaterals, inability to protect major side branches, and degenerated vein grafts with friable lesions.

CABG = coronary artery bypass grafting; CHF = congestive heart failure; MI = myocardial infarction; PCI = percutaneous coronary intervention; SVG = saphenous vein graft.

tation modalities are further outlined in Table 3. Of note, 81% of the off-site programs reported that their interventional operators also rotated and performed PCI at on-site facilities.

Clinical characteristics. Clinical characteristics are shown in Table 1. In aggregate, on-site PCI centers generally treated patients with more risk factors and performed a greater percentage of PCI in multiple-lesion (33% vs. 29%, $p < 0.001$), saphenous vein graft (7% vs. 5%, $p < 0.001$), and higher lesion-risk cases (41% vs. 39%, $p = 0.001$). This difference was more pronounced in patients who underwent nonprimary PCI. In contrast, off-site facilities had a greater incidence of patients who had a clinical presentation of STEMI or NSTEMI (41% vs. 29%, $p < 0.001$) (Fig. 1).

Observed unadjusted procedural outcomes. Observed unadjusted procedural outcomes are shown in Table 4. Off-site facilities had slightly higher aggregate procedural success (94% vs. 93%, $p = 0.010$), predominantly due to higher success rates in nonprimary PCI cases. Aggregate total complications were similar in both off- and on-site facilities (6.5% vs. 6.3%), but off-site programs tended to have more bleeding events, and on-site more vascular complications. Off-site programs had fewer total complications in primary PCI (11.6% vs. 13.4%, $p = 0.029$) and had lower general (2.6% vs. 3.3%, $p = 0.001$) and vascular (0.8% vs. 1.1%, $p = 0.017$) complication rates in nonprimary PCI patients compared with on-site facilities.

In the overall PCI cohort, there was no significant difference in the incidence of emergency CABG surgery (0.3% vs. 0.4%, $p = 0.271$) or mortality with emergency CABG (13.6% vs. 12.8%, $p = 0.907$) between off- and on-site facilities, respectively. There was no difference in either of these variables when the analysis was stratified into primary PCI and nonprimary PCI patients. Although the unadjusted aggregate mortality rate was higher in off-site facilities (1.7% vs. 1.2%, $p < 0.001$) and appeared to be confined to patients who did not require emergency surgery, this difference did not persist when stratified by primary or nonprimary PCI. This increased unadjusted aggregate mortality was most likely due to a higher proportion of primary PCI patients (22% vs. 10%, $p < 0.001$) and STEMI and NSTEMI presentations (41% vs. 29%, $p < 0.001$) in off-site compared with on-site programs, respectively.

Primary PCI reperfusion times in nontransferred patients were significantly shorter in off-site PCI centers (mean 2.1 ± 5.1 h, median 1.4 h) compared with on-site (mean 2.6 ± 8.4 h, median 1.5 h, $p < 0.001$). These "reperfusion times" were defined as the time of arrival at the facility to the time of first treatment device deployment (27). Although both groups followed the same definition, these data were collected before there were major national quality

Table 2 Institutional Characteristics

Variable	Off-Site (n = 60)	On-Site (n = 405)	p Value
Number of CMS-certified beds			
Median	198	371	<0.001
Mean ± SD	212 ± 109	403 ± 188	
<200	31 (52%)	40 (10%)	<0.001
≥200 and <400	27 (45%)	178 (44%)	
≥400	2 (3%)	185 (46%)	
Location/community type			
Rural	21 (35%)	67 (17%)	<0.001
Suburban	24 (40%)	115 (28%)	
Urban	15 (25%)	223 (55%)	
Average annual PCI volume			
Median	134	612	<0.001
Mean ± SD	166 ± 138	745 ± 551	
<200	43 (72%)	23 (6%)	<0.001
≥200 and <400	14 (23%)	98 (24%)	
≥400	3 (5%)	284 (70%)	
Average annual primary PCI volume			
Median	32	66	<0.001
Mean ± SD	35 ± 22	78 ± 52	
≥36	25 (42%)	324 (80%)	<0.001

Two sites had missing Centers for Medicare and Medicaid Services (CMS) bed data. Primary percutaneous coronary intervention (PCI) indicates PCI performed as first-line therapy for reperfusion in the presence of ST-segment elevation myocardial infarction (STEMI), and does not include rescue or facilitated PCI or PCI for non-STEMI.

Table 3 Off-Site Capabilities Survey

Characteristic	Off-Site (n = 53)
Average travel distance to surgical facility, miles	
Mean ± SD	36 ± 59
<10	11 (21%)
≥10 and <20	18 (34%)
≥20 and <40	11 (21%)
≥40	13 (25%)
Average transit time to surgical facility, min	
Mean ± SD	25 ± 17
<10	4 (8%)
≥10 and <20	16 (30%)
≥20 and <30	19 (36%)
≥30	14 (26%)
Predominant transportation mechanism	
Ground ambulance	28 (53%)
Helicopter	11 (21%)
Fixed wing aircraft	1 (2%)
Combination of ground or air	13 (25%)
Dedicated staff and facilities for PCI	
24 h, 7 days a week	49 (92%)
Daytime during weekdays only	3 (6%)
Variable time frames	1 (2%)
Type of PCI provided	
Only primary PCI for acute MI	11 (21%)
Both primary PCI and elective PCI	42 (79%)
Only elective PCI	0 (0%)
Catheterization laboratory staff experience*	
Work only at off-site PCI center	41 (77%)
Rotate between off- and on-site PCI centers	11 (21%)
Interventional operators at facility	
Mean ± SD	5 ± 4
1	5 (9%)
2 to 3	18 (34%)
4 to 5	11 (21%)
6 or more	19 (36%)
Interventional operators' experience*	
Work only at off-site PCI center	9 (17%)
Rotate between off- and on-site PCI centers	43 (81%)

*One site did not respond.
Abbreviations as in Table 1.

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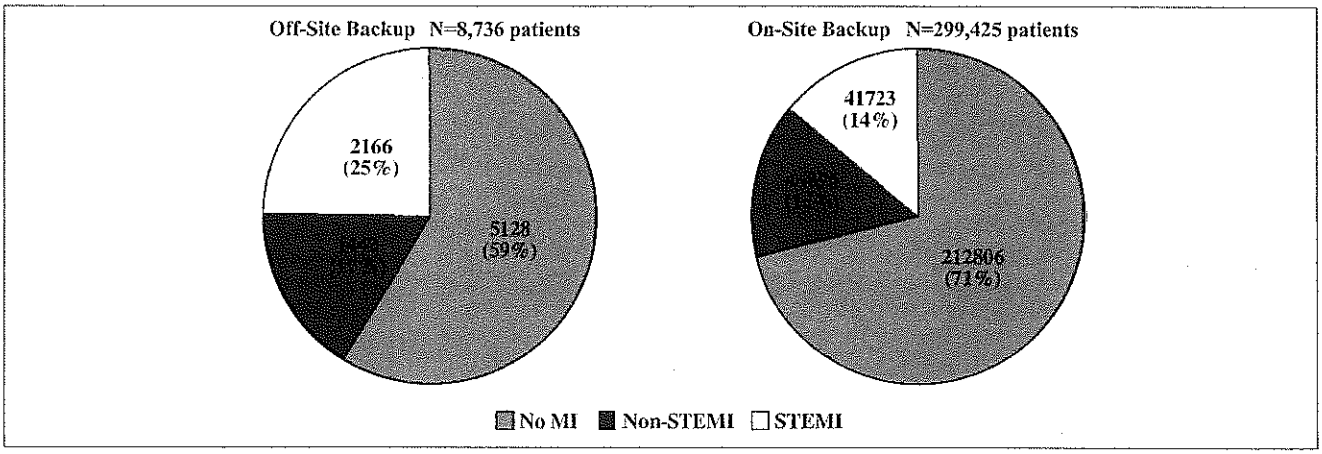
Figure 1 MI Presentation Status

Pie charts showing the relative distribution of myocardial infarction (MI) presentation within centers with on- or off-site surgical backup. **Blue areas** indicate no MI; **purple areas** indicate non–ST-segment elevation myocardial infarction (non-STEMI); **yellow areas** indicate STEMI. $p < 0.001$.



improvement initiatives and attention to the detailed measurements of true "door-to-balloon" times. Therefore, these times do not reflect the current door-to-balloon standards.

Risk-adjusted outcomes. After risk adjustment, there were no mortality differences between off- and on-site facilities among total PCI patients, primary PCI patients, nonprimary PCI patients, or patients who did not require emergency surgery (Fig. 2). There was a higher risk-adjusted odds of emergency surgery in on-site PCI centers (odds ratio: 0.60 [95% confidence interval: 0.37 to 0.98], $p = 0.042$).

A sensitivity analysis was performed comprising models that imputed missing mortality from off-site centers to 2 potential scenarios. Although the point estimate changed from 0.88 to 1.21, the confidence intervals surrounding these estimates were not statistically significant between off- and on-site facilities under either of these extreme assumptions.

Discussion

This study represents the largest and most comprehensive clinical comparison of PCI centers in the U.S. with and without cardiac surgery support on site. Despite lower annual PCI procedural volumes and more patients presenting with MI subsets, off-site PCI facilities reporting to the NCDR CathPCI Registry had similar rates of procedural success, morbidity, emergency surgery, and risk-adjusted mortality when compared with on-site PCI centers. These results persisted whether PCI was performed as primary therapy for STEMI or in a less urgent nonprimary PCI setting. In addition, the off-site Capabilities Survey in this study provided more descriptive information than has been previously reported in the literature regarding the organization and logistics of established off-site PCI programs.

It is important to contrast this study with the few large comparative reports in the literature. Wennberg et al. (16) found no difference in risk-adjusted mortality for primary PCI at facilities without surgery backup on site, but an increase in mortality for nonprimary/rescue PCI, particularly at very low-volume programs (<50 Medicare PCIs per year). Although their study had more hospitals without surgery on site (n = 178) and similar patient volumes (n = 8,168), the time period was from 1999 to 2001, and the data were derived from coded admission/discharge billing diagnoses confined to the Medicare population. In contrast, our study was based on well-defined contemporary clinical parameters and included clarification of ambiguous transfer data from the off-site PCI programs. We found no significant difference for risk-adjusted mortality between centers with and without surgery on site, in either primary or nonprimary PCI patients.

Ting et al. (17) previously reported comparable acute and long-term outcomes for both primary and elective PCI in a propensity score analysis of 1,007 cases from a PCI center without surgery on site matched to the same number of patients from a center with surgery on site. Of note, these Mayo Clinic facilities did not participate in the NCDR, and thus their patients were not included in our analysis.

Finally, in a recent report based on SCAAR (Swedish Coronary Angiography and Angioplasty Registry), Carlsson et al. (18) compared 8,838 PCI procedures from 14 PCI facilities that did not have cardiac surgery on site to 25,525 procedures from 10 PCI centers that did have surgery on site. Their analysis was adjusted for baseline variables, and demonstrated comparable 30-day and 1-year mortality and morbidity outcomes for both primary PCI and nonacute PCI. Although different variables were used in our risk-

Table 4 Observed Unadjusted Procedural Outcomes

Outcome	All PCI Patients			Primary PCI Patients			Nonprimary PCI Patients		
	Off-Site (n = 8,736)	On-Site (n = 299,425)	p Value	Off-Site (n = 1,934)	On-Site (n = 31,099)	p Value	Off-Site (n = 6,802)	On-Site (n = 268,312)*	p Value
PCI procedure success	8,194 (94)	278,844 (93)	0.010	1,766 (92)	27,909 (91)	0.139	6,438 (95)	250,923 (94)	<0.001
Total complications	567 (6.5)	18,796 (6.3)	0.399	222 (11.6)	4,104 (13.4)	0.029	345 (5.1)	14,692 (5.5)	0.150
General complications	320 (3.7)	11,629 (3.9)	0.304	144 (7.5)	2,792 (9.1)	0.021	176 (2.6)	8,837 (3.3)	0.001
Bleeding complications	261 (3.0)	7,036 (2.4)	<0.001	104 (5.4)	1,620 (5.3)	0.749	157 (2.3)	5,416 (2.0)	0.093
Vascular complications	66 (0.8)	3,198 (1.1)	0.005	14 (0.7)	344 (1.1)	0.115	52 (0.8)	2,854 (1.1)	0.017
Overall mortality	151 (1.7)	3,632 (1.2)	<0.001	97 (5.1)	1,607 (5.2)	0.869	54 (0.8)	2,025 (0.8)	0.700
Emergency CABG	26 (0.3)	1,110 (0.4)	0.271	14 (0.7)	357 (1.2)	0.091	12 (0.2)	753 (0.3)	0.107
Mortality									
Emergency CABG	3/221† (13.6)	142/1,110† (12.8)	0.907	2/12† (16.7)	59/357† (16.5)	0.990	1/10† (10.0)	83/753† (11.0)	0.918
No emergency CABG	148/8,669† (1.7)	3,488/298,293† (1.2)	<0.001	95/1,894† (5.0)	1,547/30,741† (5.0)	0.975	53/6,775† (0.8)	1,941/267,538† (0.7)	0.587
Reperfusion times (h), nontransfer patients				(n = 1,678)	(n = 19,708)				
Mean ± SD				2.1 ± 5.1	2.6 ± 8.4	<0.001			
Median				1.4	1.5				

Procedure success was defined as residual stenosis <50% with Thrombolysis In Myocardial Infarction flow grade 3 and minimal decrease in stenosis ≤20% in all lesions attempted. Total complications was defined as any of the following complications: general complications: periprocedural MI, cardiogenic shock, congestive heart failure, cerebrovascular accident, tamponade, thrombocytopenia, contrast reaction, renal failure; bleeding complications: bleeding at the access site, retroperitoneal, gastrointestinal, genitourinary, or other; vascular complications: access site occlusion, peripheral embolization, arterial dissection, arterial pseudoaneurysm, or arterio-venous fistula. Primary PCI was defined as PCI performed as first-line therapy for reperfusion in the presence of STEMI; does not include rescue or facilitated PCI or PCI for non-STEMI. Reperfusion time indicates time of arrival to facility to time of first intracoronary treatment device deployment. *14 patients not included due to missing value for variable "Acute PCI." †Clarified data.

Abbreviations as in **Tables 1 and 2**.

adjusted model, the in-hospital mortality/morbidity results are similar to these 2 studies.

The nonprimary PCI patient cohort in our study is not a reflection of purely elective PCI, as this group includes some patients who presented with acute coronary syndromes, NSTEMI, or after STEMI. However, the consideration of this group as "nonurgent" and a reasonable surrogate for elective PCI is consistent with the analyses done in the literature cited in the preceding text. In our study, the differentiation of patients in off-site versus on-site PCI centers into primary PCI and nonprimary PCI permitted a more comprehensive assessment and risk-adjustment analysis of the major clinical end points.

Within our study cohort, the aggregate incidence of emergency surgery was comparably low at off- and on-site PCI facilities (0.3% to 0.4%, respectively) and consistent with contemporary studies (2,3). When emergency surgery was necessary, the mortality rate was similarly high between off- (13.6%) and on-site (12.8%) facilities, and comparable to that reported in prior literature (2,3).

There have been concerns that off-site PCI facilities may tend to keep some borderline stable patients with suboptimal procedural results rather than initiate the logistics of emergency transfer to an outside surgical center. These patients may have adverse outcomes, as seems to be suggested by the aggregate unadjusted mortality rate in our study. However, in the risk-adjusted analyses, there was comparable in-hospital mortality for those off-site patients who were not transferred for emergency surgery.

Conversely, the 1.5-fold higher risk-adjusted incidence of emergency surgery at on-site PCI centers could reflect a lower threshold to opt for emergency surgery if there is any doubt about a suboptimal result, as surgery is available without the added logistics of transfer. An alternative explanation could be that on-site centers perform higher risk elective cases, as is suggested by the clinical and lesion characteristics profiles in this study. In addition, it is possible that patients may have had initial angiography at off-site facilities, found to have complex coronary anatomy and/or high-risk MI subsets with a higher predisposition to emergency surgery, then deferred and transferred to an on-site center for PCI. These complicated potential scenarios and the detailed reasons for case selection were beyond the scope of the NCDR database elements. Regardless, the increased risk-adjusted incidence of emergency surgery at on-site PCI programs did not translate into an increase in mortality.

Data from the Capabilities Survey revealed a mean transit time of 25 ± 17 min from off-site facilities. The British Cardiovascular Interventional Society has recommended a 90 min to emergency surgery standard (29).

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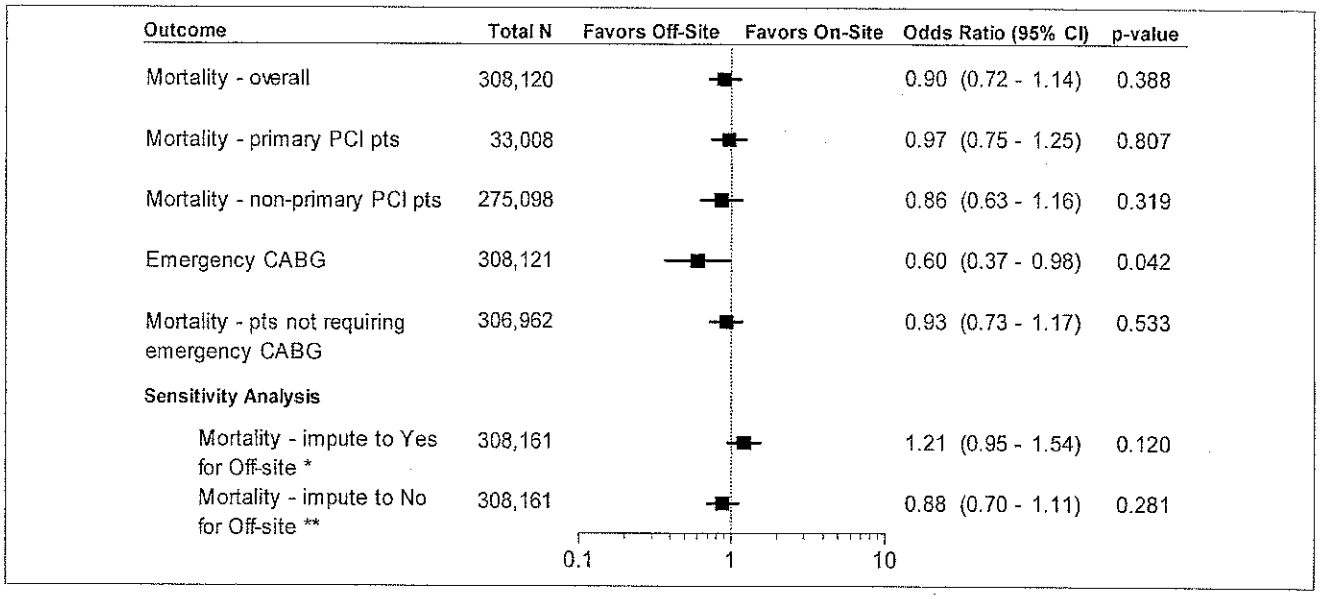
Figure 2 Risk-Adjusted Analysis of Outcomes

Odds ratio plot of risk-adjusted outcomes, including sensitivity analysis for missing mortality data. Odds ratio: outcomes for patients at off-site (vs. on-site) facilities, adjusting for within site correlations and potential confounding variables. *Worst case scenario: all patients with missing mortality data were considered to have died. **Best case scenario: all patients with missing mortality data were considered as alive. CABG = coronary artery bypass graft surgery; CI = confidence interval; PCI = percutaneous coronary intervention; pts = patients.



This includes not only the transit time, but also the total time from the initial decision to transport (including call time, transfer of patient from catheterization laboratory to vehicle, vehicle to operating suite), to the actual time of initiating cardiopulmonary bypass at the receiving surgical center. The transit time in the NCDR survey was an estimate of basic travel time and did not include the above additional time elements. However, based on the transit time, most off-site PCI programs in our study may be able to meet this global standard of 90 min by having a clear decision process and heightened logistical coordination with ambulance services and the receiving surgical center.

The demographics of the off-site centers in our study suggests these facilities conform to the stated goals of lowering geographic barriers and facilitating access to PCI, particularly for those patients presenting with STEMI (5,6). The Capabilities Survey also indicates these programs are well staffed and organized with good logistical plans. The fact that 81% of the off-site center operators rotated to an on-site PCI center suggests that most of the off-site facilities were hub-and-spoke centers staffed by large group practices. Overall, the information suggests that the off-site PCI programs in this study have demonstrated a strong commitment to the classic Donabedian triad of structure, process, and outcomes measurements (30).

Study limitations. First, this study is subject to the usual concerns regarding observational registry data. There may be an inherent bias in off-site PCI programs that are either mandated by regulatory agencies or choose on their own to participate in the NCDR. Participants in any registry may be prone to "game" the system, particularly if score carding and public disclosure is an issue.

Second, this study includes outcomes up to the time of hospital discharge. Data regarding long-term outcomes are not currently captured in the NCDR CathPCI Registry. In addition, outcomes are assessed and analyzed on an institutional level, not on an individual operator level.

Third, specific in-depth details regarding clinical presentation, case selection, procedural complications, morbidity, and mortality were sometimes beyond the purview of the basic datasets. However, a special data clarification effort was utilized to resolve the 172 of 8,736 off-site patients (2%) for whom mortality or transfer data were questioned, resulting in clarification of 154 of these patients (90%), leaving 18 of 8,736 (0.2%) not clarified. A sensitivity analysis confirmed that the unclarified data would not have affected the risk-adjusted mortality analysis results.

Fourth, although this NCDR study indicates that nonprimary PCI can be done safely at off-site facilities, the efficacy of truly elective PCI at off-site facilities can perhaps be best addressed by a large randomized prospective trial such as the C-PORT (Cardiovascular Patient Outcome Research Team) Elective Angioplasty Study, which is under way. However, such studies are difficult to conduct, and results may not be forthcoming for some time. In the interim, a comprehensive large database such as the NCDR CathPCI Registry offers a realistic and

relative contemporary quality assurance standard to monitor these issues. Based on the experiences gained with this current study, the NCDR plans to sponsor a proactive comprehensive working group of off-site PCI centers to further communicate and track outcomes. This effort will coincide with the upcoming transition to the next CathPCI database version 4.0.

Finally, a participation bias cannot be excluded. The total number of PCI centers in the U.S. that do not have surgery on site is not definitively known (22) but may number ≈250. Of these, it is estimated that one-third submit data to another peer-reviewed registry, a spoke and hub partner database, or a multicenter trial. Thus, the 60 off-site PCI facilities in this NCDR study may represent a minority of such programs in the nation and are probably in the upper tier of quality. With this perspective, the results reported here may not be applicable to all PCI centers without surgical backup on site, particularly those that do not participate in any formal data registry or clinical trial.

Conclusions

Compared with on-site PCI centers, off-site PCI programs in the NCDR were predominantly located in nonurban areas, had lower annual PCI volume, treated a higher percentage of patients who presented with subsets of MI, and had better reperfusion times in primary PCI. Off-site PCI centers had similar observed procedure success, morbidity, emergency cardiac surgery rates, and mortality in cases that required emergency surgery. The risk-adjusted mortality rates in off-site PCI facilities were comparable to those of PCI centers that had cardiac surgery on site, regardless of whether PCI was performed as primary therapy for STEMI or in a nonprimary setting.

These findings should not be extrapolated to encourage the widespread proliferation of more PCI programs without surgery on site to fulfill a political or an economic agenda. Rather, our study does confirm the safety of an off-site strategy at PCI centers where rigorous clinical, operator, and institutional criteria are in place and where data are submitted and reviewed in a comprehensive multicenter registry such as the NCDR.

Acknowledgments

The authors would like to thank Jessica Morris, MBA, and Kristi Mitchell, MA, MPH, of the NCDR for their tireless work and outstanding efforts in the conduct of the data clarification project. Tammy Davis and Susan Queen of Wake Forest University School of Medicine deserve special thanks for their expertise in the preparation of this paper.

Reprint requests and correspondence: Dr. Michael A. Kutcher, Professor of Internal Medicine (Cardiology), Wake Forest University School of Medicine, Medical Center Boulevard, Winston-Salem, North Carolina 27157-1045. E-mail: mkutcher@wfubmc.edu.

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Key Words: percutaneous coronary intervention ■ cardiac surgery ■ outcomes analysis.

APPENDIX

For supplemental NCDR information, please see the online version of this article.

Testimony of
Christopher Howes, MD
Yale-New Haven Heart and Vascular Center at Greenwich Hospital
Docket Number: 12-31748

Introduction

Good morning Hearing Officer Yandow and OHCA staff. My name is Dr. Christopher Howes and I am an Assistant Professor at the Yale University School of Medicine (YSM) and a practicing interventional cardiologist. I am also the Chief of Cardiology and the Medical Director of the primary angioplasty program at Greenwich Hospital. I perform diagnostic and interventional procedures at Greenwich Hospital along with my colleague, Dr. John Setaro. I would like to speak to you today about the need for the proposed YNHHVC elective angioplasty satellite program at Greenwich Hospital.

You have already heard from Dr. Cabin about the recent changes to the 2011 ACCF/AHA/SCAI Guidelines for Angioplasty. We believe that these changes along with the results from the CPORT-E study essentially end the debate over the safety of elective angioplasty programs without onsite cardiac surgery as long as programs adhere to the SCAI program requirements. As demonstrated in the CON and completeness questions, the program at Greenwich Hospital already adheres to both the guidelines and the program requirements and is well positioned to provide elective angioplasty to patients. I would like to focus my testimony on the need for the proposed program.

Patient Choice and Referral Relationships

As OHCA is aware, physician referral patterns develop from long standing relationships where trust, confidence and familiarity exist. The physicians who refer patients to YNHHVC physicians do so because of the relationships we have developed with them over many years. Limited relationships exist between these referring physicians and with the interventional cardiologists at Stamford Hospital and in fact, there is minimal cross-over between Stamford and Greenwich Hospitals' cardiovascular physicians. Although there is some overlap in service area towns, when one analyzes the patient volume from these towns, it is clear that similar to other communities in the State; the two hospitals basically serve different patients. I would like to illustrate this point with the following data. Table I below summarizes 2011 inpatient cardiovascular discharge volume by patient town of origin for Stamford and Greenwich

Hospitals. Those communities which represent the top 80% of inpatient cardiovascular patients at Greenwich Hospital are low volume communities for Stamford Hospital. Specifically the communities of Greenwich, Port Chester and Rye comprise 81% of Greenwich Hospital's cardiovascular patients but only 4.6% of Stamford Hospital's. Patients who live in the city of Stamford and the town of Darien are Stamford Hospital's highest patient origin towns (88% of volume) and comprise only 7% of Greenwich Hospital's cardiovascular patients.

Table I. Greenwich Hospital Service Area
FY 2011 Inpatient Discharges

		Greenwich Hospital		Stamford Hospital	
Town	State	Volume	% Total	Volume	% Total
Darien	CT	48	1.5%	323	6.9%
Greenwich	CT	1,503	47.2%	199	4.2%
New Canaan	CT	19	0.6%	112	2.4%
Norwalk	CT	40	1.3%	135	2.9%
Stamford	CT	188	5.9%	3,837	81.4%
Weston	CT	1	0.0%	2	0.0%
Westport	CT	13	0.4%	17	0.4%
Wilton	CT	11	0.3%	15	0.3%
Armonk	NY	12	0.4%		0.0%
Bedford	NY	11	0.3%	2	0.0%
Larchmont	NY	23	0.7%	2	0.0%
Lewisboro	NY	2	0.1%	12	0.3%
Mamaroneck	NY	111	3.5%	9	0.2%
Mount Vernon	NY	14	0.4%	1	0.0%
Mt. Kisco	NY		0.0%	1	0.0%
New Rochelle	NY	45	1.4%	2	0.0%
Port Chester	NY	740	23.2%	11	0.2%
Pound Ridge	NY	3	0.1%	17	0.4%
Purchase	NY	7	0.2%		0.0%
Rye	NY	321	10.1%	11	0.2%
Scarsdale	NY	26	0.8%		0.0%
White Plains	NY	49	1.5%	3	0.1%
Grand Total		**3,187**	**100.0%**	**4,711**	**100.0%**

Source: CHIME

I think it is also important to note that Greenwich Hospital's emergency angioplasty and number of transfer cases for elective angioplasty have remained fairly consistent, even with the presence of a full service program at Stamford. This point further demonstrates the fact that the two hospitals serve different patient populations. As a result, the proposed program will not be

drawing elective angioplasty volume from Stamford Hospital, but will be providing services to patients seeking care from the YNHHVC. This point is further supported by a review of 2011 CHIME admission data for cardiovascular cases which showed almost no activity at Greenwich Hospital by any of Stamford Hospital's attending physicians. In fact, for the top 20 physicians (based on discharge volume and representing more than 50% of the total), only one physician, an internist, had admission volume at Greenwich Hospital. This is illustrated in Table 2 below.

Table 2. Top 20 MDs: Stamford Hospital D/Cs
FY 2011 Cardiovascular Inpatient

Attending Physician Name	Greenwich Hospital	Stamford Hospital	Grand Total
ORAEDU, CHINYELU		210	210
DESHPANDE, SATISH		189	189
MUDRIC-TIGANU, BRINDUSA		187	187
MADHOUN, MAHER		172	172
RADULOVIC, MIROSLAV		167	167
MODY, HIREN		156	156
DRUMMOND, JENIFER		152	152
TENICKI, PETER		144	144
JOHNSON, CLIVE		139	139
NARAYANASWAMY, GIRIJA		138	138
COADY, MICHAEL A		118	118
TRAN, PHI		117	117
BIVONA, JAMES		112	112
MALLOZZI, ANGELO		109	109
SILVA, LEE		104	104
FUSCO, MICHAEL	64	94	158
ACOSTA, RODRIGO		93	93
MATHEW, SANTY		88	88
MANONI, TIMOTHY		85	85
HENNESSY, BRIAN		81	81

*Cardiovascular discharges defined by principle procedure code.

This proposal also offers us the opportunity to bring patients to the State for their cardiac care. As a border hospital, Greenwich Hospital serves many patients from New York State (Westchester County) who live closer to Greenwich Hospital than other Westchester hospitals. We know for a fact, and as demonstrated by the letters of support included in the CON and the additional letters attached to my testimony (see Attachment I), that several physicians in Westchester County, with whom we have existing referral relationships, would utilize and refer elective angioplasty cases to Greenwich Hospital. They want their patients cared for in the

setting and facilities that Greenwich Hospital offers. There are 2 interventional cardiologists who currently perform procedures at New York hospitals and would like to offer Greenwich Hospital as a location for elective angioplasty. These physicians have committed to bringing between 80-105 angioplasty cases each year. These physicians will be credentialed by both Greenwich Hospital and YNHHVC and would adhere to the policies and procedures of YNHHVC. The volume that would result from Westchester County interventionalists would be a major benefit to the State of Connecticut's health care system, increasing volume, revenue and potentially jobs.

Patient Stress with Current Program

Our CON application emphasizes the significant stress and strain placed on Greenwich Hospital patients and their families when they receive either a diagnostic catheterization or an emergency angioplasty but then require an elective angioplasty procedure and must either be transferred or referred to another facility. I personally have cared for many of the patients who have had to endure this and can attest that it is a significant hardship that we place on patients during their time of need. We have included letters from several patients, in Attachment II, and highlight their personal situations which are representative of what our physicians hear from many patients. It is important for OHCA to consider the patient's perspective, especially in light of the fact that this program can be implemented safely, with no capital expense and will reduce the costs of angioplasty care. As has been said several times, everything is already in place today to treat elective angioplasty patients at Greenwich Hospital.

Existing Infrastructure and Expertise

We currently staff our emergency angioplasty program with either onsite or on-call staff 24 hours per day, 7 days per week, 52 weeks per year. Our staff are ready, at any time, on any given day, to provide the highest quality cardiac care to any patient who presents to Greenwich Hospital. Our catheterization laboratory equipment is state-of-the-art and the catheters, stents, and other supplies we utilize are extensive and from leading vendors.

We are currently providing angioplasty services to some of the sickest cardiac patients, ST segment elevation myocardial infarction patients. We certainly have the equipment, staff and physician expertise to provide this same service to the less acute population, those who need an angioplasty but not in an emergency situation. Research and guidelines now support such programs and health care regulators throughout the United States have approved the

establishment of such programs. Increased utilization of existing cardiac catheterization and angioplasty infrastructure is completely consistent with health reform and the efforts of OHCA to improve access and financial feasibility.

The emergency angioplasty program is a necessary life-saving program and must continue. Now that we know from recent research and leading experts in the nation that elective angioplasty without onsite surgery is safe and appropriate, how can we not improve the utilization of our infrastructure and improve the experience for Connecticut residents.

Conclusion

We have reached the point in time where this proposal can and should be approved. Earlier barriers have been removed and patients and physicians seek these services at Greenwich Hospital. The clinical infrastructure and expertise is present and ready to care for elective angioplasty patients in need. I urge OHCA to approve this CON application. I would like to introduce Mr. Frank Corvino, President of Greenwich Hospital.

The foregoing is my sworn testimony.

Christopher Howes, MD
Assistant Professor at the Yale University School of Medicine
Medical Director, Greenwich Hospital Primary Angioplasty Program

ATTACHMENT I

WESTMED
MEDICAL GROUP

Barney Newman, MD
Medical Director

July 10, 2012

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P.O. Box 340308, Hartford, CT 06134

Dear Deputy Commissioner Davis:

I am writing this letter in support of Greenwich Hospital's application to provide elective angioplasty to the communities it serves. I am the Medical Director of WESTMED Medical Group which has over a dozen internists and cardiologists on the medical staff at Greenwich Hospital. Many of our patients use the Hospital's services for their health care needs including cardiac services. If Greenwich Hospital offered elective angioplasty, I feel confident that our patients in the Greenwich Hospital service area would prefer the convenient location of Greenwich Hospital along with the high quality and competent physicians and staff, up-to-date facilities and appropriate safety measures in place at the Hospital.

An elective angioplasty service at Greenwich Hospital will allow our physicians to provide cardiac patients with local access to high quality interventional cardiology services. Patients from the Greenwich Hospital service area that need elective angioplasty are currently required to go to another hospital to receive these services since Greenwich Hospital is not approved to provide elective angioplasty services. However, the same facility, physicians, staff and equipment required to perform *elective* angioplasty services are already in place for Greenwich Hospital's approved *emergency* angioplasty program. This is a more cost effective use of resources. In addition, the ability to provide elective angioplasty will improve the continuity of care available to patients at Greenwich Hospital.

If Greenwich Hospital was granted permission to provide elective angioplasty, my cardiology staff would provide this service to our patients choosing to have their procedures completed in this institution. I estimate that we would complete 50-75 angioplasties at Greenwich Hospital that we currently treat at a hospital outside of Connecticut.

Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Barney Newman, M.D.
Medical Director
WESTMED Medical Group

NewYork-Presbyterian
The University Hospital of Columbia and Cornell

COLUMBIA UNIVERSITY
MEDICAL CENTER

ColumbiaDoctors Medical Group
www.cumc.columbia.edu/dept/card

July 10, 2012

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
PO Box 340308
Hartford, CT 06134

Dear Deputy Commissioner Davis:

I am writing this letter in support of Greenwich Hospital's application to provide elective angioplasty to the communities it serves. I am on the medical staff at Greenwich Hospital. Many of my patients use the Hospital's services for their health care needs including cardiac services. If Greenwich Hospital offered elective angioplasty, I feel confident that my patients in the Greenwich Hospital service area would prefer the convenient location of Greenwich Hospital along with the high quality and competent physicians and staff, up-to-date facilities and appropriate safety measures in place at the Hospital.

An elective angioplasty service at Greenwich Hospital will allow me to provide cardiac patients with local access to high quality interventional cardiology services. Patients from the Greenwich Hospital service area that need elective angioplasty are currently required to go to another hospital to receive these services since Greenwich Hospital is not approved to provide elective angioplasty services. However, the same facility, physicians, staff and equipment required to perform *elective* angioplasty services are already in place for Greenwich Hospital's approved *emergency* angioplasty program. This is a more cost effective use of resources. In addition, the ability to provide elective angioplasty will improve the continuity of care available to patients at Greenwich Hospital.

If Greenwich Hospital was granted permission to provide elective angioplasty, I would provide this service to my patients choosing to have their procedures completed in this institution. I estimate that I would complete 30 angioplasties at Greenwich Hospital that I currently treat at a hospital outside of Connecticut. My annual angioplasty volume exceeds the recommended volume of 75 cases and, in fact, my volume is in the range of 300 cases per year.

Thank you for your consideration of the Greenwich Hospital application to add elective angioplasty to the continuum of cardiac services already provided by the Hospital.

I urge you to approve this application.

Sincerely,

Craig Hjemdahl-Monsen, MD

CHM/cb

Cardiology
19 Bradhurst Avenue, Suite 700, Hawthorne, NY 10532
Telephone: 914-593-7800 Fax: 914-593-7856

ATTACHMENT II

July 5,2012

Greenwich Hospital
Att: Mr. Frank Corbino, C.E.O.
Re: Stent Procedure

Last July, my husband went to Rivehead Hospital where we were advised he was having a heart attack. It was suggested that we go to St. Mary's to have an angiogram and, if necessary, immediately implant a stent. We chose to come home to Greenwich Hospital where Dr. .Brunetti brought in Dr. Howes and his staff. We couldn't be more satisfied with the way this group handled the situation. Now that our cardiologist is preparing to retire, we are so pleased to have Dr. Howes and his group.

As usual, Greenwich Hospital stepped up to the plate, doing a wonderful job .However, if the angiogram showed a stent was needed, the stent procedure could only be performed in case of an emergency. Otherwise, we would have to go to Yale-New Haven.

After the angiogram was done, there was no doubt a stent was needed. He had to go to Yale to have the procedure performed. This was not only a burden for him, but my daughter and I had to drive to Yale late in the evening and then drive home at 1:00 a.m.. Dr. Howes group could have performed the operation at Greenwich as they performed at Yale. Going to Yale not only was stressful to all, but also
incurred additional costs all around.

Greenwich Hospital and its' patients would benefit having this procedure performed at the hospital. Cost savings, patient convenience and the same Yale doctors performing the procedure.

We hope strong consideration would be given to perform this procedure at Greenwich Hospital. Thank you for your consideration.

Very truly yours,

Robert A. Durso

Mariann Durso

176 Barnard Road
New Rochelle, NY 10801

July 6, 2012

Rosemary McElwain
Nurse Manager - Cardiology
Greenwich Hospital
5 Perryridge Road
Greenwich, CT 06830

Dear Ms. McElwain:

On Tuesday, February 7th, 2012 I came to Greenwich Hospital's Emergency Room with chest pain. The Doctors in the ER told me I was having a heart attack and that I needed to have an emergency angioplasty procedure which was done in your cardiac catheterization room. The cardiologist found that I had a 100% blockage on the left side of my heart which was corrected. In addition, he also found that I had a 95% blockage on the right side. This second blockage could not be repaired at Greenwich Hospital because it was technically an "elective" procedure, so I was transferred that evening to Yale New Haven Hospital for a second procedure. The second procedure was initially scheduled for Wednesday, February 8th but I had to wait until Thursday, February 9th to have it done due to other emergencies that took place on the 8th.

While I understand that Greenwich Hospital is not able to do elective angioplasty, I would have preferred to stay in your hospital and have all of my complications taken care of at once. The transfer elsewhere and the fact that I had to have a second procedure was very difficult for me and my family. I had an excellent experience at Greenwich Hospital and I hope that in the future Greenwich Hospital is able to offer these procedures to other patients in need.

Sincerely,

Theodore S. Francavilla

680

Mr.Frank Corvino,
President
Greenwich Hospital
Greenwich, CT 06830

RECEIVED
NOV 21 2011
GREENWICH HOSPITAL
ADMINISTRATION DEPT.

November 13, 2011 NOV 23 2011

Dear Mr. Corvino,

My name is Milburn A. Muirhead. My wife, Nancy, and I live in Fredericksburg, Texas. We visit the Greenwich/Riverside area about 4 times a year because our son, Chris Hearn, his wife Wendy and our two young grandsons live there. We were in their home on Saturday, October the 29th when I began having a heart attack about 10:30 a.m. I was able to call for help; my daughter-in-law, Wendy, called 911 and the police and EMS came very quickly. My Nancy rode with me in the ambulance to your hospital. You might remember that October 29 was the day of the earliest, heaviest snow storm that Greenwich has ever had.

Your ER staff was terrific. They were all very caring, well trained and efficient. Dr. Setaro was at the hospital when I arrived. He confirmed that the EKG indicated that I was having a heart attack. He told me they were taking me to the cath-lab for a procedure. Well, what a procedure it was. They installed two stents in my right heart artery, which Dr. Setaro indicated was 100% clogged. My comfort and attitude toward life increased immediately. The left heart artery was also clogged between 90-99%. But that artery could not be opened in Greenwich because the blockage was hardened calcium and they needed a special tool to open it for a stent. The Greenwich hospital did not have the equipment necessary, so Dr. Setaro wanted me to go immediately to the Yale Hospital in New Haven in case the left artery developed into an emergency. This situation was made more awkward because of the freak early snow storm that day. We went to New Haven by ambulance Saturday evening. Dr. Curtis performed the angioplasty on my left artery on Monday. When I was released on Tuesday, Dr. Curtis said I would be a new man. I left the hospital knowing the Lord intended for me to have that heart attack in your city, in your hospital, complete with an excellent cardiac unit.

What a series of MIRACLES. Mr. Corvino, your hospital and staff, led by Dr. Heffer in the ER and Dr. Setaro in the cath-lab, saved my life that day. Dr. Setaro indicated there was little if any damage to my heart because we got to the hospital so quickly. If the cardiac unit had not been available at the Greenwich hospital, the delay in treatment due to the snow storm likely would have cost me significant heart damage, if not my life. We live in a small town. Although we have a good hospital there, I could not have received the care and the cath-lab procedures available in your hospital.

Thank you. Thank you for my life.

A truly grateful man,

M. A. Muirhead

M. A. Muirhead

cc: Dr. John Setaro

Testimony of
Frank Corvino
Yale-New Haven Heart and Vascular Center at Greenwich Hospital
Docket Number: 12-31748

Introduction

Good morning Hearing Officer Yandow and OHCA staff. My name is Frank Corvino and I am the President and CEO of Greenwich Hospital. You have heard from my colleagues about the clinical appropriateness, existing clinical, infrastructure and physician expertise, and referral relationship associated with the proposed program. I would like to focus my testimony on the high level of quality and excellence of care at Greenwich Hospital and our commitment to providing the best possible cost-effective care to our patients who require elective angioplasty services.

Greenwich Hospital's commitment to quality, service excellence and employee satisfaction is well documented. The hospital draws some of the finest healthcare professionals in the field for the same reasons that so many area residents choose the hospital – access to the latest technology, a nurturing environment and a staff that focuses on safety, quality and patient satisfaction.

As a five-time recipient of the prestigious Press Ganey Summit Award for patient satisfaction, our hospital has set a national standard for service excellence. Our efforts to consistently provide high-quality and safe patient care have earned top marks from many national organizations, including the Joint Commission, the Connecticut Hospital Association, the Connecticut Quality Improvement Award Partnership and the Leapfrog Group, just to name a few. It's no wonder patients gave us the highest rating in "willing to recommend to others" among all hospitals in Connecticut and Westchester County, NY, in patient surveys conducted by the Centers for Medicare and Medicaid Services. Attachment I contains copies of several of the reports I just referenced.

Greenwich Hospital is committed to the significant investment required to offer emergency angioplasty to our community. In this era of health reform and the need for all health care providers and health systems to provide more cost effective services, we believe this program will reduce the overall costs of angioplasty care to the Connecticut health system. The repeat

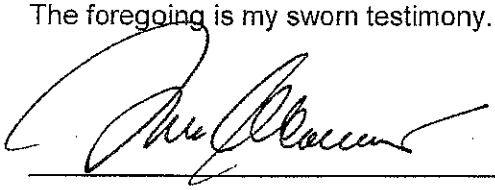
procedures, second hospitalization and emergency transport costs that result from Greenwich Hospital's inability to provide elective angioplasty are expenses that can no longer be wasted. As you have heard from our other witnesses, the proposed program can utilize the existing staff, physicians and equipment at Greenwich Hospital's emergency angioplasty program and reduce costs for this care for the overwhelming majority of our patients. We estimate the unnecessary costs that now result and impact payors and patients total approximately $425,000 each year. This amount is based on an average of 53 cases currently transferred that could be cared for by a Greenwich Hospital elective angioplasty program multiplied by $8,000 which includes $7,000 for the average costs of an angioplasty admission at YNHH plus $1,000 for emergency transportation.

We are committed to providing the services that our communities have come to rely on us for and will need in the future. However, in this era of healthcare reform and increased financial pressures on hospitals, we need to ensure we are providing care in a cost effective and efficient manner. It just makes sense to maximize both the use of our existing clinical capabilities and resources as well as maximize the benefit to meeting community need. There is no downside.

In summary, I want to emphasize that this proposal is all about patient care and patient access. It does not make sense that Greenwich Hospital is able to do the most difficult angioplasty cases – and do them with excellent outcomes—and is not allowed to do the elective cases. Especially in light of the revised guidelines, it does not make sense for our patients.

Thank you for your time and attention and I urge you to approve this CON application.

The foregoing is my sworn testimony.



Frank A. Corvino
President & Chief Executive Officer
Greenwich Hospital

ATTACHMENT I

Greenwich Hospital Receives "Gold Seal of Approval"
for Excellence in Spine and Joint Surgery

Greenwich, Conn. (February 17, 2011) – Greenwich Hospital has become one of six facilities nationwide and the only hospital in Connecticut to receive The Joint Commission's "Gold Seal of Approval™" for spinal fusion and total hip and knee replacement surgery.

Two Greenwich Hospital programs – The Spine Institute and The Center for Joint Replacement – received certification for disease-specific care for adhering to national standards for excellence, quality and safety.

The certification for spinal fusion and hip and knee replacement procedures recognizes Greenwich Hospital's commitment to maintain clinical excellence and patient satisfaction, while continuously working to improve patient care.

"This accomplishment is the result of our commitment to maintaining clinical excellence and patient satisfaction, while continuously working to improve patient care," said Frank Corvino, President/CEO. "It is a major accomplishment for us and benefit for the communities we serve."

Personalized attention for better outcomes
Greenwich Hospital's spinal fusion and total joint replacement programs offer a level of continuity that sets it apart from other facilities. A clinical resource nurse helps patients every step of the way – before, during and after surgery and throughout rehabilitation and recovery. Patients receive the practical information, emotional support and follow-up care they need to guide them through the entire process.

Certification by The Joint Commission means Greenwich Hospital has demonstrated a commitment to excellence by complying with the highest national standards for safe and quality care. The hospital underwent a vigorous on-site survey as part of the process.

Orthopedic and neurosurgeons at Greenwich Hospital perform about 700 spinal fusion and total joint replacement procedures a year. The Spine Institute at Greenwich Hospital was certified for cervical (neck) and lumbar (lower back) spinal fusion. The Center for Joint Replacement at Greenwich Hospital was certified for hip and knee replacement surgery.

The Joint Commission is an independent organization that evaluates and accredits more than 15,000 healthcare organizations nationwide.

###

The Joint Commission

Greenwich Hospital
5 Perryridge Road
Greenwich, CT 06830

Organization Identification Number: 5666

DISEASE
Spinal Fusion

Program
Disease-Specific Care Certification

Reviewer(s) and Review Date(s)
Richard W.Cohen, MD - (01/18 - 01/18/2011)

Executive Summary

Disease-Specific Care Certification : As a result of the certification review conducted on the above date(s), there are no Requirements for Improvement identified.

If you have any questions, please do not hesitate to contact your Account Executive.

Thank you for collaborating with The Joint Commission to improve the safety and quality of care provided to patients.

The Joint Commission

Greenwich Hospital
5 Perryridge Road
Greenwich, CT 06830

Organization Identification Number: 5666

DISEASE

Joint Replacement - Knee

Program	**Reviewer(s) and Review Date(s)**
Disease-Specific Care Certification	Richard W.Cohen, MD - (01/17 - 01/17/2011)

Executive Summary

Disease-Specific Care Certification :	As a result of the certification review conducted on the above date(s), there are no Requirements for Improvement identified.

If you have any questions, please do not hesitate to contact your Account Executive.

Thank you for collaborating with The Joint Commission to improve the safety and quality of care provided to patients.

The Joint Commission

Greenwich Hospital
5 Perryridge Road
Greenwich, CT 06830

Organization Identification Number: 5666

DISEASE

Joint Replacement - Hip

Program
Disease-Specific Care Certification

Reviewer(s) and Review Date(s)
Richard W.Cohen, MD - (01/17 - 01/17/2011)

Executive Summary

Disease-Specific Care Certification :	As a result of the certification review conducted on the above date(s), there are no Requirements for Improvement identified.

If you have any questions, please do not hesitate to contact your Account Executive.

Thank you for collaborating with The Joint Commission to improve the safety and quality of care provided to patients.

CONNECTICUT HOSPITAL ASSOCIATION

For Immediate Release
May 28, 2012

Contact: Michele Sharp
Director of Communications and Public Affairs
(203) 294-7213
Sharp@chime.org

Greenwich Hospital Awarded the CHA's 2012 John D. Thompson Award for Excellence in the Delivery of Healthcare Through the Use of Data

WALLINGFORD – At its 94th Annual Meeting on June 27, the Connecticut Hospital Association (CHA) will recognize Greenwich Hospital with the 2012 John D. Thompson Award for Excellence in the Delivery of Healthcare Through the Use of Data. The team from Greenwich Hospital is recognized for its project, ***A Novel, Comprehensive, Multimodal Analgesic Regimen for Joint Replacement Surgery***.

In 2011, members of Greenwich Hospital's Center for Joint Replacement designed and implemented a new, comprehensive, multimodal protocol to address the significant problem of postoperative management of pain in patients undergoing joint replacement surgery.

The new protocol at Greenwich Hospital is to treat pain before it starts. Instead of exclusively utilizing traditional opioid pain medications, a multimodal regimen is recommended. Using a Plan- Do-Study-Act (PDSA) cycle, the protocol is continually monitored.

Results were dramatic. Compared to historical controls, patients receiving the new protocol required an average of 40 percent fewer opioids during their hospital stay with a decrease in opioid-related side effects. Increased comfort improved compliance with physical therapy. Patients became more satisfied with the management of their pain.

As a result of this success, Greenwich Hospital developed a similar protocol for use in its ambulatory surgical center. Future projects may include general surgery, bariatric surgery, major gynecological surgery, and oncologic surgery.

The John D. Thompson Award honors the contributions made by John D. Thompson to healthcare administration and patient care quality during his career. Winners of this prestigious award have achieved excellence in patient care through the use of data, as demonstrated by the improvement of internal operations, procedures, and outcomes.

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PRESS GANEY®
PARTNERS IN IMPROVEMENT™

Summit Award Recipient Information

Congratulations on winning the 2010 Press Ganey Summit Award! You can read about this award's criteria and the benefits on our web site.

Award book: There are many benefits to being a Summit Award winner, including having your narrative appear in our annual award book. To facilitate this, we ask that you complete and return two forms: a narrative request and a release form (attached to your e-mail).

To be included in our annual award book, the narrative form must be completed in its entirety and e-mailed in Microsoft Word format to Cathi Kennedy (ckennedy@pressganey.com) by the end of your business day on **Friday, October 8**. *Due to our tight timeframe, we are unable to extend this deadline.*

The release form must be printed, signed and faxed to Cathi (574.246.4924). Alternatively, you can scan and e-mail the signed to ckennedy@pressganey.com.

Award lunch: We are hosting a special award lunch on Tuesday, November 9 at our National Client Conference. During the lunch, all 2010 award winner names will be called and the winners asked to stand and be recognized. Click here for more information on our National Client Conference or contact your account manager.

Award winner photos: At the conference, you and members of your facility may have your picture taken with a full-size replica of the award. Photo times are:

Monday, Nov. 8 from 5:30 – 6:30 p.m.
Wednesday, Nov. 10 from 8:00 – 9:00 a.m.

Media kit: You will be sent a link to a media kit before the conference in November. The media kit will have suggestions on how to publicize your award-winning status and gain recognition for your achievement. ***We ask that you only share your award-winning status internally and delay all external promotions until after Press Ganey's official announcement in November.***

Lapel pins: 100 lapel pins will be shipped to your facility before the conference.

Award shipment: Your award will be shipped to arrive at your facility the week of November 8.

HOSPITAL SAFETY SCORE

CONTACT:

Erica Newman
The Leapfrog Group
202-644-9408
Enewman@leapfroggroup.org

Hillary Blum
Stern + Associates (on behalf of
The Leapfrog Group)
908-276-4344, x227
LeapfrogTeam@sternassociates.com

Embargoed Until Wednesday June 6, 2012

Hospitals Receive A, B, C, D or F Scores for Patient Safety

Infections, Medication and Medical Errors, and Injuries Still Rampant, but Some Hospitals Are Safer Than Others

Washington, DC, June 6, 2012 – Approximately 400 people die every day because of a preventable hospital error – the equivalent of a jet crashing every day and killing all aboard. In response to this silent epidemic, more than 2,600 U.S. hospitals will now receive A, B, C, D or F Hospital Safety Scores based on patient safety via a first-of-its-kind initiative. A Blue Ribbon Panel of the nation's top patient safety experts provided guidance to The Leapfrog Group, an independent national nonprofit run by employers and other large purchasers of health benefits, to develop the Hospital Safety Score. The Hospital Safety Score is calculated using publicly available data on patient injuries, medical and medication errors, and infections.

"The Leapfrog Group's goal is to give patients the vital information they need and deserve before even entering a hospital," said Leah Binder, president and CEO, The Leapfrog Group. "We hope people will use this score to talk with their doctor, make informed decisions about where to seek care, and take the right precautions during a hospital stay."

For the first time, the Hospital Safety Score will highlight the country's best hospitals and warn against the worst to save lives and bring attention to the nation's silent safety epidemic. According to recent studies, one in four Medicare patients will leave a hospital with a potentially fatal issue they didn't have prior to hospitalization. On average, one medication error per day occurs for each hospitalized patient, and more than 180,000 Americans die every year from hospital accidents, errors, and infections.

The Hospital Safety Score website – www.hospitalsafetyscore.org – allows visitors to search hospital scores for free, and also provides information on how the public can protect themselves and loved ones during a hospital stay. More information on the Hospital Safety Score can also be found on Sharecare, an online resource of health questions and answers, at www.sharecare.com/group/hospital-safety-score. Patients should visit the Sharecare website for detailed questions and answers on how to stay safe and protect themselves during a hospital stay.

"The Leapfrog Group board has been frustrated with the lack of progress in improving patient safety, despite significant industry efforts over the past decade," said David Knowlton, immediate past chair of The Leapfrog Group Board of Directors and chair of The Leapfrog Group's Patient Safety Committee. "It is time for a game changer. It's time to give American families the heads-up they need to protect themselves if they face the need for a hospital stay."

(MORE)

The Leapfrog Group's membership of employers and other purchasers of health benefits, and business coalitions on health across the country, will be working to engage communities, employers, health plans, and hospitals in using the Hospital Safety Score to improve safety. The Hospital Safety Score will be reissued using updated data in November 2012, with an annual Hospital Safety Score to follow in 2013 and beyond.

Key Findings

- Of the 2,652 general hospitals issued a Hospital Safety Score, 729 earned an "A," 679 earned a "B," and 1243 earned a "C" or below.
- A wide range of hospitals earned "As," with no one class of hospitals dominating among those showing the highest safety scores. Hospitals earning an "A" include academic medical centers Massachusetts General, NYU Langone Medical Center, and University of California San Francisco. Many rural hospitals earned an "A," including Grinnell Regional Medical Center in Iowa and Baptist Health South Florida Homestead Hospital in Florida.
- Hospitals with myriad national accolades, such as Mayo Clinic, Virginia Mason Medical Center, and University of Michigan Medical Center, each earned an "A."
- Less predictable were the "A" scores earned by hospitals serving highly vulnerable, impoverished, and/or health-challenged populations, such as Bellevue Hospital, Montefiore Hospital, and Detroit Receiving Hospital.
- "A" scores were awarded to for-profit hospitals including many in the HCA systems, as well as hundreds of not-for-profit and public hospitals.
- Community hospitals showed excellence as well, such as OSF St. Joseph Medical Center in Illinois.

Not all hospitals earned "A," and there are some surprises, including hospitals with outstanding reputations for quality appearing with Hospital Safety Scores of "B," "C," or below. "The Hospital Safety Score exclusively measures safety – meaning errors, accidents, and infections. Hospitals that excel in excellent surgery programs, use state-of-the-art diagnostic equipment, and/or run model programs for treating disease may still need this score as a reminder to put a priority on keeping patients safe," said Dr. Ashish Jha of Harvard, a member of the Blue Ribbon Expert Panel.

States had variations in performance. Massachusetts hospitals on average had the highest Hospital Safety Scores, while District of Columbia had the lowest average scores.

Methodology and Experts

Calculated under the guidance of The Leapfrog Group's nine-member Blue Ribbon Expert Panel, the Hospital Safety Score uses 26 measures of publicly available hospital safety data to produce a single score representing a hospital's overall capacity to keep patients safe from infections, injuries, and medical and medication errors. The panel includes: John Birkmeyer (University of Michigan), Ashish Jha (Harvard University), Lucian Leape (Harvard University), Arnold Milstein (Stanford University), Peter Pronovost (Johns Hopkins University), Patrick Romano (University of California, Davis), Sara Singer (Harvard University), Tim Vogus (Vanderbilt University), and Robert Wachter (University of California, San Francisco).

"Developing the Hospital Safety Score was an intensive nine-month process of deliberation by a very thoughtful and informed group of experts in patient safety from across the country, and it resulted in what we consider the fairest way possible to assess a hospital's performance," said Dr. Jha. "We in academia know what information to use when we are admitted to a hospital, and we believe non-experts deserve the same information to protect their families. We've been glad to guide The Leapfrog Group in developing the Hospital Safety Score to give the public a way to guide their own decisions."

(MORE)

The Blue Ribbon Expert Panel designed the methodology for hospitals with the most data publicly available at the national level: general short-stay hospitals. As a result, excluded from this first round of the Hospital Safety Score are critical access hospitals, specialty hospitals such as children's hospitals and cancer hospitals, government hospitals such as VA and military hospitals, and long-term care facilities.

To develop the Hospital Safety Score, the Blue Ribbon Expert Panel gathered data publicly reported at the national level, including measures reported by the federal government via the Centers for Medicare and Medicaid Services (CMS) and the annual Leapfrog Hospital Survey. The final 26 measures calculated in the Hospital Safety Score cover falls and trauma, central line-associated bloodstream infections, very severe pressure ulcers, and preventable complications from surgery such as foreign objects retained in the body, postoperative hazards, and accidental punctures or lacerations. The Hospital Safety Score also credits hospitals on measures of the procedures and protocols known to prevent infections, errors and accidents, such as strong nursing leadership and engagement, hand hygiene policies, computerized physician order entry systems, adherence to medical and medication protocols that prevent complications, safety-first organizational leadership and culture, and the right level of staffing for the ICU.

Not all hospitals make the full list of 26 measures publicly available, in which case the Hospital Safety Score was calculated only for the available measures. The Blue Ribbon Expert Panel required at least 14 measures for a hospital in order to calculate a Hospital Safety Score. Those without 14 measures were not scored. Unscored hospitals include all hospitals from the State of Maryland, and certain territories including Guam and Puerto Rico, which the federal government excluded from required public reporting at the national level.

"Residents of Maryland, Guam, and Puerto Rico should be very concerned that they do not have information on safety that other U.S. residents have," said Binder, a Maryland resident. "We will be working to improve hospital transparency, and people should contact their elected officials and local hospitals to insist on better public disclosure."

For more information about the Hospital Safety Score, please visit www.hospitalsafetyscore.org. Journalists interested in scheduling an interview with a member of the Blue Ribbon Expert Panel or The Leapfrog Group should contact LeapfrogTeam@sternassociates.com.

About The Leapfrog Group
The Leapfrog Group (www.leapfroggroup.org) is a national organization using the collective leverage of large purchasers of health care to initiate breakthrough improvements in the safety, quality, and affordability of health care for Americans. The flagship Leapfrog Hospital Survey allows purchasers to structure their contracts and purchasing to reward the highest performing hospitals. The Leapfrog Group was founded in November 2000 with support from the Business Roundtable and national funders, and is now independently operated with support from its purchaser and other members.

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RESULTS - CONNECTICUT HOSPITALS

Bridgeport Hospital	C	267 GRANT STREET	Bridgeport	CT
BRISTOL HOSPITAL	B	BREWSTER RD	Bristol	CT
Danbury Hospital	B	24 HOSPITAL AVE	Danbury	CT
DAY KIMBALL HOSPITAL	B	320 POMFRET STREET	Putnam	CT
Greenwich Hospital	A	5 PERRYRIDGE RD	Greenwich	CT
Griffin Hospital	B	130 DIVISION ST	Derby	CT
HARTFORD HOSPITAL	B	80 SEYMOUR STREET	Hartford	CT
HOSPITAL OF CENTRAL CONNECTICUT, THE	B	100 GRAND STREET	New Britain	CT
JOHN DEMPSEY HOSPITAL	C	263 FARMINGTON AVE	Farmington	CT
JOHNSON MEMORIAL HOSPITAL	B	201 CHESTNUT HILL RD	Stafford Springs	CT
LAWRENCE & MEMORIAL HOSPITAL	B	365 MONTAUK AVE	New London	CT
MANCHESTER MEMORIAL HOSPITAL	C	71 HAYNES ST	Manchester	CT
MIDDLESEX HOSPITAL	B	28 CRESCENT ST	Middletown	CT
MidState Medical Center	B	435 LEWIS AVE	Meriden	CT
Milford Hospital	C	300 SEASIDE AVENUE	Milford	CT
New Milford Hospital	C	21 ELM ST	New Milford	CT
Norwalk Hospital	B	24 STEVENS STREET	Norwalk	CT
ROCKVILLE GENERAL HOSPITAL	C	31 UNION ST	Rockville	CT
Sharon Hospital	B	50 HOSPITAL HILL ROAD, PO BOX 789	Sharon	CT
ST FRANCIS HOSPITAL & MEDICAL CENTER	A	114 WOODLAND STREET	Hartford	CT
St. Mary's Hospital of Waterbury	C	56 FRANKLIN ST	Waterbury	CT
St. Raphael Healthcare System	A	1450 CHAPEL ST	New Haven	CT
St. Vincent's Medical Center of Bridgeport	A	2800 MAIN ST	Bridgeport	CT
Stamford Hospital	C	SHELBURNE RD & WEST BROAD ST	Stamford	CT
The Charlotte Hungerford Hospital	C	540 LITCHFIELD ST	Torrington	CT
Waterbury Hospital	C	64 ROBBINS ST	Waterbury	CT
William W Backus Hospital	C	326 WASHINGTON ST	Norwich	CT
WINDHAM COMM MEM HOSP & HATCH HOSP	B	112 MANSFIELD AVE	Willimantic	CT
Yale-New Haven Hospital	C	20 YORK ST	New Haven	CT

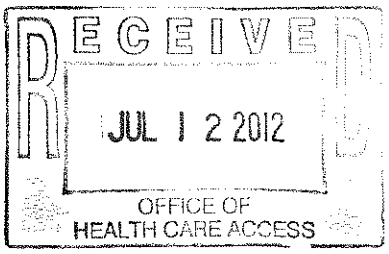
JEFFERS
COWHERD

JEFFERS COWHERD P.C.
ATTORNEYS AT LAW

55 WALLS DRIVE
FAIRFIELD, CT 06824
203-259-7900
203-259-1070 FAX
WWW.JEFFERS-LAW.COM

STEPHEN M. COWHERD
Email: scowherd@jeffers-law.com

July 12, 2012



VIA HAND DELIVERY

Lisa A. Davis, MBA, BSN, RN
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: Certificate of Need Application; Docket Number: 12-31748-CON
Yale-New Haven Hospital and Greenwich Hospital to
Establish and Operate an Elective Angioplasty Program at Greenwich Hospital

Dear Deputy Commissioner Davis:

Enclosed please find our firm's Notice of Appearance and an original and five (5) copies of The Stamford Hospital's Petition for Intervenor Status in the above-referenced Certificate of Need Application. Also enclosed are the pre-filed testimonies of Sharon Kiely, M.D., Stamford Hospital's Senior Vice President of Medical Affairs and Chief Medical Officer, and William A. Gray, M.D., Associate Professor of Clinical Medicine at Columbia University and Director, Endovascular Services at the Columbia University Medical Center/New York Presbyterian Hospital.

Please contact the undersigned should you have any questions.

Respectfully submitted,

Stephen M. Cowherd

Enclosures

cc: Kimberly Martone, Director of Operations, OHCA (w/out enc.)
David L. Smith, Senior Vice President, Stamford Hospital (via email)

STATE OF CONNECTICUT

OFFICE OF HEALTH CARE ACCESS

BEFORE THE OFFICE OF HEALTH CARE ACCESS	:	Docket No. 12-31748-CON
IN RE APPLICATION OF YALE-NEW HAVEN HOSPITAL AND GREENWICH HOSPITAL TO ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM AT GREENWICH HOSPITAL	:	July 12, 2012

NOTICE OF APPEARANCE

Please enter the appearance of Jeffers Cowherd P.C. on behalf of The Stamford Hospital in the above entitled proceeding.

Respectfully submitted,
THE STAMFORD HOSPITAL

By _____

Stephen M. Cowherd
Carolyn R. Linsey
Stephanie Sprague
Jeffers Cowherd P.C.
55 Walls Drive
Fairfield, CT 06824
Telephone: (203) 259-7900
Facsimile: (203) 259-1070
scowherd@jeffers-law.com
clinsey@jeffers-law.com
ssprague@jeffers-law.com
Its Attorneys

CERTIFICATE OF SERVICE

This is to certify that a true and accurate copy of the foregoing Notice of Appearance was sent by U.S. mail postage pre-paid this 12th day of July 2012 to:

Jean Ahn
System Director
Yale-New Haven Hospital
789 Howard Avenue
New Haven, CT 06519

Stephen M. Cowherd

BEFORE THE OFFICE OF HEALTH CARE ACCESS DIVISION OF THE DEPARTMENT OF PUBLIC HEALTH	:	Docket No. 12-31748-CON
IN RE APPLICATION OF YALE-NEW HAVEN HOSPITAL AND GREENWICH HOSPITAL TO ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM AT GREENWICH HOSPITAL	:	July 12, 2012

PETITION OF THE STAMFORD HOSPITAL FOR INTERVENOR STATUS WITH FULL PROCEDURAL RIGHTS

The Stamford Hospital ("TSH" or the "Petitioner"), a non-profit, acute care general hospital located at 30 Shelburne Road, Stamford, Connecticut, requests that the Office of Health Care Access ("OHCA") grant it intervenor status with full procedural rights, including rights to inspect and copy records; to present written and oral testimony, evidence and argument; and to cross-examine witnesses in the above-captioned proceeding. The Petitioner's participation in the public hearing concerning the elective angioplasty without cardiac surgical backup on-site ("Elective PCI Without SOS") program proposed by Greenwich Hospital ("GH") and Yale-New Haven Hospital ("YNHH") (collectively, "Applicants") fully meets the requirements for intervenor status as set forth in the Connecticut Uniform Administrative Procedures Act, Connecticut General Statutes (C.G.S.) §§ 4-166, *et seq.* (the "UAPA") and §19a-9-27 of the Regulations of Connecticut State Agencies for the reasons set forth below.

Preliminary Statement

Petitioner intends to present evidence that there is no clear public need for the proposed Elective PCI Without SOS program. *See* C.G.S. §19a-639(a)(3). It will provide data omitted from Applicants' CON Application (the "Application") which shows that angioplasty volumes are flat to declining in Connecticut and that demand for the service is also not growing in the Applicants' proposed service area where residents can presently choose to receive elective PCI

procedures from four (4) existing full-service cardiac programs in Fairfield County, two (2) existing providers in Westchester County and many leading heart programs in New York City.

Evidence will also be presented that Applicants have failed to carry their burden of demonstrating how their proposal will improve quality, accessibility and cost-effectiveness of health care delivery in the region as required by C.G.S. § 19a-639(a)(5). This will be demonstrated though authoritative clinical literature that gives the performance of elective angioplasty without cardiac surgical back-up on site a Class IIb recommendation, which means that the procedure may be considered and that the benefit is greater than or equal to the risk. *See 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: a Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions* (the "2011 ACCF/AHA/SCAI Guideline"), Attachment VI to the Application ("Attachment VI"), p. 164 (emphasis added).

Such a recommendation falls far short of both a Class I recommendation, which means that the benefit of the procedure far outweighs the risk and should be performed and a Class IIa recommendation where the benefit is much greater than the risk and it has been determined that it is reasonable to perform the procedure. *Id.*, p. 144. In addition, the 2011 ACCF/AHA/SCAI Guideline clearly states as follows:

> It is only appropriate to consider initiation of a PCI program without on-site cardiac surgical backup if this program will clearly fill a void in the healthcare needs of the community. Competition with another PCI program in the same geographic area, particularly an established program with surgical back-up, may not be in the best interests of the community.

Id., p. 164.

Petitioner will demonstrate that there is no void in the cardiac services available to lower Fairfield County and Westchester County residents, and, except for the recently-established elective angioplasty program at White Plains Hospital ("WPH"), every existing PCI provider with which the proposed program would compete has on-site cardiac surgery capabilities. Moreover, Applicants have not provided a shred of evidence that the existing programs are operating at or near full capacity, are not accessible to area residents or are not providing high quality care. They also have not demonstrated how the addition of what promises to be a low volume elective angioplasty program at GH and the further dilution of elective cases for existing providers that will be created in its wake improves the cost-effectiveness of health care delivery in the region.

Accordingly, Petitioner's evidence will show that Applicants have also failed to demonstrate that the proposed project will not result in an unnecessary duplication of existing or approved health care services as required by C.G.S. § 19a-639(a)(9). In fact, a little more than three years ago, OHCA denied an almost identical proposal by these same Applicants for what was then styled as a "five year demonstration project" with words that could just as easily apply to their present CON application:

> Based upon the Applicants relatively low volume projections as well as the declining statewide PCI volumes, OHCA is unable to conclude that the proposed demonstration project would improve the quality and accessibility of care provided in the Greenwich area, particularly in light of the availability of full service cardiac programs in Fairfield County.

Final Decision Docket No. 08-31210-CON ("2009 Final Decision"), p. 16 (citation omitted).

Then, as now, Applicants based their application primarily on volume originating from New York despite the language in OHCA's enabling statutes that focuses the agency on coordinating health system planning for Connecticut and OHCA's statement at the time that "it

does not consider out of state volume in its evaluation of need for a proposed service." 2009 Final Decision, Finding of Fact 39. The subsequent Declaratory Ruling requested by Applicants and issued under Docket No. 09-31433-DCR makes clear that OHCA retains the ability to exercise its discretion to disregard out-of-state volume as part of its CON deliberations. In assessing Applicants' current proposal, OHCA should be especially wary of relying on any anticipated influx of New York volume given the many existing providers that service the Westchester County market. This now includes the WPH elective angioplasty program that was established in 2010. The WPH program, which is located approximately 10 miles from GH, did not exist at the time OHCA denied the demonstration project proposal, and Petitioner will show that this program currently provides local access to PCI services for much of the New York market targeted by the Applicants.

In the 2009 Final Decision, OHCA also found that, "[t]he only credible evidence the Applicants have provided in support of their volume projections are the actual number of patients who were either transferred or referred from GH to another facility for PCI...." 2009 Final Decision, p. 16 (citing Findings of Fact 17-18). The Applicants own volume projections show that the number of patients who require such transfers or referrals and that would be appropriate for their Elective PCI Without SOS program to treat amounts to approximately 50 per year. *See* CON Application, pp. 31-32. Petitioner will demonstrate that this small number of patients could easily be accommodated by existing providers in the service area, especially at TSH which is located just six miles to GH's east, offers a full-service elective angioplasty program with surgical back-up and is closer than GH to every one of the Connecticut service area towns (except for parts of Greenwich) that Applicants hope to serve.

Petitioner will present evidence that entering into collaborative service arrangements of this kind would not only better utilize existing capacity and resources within the region's health delivery system, it would also foster cooperation among local health systems and avoid the potentially harmful competition with existing providers that the 2011 ACCF/AHA/SCAI Guideline warns against.

TSH's Interests Are Affected By the Proceeding

1. TSH is a "healthcare facility" as defined by C.G.S. § 19a-630. Petitioner provides a comprehensive array of health care services, including an interventional cardiac program that was approved by OHCA in January 2006. TSH's elective angioplasty and open heart surgery programs are supported by the clinical leadership of New York-Presbyterian Healthcare System, Inc. and the Columbia University College of Physicians.

2. The Petitioner requests to be designated as an intervenor with full procedural rights. Petitioner's legal rights and interests will be specifically affected by OHCA's decision in this matter because TSH's primary and secondary service areas for elective angioplasty are identical to GH's proposed Connecticut service area, and there is not adequate volume in the region to support the addition of another elective angioplasty program.

3. Based on TSH's FY 2012 PCI volume to date, it is on track to perform 277 PCIs in FY 2012. While this volume exceeds the minimum volume recommendation of 200 procedures contained in the 2011 ACCF/AHA/SCAI Guideline (*see* p. 193), a new program operating in the same crowded market and located only six (6) miles from TSH will negatively impact its institutional volume and could potentially lead to a decrease in the quality of PCI services for residents of the service area.

Summary of Other Evidence

4. In addition to the evidence mentioned above, Petitioner will show that the declining trend in PCI volume identified in OHCA's 2009 Final Decision has continued statewide and that there is no volume growth in the Applicants' proposed service area. These trends have negatively impacted the volumes of a number of hospitals in Connecticut, including each of the four existing full-service programs in Fairfield County, and is consistent with increased efforts by the health care community to combat heart disease through better control of high blood pressure and high cholesterol, a decline in smoking, and improvements in treatments, medications and quality of care. The use of statin drugs and other non-interventional treatments will also likely continue to suppress PCI volumes for the foreseeable future.

5. GH's primary angioplasty volumes have also has been flat since 2006 (38, 33, 41, 40, 32, 38 for FYs 2006-2011). Application, p. 31; 2009 Final Decision, p. 4. Notwithstanding this fact and the continued flat to declining volumes in Connecticut as well as the establishment of a new provider (WPH) in the proposed service area, Applicants have increased their volume projections from what they projected four years ago. Much of the projected new volume is based on a purported telephone survey of physicians on the GH medical staff who were asked to "estimate" the number of patients they would refer to GH for cardiac catheterization if the CON Application were granted. *See* Application, p. 33. This methodology is inherently unreliable and speculative and does not support the need for the elective PCI program proposed by Applicants.

6. Approving the proposed Elective PCI Without SOS program and creating a scenario where three elective angioplasty providers – GH, TSH and WPH – will operate within a span of 16 miles of each other, will not add to the effectiveness or efficiency of the local delivery system and does not adequately balance health care resources. As described in Lawrence &

Memorial Hospital's recent CON Application for an elective PCI program without on-site cardiac surgery back-up, other areas of the state such as Southeastern Connecticut -- where the nearest elective angioplasty provider is approximately fifty (50) miles away from the local community hospital – lie in stark contrast to Southwestern Connecticut where residents have access to a number of nearby programs.

7. The 2011 ACCF/AHA/SCAI Guideline does not support the notion that providing elective angioplasty without on-site surgical back-up is safer or more efficacious than providing the same service with surgical back-up. However, in remote geographic regions, the benefits of providing such a service to patients may outweigh the risk. What the 2011 ACCF/AHA/SCAI Guideline does state is that an institution with a volume of fewer than 200 procedures per year, unless underserved because of geography, should carefully consider whether it should offer this service. Attachment VI, p. 193. Applicants have offered no credible evidence that GH could attain a PCI volume exceeding 200 cases per year, and there is a real risk that a new PCI program could prevent other hospitals in the region from attaining that that threshold as discussed above.

8. YNHH and GH have also failed to provide any recent studies of cardiovascular health or utilization rates in the proposed Connecticut service area towns of Greenwich, Stamford, Darien, New Canaan, Norwalk, Wilton, Weston and Westport to indicate that Fairfield County's existing elective angioplasty programs with cardiac surgery on site are not fully meeting residents' needs, nor have Applicants offered any evidence of backlogs or scheduling problems at these hospitals. They have also not identified any such deficiencies in their proposed New York market which is amply served by a host of hospitals, including but not limited to, WPH, Westchester County Medical Center, Montefiore Medical Center, New York Presbyterian-Weill Cornell Medical Center, New York Presbyterian-Columbia University

Medical Center, Lenox Hill Hospital and Mount Sinai Medical Center. New York regulation also limits the establishment of new PCI-capable programs.

9. The best course for patients and interventional cardiology's future would be to limit the proliferation of elective angioplasty programs without on-site cardiac surgical backup in areas that are served by existing full service programs as angioplasty-only programs unnecessarily fragment services. With the development of new facilities such as "hybrid operating rooms" that combine aspects of a cath lab with advanced imaging techniques and all the amenities of the traditional surgical suite, leading interventional programs are now providing physicians and patients with the flexibility to conduct an initial diagnostic procedure that can be immediately followed up by procedures such as aortic valve replacement, cardiac ablation and open heart surgery as well as angioplasty. Accordingly, the future of interventional cardiology will be to provide more comprehensive and cost effective care by coalescing these services at hospitals that have established full service cardiac programs. Approval of the proposed Elective PCI Without SOS program at GH would unnecessarily pull the health delivery system in Southwestern Connecticut in the opposite direction.

Manner in Which TSH Will Furnish Assistance to OHCA

10. The evidence summarized above as well as related points will be provided at the public hearing through the attached pre-file testimony of the following witnesses: Sharon Kiely, M.D., Senior Vice President of Medical Affairs and Chief Medical Officer for TSH and William Gray, M.D., Associate Professor of Clinical Medicine at Columbia University and Director, Endovascular Services of the New York Presbyterian Hospital/Columbia University Medical Center, with which TSH is affiliated. Petitioner also seeks permission to offer rebuttal testimony

and cross-examine Applicants' witnesses as permitted by OHCA in its discretion during the course of the public hearing.

11. TSH's status as an existing provider of elective angioplasty, and as a hospital whose program was established to address the geographic and transportation barriers faced by Southwestern Connecticut residents in attempting to access interventional cardiac services, makes it uniquely qualified to offer evidence and information that would not otherwise be available to OHCA and will assist the agency in evaluating Applicants' proposal.

12. Petitioner's participation in the public hearing will not disrupt the orderly conduct of the proceedings and is in the interest of justice.

Conclusion

Petitioner will demonstrate through the above summarized evidence, as well as other evidence that may be discovered or presented in rebuttal or cross examination, that Applicants have failed to meet their burden of establishing clear public need for the proposed elective angioplasty service. The current proposal for an Elective PCI Without SOS program differs very little from the demonstration project the Applicants proposed and OHCA denied three years ago except that patient volumes for PCI services have continued to stagnate while the number of existing providers in the service area has increased. This makes it clearer than ever that Southwestern Connecticut cannot support an elective angioplasty program that departs from the recommendations contained in the 2011 ACCF/AHA/SCAI Guideline and is unlikely to meet the recommended minimum of performing 200 cases annually.

For all the above reasons, TSH respectfully requests that this Petition should be granted and that it be designated as an intervenor in the public hearing with full procedural rights.

THE STAMFORD HOSPITAL

BY _____

Stephen M. Cowherd
Stephanie Sprague
Jeffers Cowherd P.C.
55 Walls Drive
Fairfield, CT 06824
Tel.: 203-259-7900
Fax: 203-259-1070
scowherd@jeffers-law.com
ssprague@jeffers-law.com
Its Attorneys

CERTIFICATE OF SERVICE

This is to certify that a true and accurate copy of the foregoing Petition of The Stamford Hospital for Intervenor Status with full procedural rights and supporting pre-file testimony was sent by U.S. mail, postage prepaid this 12th day of July 2012 to:

Jean Ahn
System Director
Yale-New Haven Hospital
Planning & Business Development
20 York Street (Howe 3)
New Haven, CT 06504

Stephen M. Cowherd

EXHIBIT 1

CURRICULUM VITAE

Name: Sharon Cabrina Kiely, MD, MPM
Date of Birth: June 18, 1957
Place of Birth: Orange, New Jersey USA
Home address: 22 Wilson Avenue
Rowayton, CT 06853

Office Address: Senior Vice President, Medical Affairs & Chief Medical Officer
Stamford Health System
30 Shelburne Road
Stamford, CT 06904-9317
Tel: (203) 276- 5941 FAX: (203) 276- 7366 Cell: (203) 807-2219
E-mail: skiely@stamhealth.org

EDUCATION AND TRAINING

Undergraduate

1975 - 1977 Georgetown University School of Nursing, Washington, D.C., 20057
1977 - 1980 Bachelor of Science; Major-Psychology, Minor-Biology
Georgetown University College of Arts and Sciences, Washington, D.C., 20057

Graduate

1980 - 1984 Doctor of Medicine, Georgetown University School of Medicine, Washington, D.C., 20007
1998 - 1999 Master of Public Management (Highest Distinction), H. John Heinz III School of Public Policy & Management, Carnegie Mellon University, Pittsburgh, PA
2009 Certificate, University of Pennsylvania, The Wharton School, Aresty Institute of Executive Education. West Penn Allegheny Health System Leadership Development Program. Academic Director: Dr. Peter Cappelli, the George W. Taylor Professor of Management, Wharton.

Postdoctoral Training

1984 - 1988 Transitional Internship (1984-85), Raymond Boller, MD, Program Director; Internal Medicine/Primary Care Track (1985-87), Chief Resident - Primary Care Track (1987-88), James T. Mazzarra, Chairman, Department of Medicine, Philip Brickner, MD, Program Director, Chairman Community Medicine, St. Vincent's Hospital and Medical Center of New York. NY, NY. 10011

ACADEMIC AND CLINICAL APPOINTMENTS

Academic

2012 - Associate Clinical Professor of Medicine, Columbia University, College of Physicians & Surgeons, New York, NY
2001- 2010 Associate Professor of Medicine, Department of Medicine, Drexel University School of Medicine, Philadelphia, PA
1997 - 2010 Clinical Assistant Professor of Health Services Administration, University of Pittsburgh Graduate School of Public Health, Pittsburgh, PA
1992 - 2002 Clinical Assistant Professor, University of Pittsburgh School of Medicine, Pittsburgh, PA
1988 - 1992 Clinical Instructor, University of Pittsburgh School of Medicine, Pittsburgh, PA

Clinical

2002 - 2005 Director, Hospitalist Service, Department of Medicine, AGH, Pittsburgh, PA
1999 - 2005 Director, Medical Ambulatory Clinic, Allegheny General Hospital, Pittsburgh, PA
1992 - 1994 Medical Director, West Penn Hospital/Peabody H.S. Partnership, Pittsburgh, PA
1990 - 1994 Founder and Program Director, Primary Care Residency Track, Department of Medicine Western Pennsylvania Hospital, Pittsburgh, PA
1990 - 1994 Founder and Director, Home Visit Program, Western Pennsylvania Hospital, Pittsburgh, PA

1988 - 1994 Associate Program Director, Internal Medicine Residency; Medical (1988-93) and Surgical (1992-94) Clinical Director, Western Pennsylvania Hospital, Pittsburgh, PA

EMPLOYMENT HISTORY

Clinical

1988- 1994 Attending, Western Pennsylvania Hospital, Department of Medicine, Pittsburgh, PA
1996- 1997 Attending, Primary Care Health Services, Inc., (FQHC) Pittsburgh, PA
1999- 2010 Attending, Dept of Medicine, Allegheny General Hospital, Pittsburgh, PA
2010- Attending, Dept of Medicine, Stamford Hospital, Stamford, CT

Administrative

1988 - 1994 Associate Program Director, Internal Medicine Residency; Medical (1988-93) and Surgical (1992-94) Clinic Director, Western Pennsylvania Hospital, Pittsburgh, PA
1994 – 1995 Special Assistant to the Deputy Secretary, U.S. Department of Health and Human Services, Washington, D.C.
1996 - 1997 Director, Health Services; Primary Care Health Services, Inc., (FQHC) Pittsburgh, PA
1997 - 1998 Medical Director, Tri-State Health System/ UPMC Health Plan, Pittsburgh, PA
1998 - 2000 Consultant: Managed Care, Integration, Quality and Education; Allegheny County Health Department, Healthy Start Inc., Pittsburgh, PA
1999- 2005 Director, Medical Ambulatory Clinic & Center for the Study and Care of the Medically Underserved, Allegheny General Hospital, Pittsburgh, PA
2002- 2006 Vice Chair, Department of Medicine, Allegheny General Hospital, Pittsburgh, PA
2005- 2010 Medical Director, Quality & Patient Safety, Allegheny General Hospital, Pittsburgh, PA
2010 VP and Chief Quality Officer, Allegheny General Hospital, Pittsburgh, PA
2010- 2011 Vice President, Quality & Chief Quality Officer, Stamford Health System, Stamford, CT
2011- present Senior Vice President, Medical Affairs, CMO, Stamford Health System, Stamford, CT

CERTIFICATION AND LICENSURE

Specialty Certification

1989 American Board of Internal Medicine #115959

Professional Licensure

1988	Pennsylvania	MD-042492
1985	New York	161615-1 (inactive)
2010	Connecticut	049332

MEMBERSHIPS IN PROFESSIONAL SOCIETIES (current)

1986 American College of Physicians
1999 Medical Administrators Conference
2000 Society of General Internal Medicine

HONORS and AWARDS

2009 Team Finalist, Milton Fine Quality Award: Reducing VAP in a Trauma ICU
1996 Fellow, American College of Physicians
1994 - 1995 White House Fellow, Assignment: U.S. Department of Health and Human Services, Donna E. Shalala, Secretary, Washington, D.C. 20201
1994 Recognition Award, Ambulatory Care Course, University of Pittsburgh School of Medicine

COMMITTEE ASSIGNMENTS

Extramural Committee Assignments

1999 - 2010 Member, Board of Advisors, Schweitzer Fellowship Program, Pittsburgh, PA.
1999 - 2000 Advisory Committee, "Access to Health and Social Services", Masters Students Systems Synthesis Project, Carnegie Mellon University, Heinz School
1996 - 1997 Member, Steering Committee, Western Pennsylvania Health Care Purchasing Partnership, Pittsburgh, PA. (Behavioral Health Managed Care)
1996 - 1998 Member, Healthier Communities Partnership, McKeesport Hospital, McKeesport, PA
1992 - 1994 Member, Advisory Committee, Corpus Christi Residence (Verona House) Pittsburgh AIDS Task Force & Presbyterian Association on Aging, Pittsburgh, PA
1991 - 1994 Member, Advisory Committee, Fund for Neighborhood Indigent Care Centers Jewish Health Care Foundation, Pittsburgh, PA
1990 - 1994 Member, Advisory Committee, Housing for the Homeless, Action Housing, Pittsburgh, PA

Regional and National Committee Assignments

2006- present Member, Advisory Council, National Institute of Allergy & Infectious Diseases, NIH, US Dept of Health & Human Services, Bethesda, MD
2002 - 2005 Member, Board of Directors, Unified Network for Organ Sharing (UNOS), Kidney/pancreas Transplantation Subcommittee (2003-2005); Organ Availability Committee (2003- 2005), Richmond, VA
2000 - 2004 Member, Secretary's Advisory Committee on Xenotransplantation, (Informed Consent Subcommittee 2001-2004), US Department of Health and Human Services, Washington, DC
2000 - 2003 Member, Pittsburgh Regional Healthcare Initiative, Clinical Advisory Committee; Diabetes Subcommittee (2001- 2002).
1996 - 1998 Member, National Advisory Council for Health Care Policy, Research and Evaluation, Agency for Health Care Policy and Research (AHCPR), US Department of Health & Human Services, Washington, DC
1996 - 2000 Member, Governor's Advisory Council and Women's Health Committee American College of Physicians, Western Pennsylvania Chapter

Institutional Committee Assignments

West Penn Allegheny Health System (WPAHS), Pittsburgh, PA
2004- 2007 Co-Chair, Board of Directors, PI Clinical Subcommittee
2003- 2007 Member, Board of Directors, Performance Improvement Committee
2003- 2010 Member, Claims Committee
2008- 2010 Member, Quality & Satisfaction Committee of the Board
2009- 2010 Member, Decision Support System Replacement Project
2009- 2010 Executive Sponsor, Disease State Management Project

Allegheny General Hospital, Pittsburgh, PA
2009-2010 Member, Finance Committee; Project Lead LOS

2005- 2010 Member: Council GME, CME Committee, Physician IS Committee
2003- 2010 Chair, Quality Management Committee
2003- 2010 Member: Serious Event Review Panel, Credentials Committee, Patient Safety Committee

Institutional Committee Assignments
Allegheny General Hospital, Pittsburgh, PA (continued)
2002- 03 Chair, Curriculum Committee, Internal Medicine Residency Program
2005- 09 Member, Council for GME
2001- 05 Physician Information Systems Initiatives
2001- 03 Drug Use and Formulary Review Subcommittee
1999- 03 Clinical Competency & Promotions Committee, Department of Medicine
1998- 06 Internship Selection Committee, Internal Medicine Residency

TriState Health System, UPMC Health Plan, Inc., Pittsburgh, PA
1997-98 Credentialling Committee
1997-98 Quality Improvement Committee

Western Pennsylvania Hospital, Pittsburgh, PA
1988 - 94 Executive Advisory Committee & Resident Education Committee, Department of Medicine
1991 - 94 Wellness & Peabody High School Adolescent Health and Wellness Center Without Walls Task Forces
1991 - 92 Clinic Relocation Committee
1992 - 94 Community Health Care Committee

University Committee Assignments
University of Pittsburgh School of Medicine
1997 - 98 Chair, Combined Clinical Years, Out of Hospital Education Task Force
1992 - 94 Member, Steering Committee, Ambulatory Care Course

EDUCATIONAL ACTIVITIES: TEACHING
Western Pennsylvania Hospital, Pittsburgh, PA
1988 - 1994 Course Director, PGYI Ambulatory Care Block; Residency Advisor (5-6 resident/per year); Attending, Medical Ambulatory Care Center; Attending, Medical Teaching Service
1988 - 1994 Lecturer, Internal Medicine
1988 - 1994 Course Director, MSIV Elective Medical Ambulatory Care
University of Pittsburgh School of Medicine Pittsburgh, PA at West Penn Hospital
1989 - 1994 Course Director, PGYIII Ambulatory Care Block
1992 - 1994 Instructor, Intern Medical Interviewing Course

University of Pittsburgh School of Medicine, Pittsburgh, PA
1991 –1994 Instructor, MSII Clinical Clerkship Ambulatory Medicine
University of Pittsburgh, School of Medicine, Pittsburgh, PA at West Penn Hospital
1993 - 1994 Small Group Leader, MSI and II, Ambulatory Care Course
1996 –1998 Small Group Leader, Medicine, Ethics and Society Course and
Clinical Instructor, Ambulatory Care Course
Primary Care Health Services, Inc., Pittsburgh, PA.
1996- 1997 General Internal Medicine Teaching Attending, Alma Illery and Rainbow Health Centers

Allegheny General Hospital, Pittsburgh, PA
1999- 2010 Internal Medicine Program Teaching Faculty
1999- 2010 Lecturer, General Internal Medicine
2002- 2005 Hospitalist Service Teaching Faculty

EDUCATIONAL ACTIVITIES: COURSES TAUGHT

University of Pittsburgh School of Medicine, Pittsburgh, PA
1989- 92 MSII Physical Diagnosis/Part2 and
1993 -96 Small Group Facilitator/Faculty, Ambulatory Medicine Course, MSI-II

EDUCATIONAL ACTIVITIES: COURSES DIRECTED

University of Pittsburgh School of Medicine, Pittsburgh, PA
1997, 1998 Co-Director -Public Health Case in the *Introduction to Being a Physician Course*, MS-I
1999 Director, *Pregnancy and Substance Abuse*; Sponsored by the Allegheny County Health Department, Healthy Start, Inc., Magee Women's Hospital and the Univ. Pittsburgh School of Medicine, Center for Continuing Education in the Health Sciences. August 30, 1999.

INVITED PRESENTATIONS
April 30, 2009 "Partnering with Nursing to Improve Patient Care & Transparency" The Healthcare Roundtable CNO's. Ft. Myers, FL
September 16, 2008 "Eliminating Hospital Acquired Infections: The Human and Financial Cost" The Healthcare Roundtable CMO's. San Francisco, CA.
May 9, 2008 2008 "Eliminating Hospital Acquired Infections: The Human and Financial Cost" The Healthcare Roundtable Joint CMO & CQO's; San Antonio TX.
June 5, 2008 "Appropriate Care Measure--Leading Transformational Change for Healthcare Quality" The Hospital & Healthsystem Association of Pennsylvania's (HAP) audio conference.
May 9, 2008 "Eliminating Hospital Acquired Infections: Human & Financial Costs" Healthcare Roundtable, San Antonio, Texas.
June 27, 2006 "Hospitalists & Rapid Response Systems" Workshop at 2nd International Conference on MET Response" Pittsburgh, PA
October 7, 2004 "Working with Stakeholders on Scientific Opportunities for Facilitating Development of Vaccines, Blood and Blood Products and Cellular, Tissue and Gene Therapies"; Panelist- Tissue and Tissue Engineering. FDA (CBER), Gaithersburg, MD
April 18, 2002 "Community Health and Hospital Resources" Invited presentation Allegheny County Library Association Business Lunch Series, Library Center, Carnegie Library of Pittsburgh.
September 7, 1999 "Stem Cell Research" Invited testimony to the American Academy for the Advancement of Science, ICS Committee, Washington, DC.
April 14, 1997 "The Promise and Peril of Managed Care for Disenfranchised and At-Risk Populations", presentation at the Sixth Annual Current Controversies in Medical Ethics: Ethical Issues in Managed Care.
January 9, 1997 "Health Care: Industry, Ethics and You". Invited presentation on the physician's perspective and small group facilitator, Leadership Pittsburgh Health Care Session, Pittsburgh, PA.
January 4, 1995 "The White House Fellows Program." Invited presentation, Public Leadership Education Network. 13th Annual Washington Seminar, Washington D.C.
July 1995 "The White House Fellows Program." Invited presentation, St. Vincent's Hospital and Medical Center of New York
January 19, 1993 "Interactions with Impaired Professionals during Residency Training." Invited presentation. Allegheny County Bar Association and Allegheny County Medical Society, Pittsburgh, PA

January 8, 1993 "Health Care Prescriptions for Pittsburgh Communities: Medical, Social and Psychological Dimensions of Primary Care." R. K. Mellon Lecture Panelist, University of Pittsburgh School of Medicine, Pittsburgh, PA. Keynote: "Broadening the Social Mission of Medical Schools", Reed V. Tuckson, M.D.
January 8, 1993 "Beyond the Ivory Tower: Hands-on Health Care in Pittsburgh Communities." Jubilee Kitchen and Clinic, Workshop Coordinator and Panelist, University of Pittsburgh School of Medicine, Pittsburgh, PA

INVITED PRESENTATIONS (continued)

December 2, 1992 "Health Care to the Homeless." Invited lecture to the Board of Directors, Action Housing, Inc., Pittsburgh, PA
October 2, 1991 "Indications for the Usefulness of Routine Examinations." Cutting Edge Series: Western Pennsylvania Hospital, Pittsburgh, PA
March 23, 1991 "Homeless Access to Health Care - The Pittsburgh Models." Pittsburgh's Triple Threat: Hunger, Homelessness, and Health Care Gaps; A Symposium. Workshop coordinator and panelist "Better Access to Health Care: Pittsburgh Models", University of Pittsburgh, School of Medicine, Pittsburgh PA
April 24, 1991 "Home Visit Program: Internal Medicine Residents and Social Workers Team Up" Neighbors Standing Together: Spotlighting Pioneer Programs for an Aging Population; Sponsored by Forbes Metro Geropsychiatry Program and Coalition on Older Adult Resources and Education, in conjunction with Aging in America, National Council on Aging
March 1, 1991 "Tutorial Based Education in Ambulatory Care." Mid-Atlantic Regional Society of General Internal Medicine Meeting, New York, NY
April 9, 1991 "Recommendation for Vaccinations in Adults." Grand Rounds: Greene County Memorial Hospital, Greene County PA
Dec. 5, 1990 "Adult Immunization" Cutting Edge Series: Western Pennsylvania Hospital, Pittsburgh, PA.
October 12, 1990 "AIDS and the Primary Care Physician." Grand Rounds: Armstrong County Hospital, PA.

GRANT SUPPORT

Administrator	Renovation Historic Singer Library, **Allegheny General Hospital Auxiliary,** $5000
Administrator	Free Medication Fund, **Allegheny General Hospital Auxiliary,** $3500
Principal Investigator	**Health Resources and Services Administration,** U.S. Public Health Service General Internal Medicine Training Grant, Granted by: Department of Health and Human Services, Rockville, MD. Grant #25-1470-766 Approved and funded: $196,000 in first year. Three-year initial approval. Effective: July 1, 1993.
Principal Investigator	Primary Care for Medically Underserved Populations, **Howard Heinz Endowment,** Pittsburgh, PA Approved and funded: $755,060 over three years. Effective: June 17, 1991

RESEARCH EXPERIENCE

1976 - 1982	Research Assistant: Georgetown University Hospital, Washington, D.C. 20007 Principles: Robert Henkin, M.D. (1976-78), and Dept. Ob/Gyn Anita Sostek, PhD. (1978-82), Dept. Of Pediatrics and Neonatology

2008-2009 Member: Delphi Consensus Group COMIRB: 08-00932, Developing an Agenda for Laboratory Practice. PI: Dana Grzybicki, MD, PhD. Cooperative agreement: Centers for Disease Control and Prevention (CDC; funding agency) and the University of Colorado Denver Health Sciences.

SERVICE: REGIONAL

1996 - 2002 President, Board of Directors (1999-2002), SW Pennsylvania Area Health Education Center, Inc. (AHEC), Pittsburgh, PA. Member, Board of Directors (1996-99), Strategic Planning Committee (1996)

1996 - 2002 Member, Board of Directors, Juvenile Diabetes Research Foundation International, Western Pennsylvania Chapter, Pittsburgh, PA. Government Relations Committee (1996-2002); Vice-President Government Relations (1997-99); Nominating Committee(1999-01)

1993 - 1994 Member, Board of Directors, Ursuline Center, Inc., Pittsburgh, PA

1989 - 1994 Member, Health Care to the Homeless Project, Primary Care Health Services, Inc. Pittsburgh, PA

SERVICE: NATIONAL

1999 - 2006 Member, Government Relations Committee, Juvenile Diabetes Research Foundation, International, New York, New York. Volunteer for transplantation issues.

2008-2009 Centers for Disease Control and Prevention (CDC) and the University of Colorado Denver Health Sciences Center (Dept Pathology; PI- Dana M Grzybicki, MD PhD) Delphi consensus - determine top 10 quality research priorities in laboratory medicine practice.

SERVICE: INTERNATIONAL

1983 Phanat Nikom, Thailand. Physician volunteer sponsored through Catholic Relief Services and Georgetown University School of Medicine at a refugee camp serving over 50,000 Laotian, Khmer, Vietnamese and Hmong and Hmein Hill tribe refugees awaiting third country placement. Delivered primary and acute care to adults and children in a camp clinic.

2000 Hôpital Albert Schweitzer, Deschapelles, Haiti. Developed residency elective rotation in international health and tropical medicine in Haiti for Allegheny General Hospital Internal Medicine Residency Program.

BIBLIOGRAPHY

Original Reports and Editorials

1. Torres, R., Barr, M., Thorn, M., Gregory, G., Kiely, S., Chanin, E., Carlos, C., Martin, M., Thornton, J. Randomized Trial of Dapsone and Aerosolized Pentamidine for the Prophylaxis of Pneumocystis Carinii Pneumonia and Toxoplasmic Encephalitis. American J Medicine.1993; 95: 573-83.
2. Kiely, SC, Prince, P: Long Term Home Health Care: The West Penn Home Visit Experience. Journal of Long Term Home Health Care. 1994; 13: 41-53.
3. Ness, R., Ukoli, F., Hunt, S. Kiely, SC, MacNeil M., Richardson, V., Weissbach, N., Belle, S. Salary Equity among Male and Female Internists in Pennsylvania. Annals of Internal Medicine. 2000; 133:104-110.
4. Raab S, Grzybicki DM, Hart A, Kiely S, Andrew-JaJa C, Scioscia E. Willingness to Pay for New Papanicolaou Test Technologies. Am JClin Pathol 2002; 117: 524-533.
5. Kiely, SC. Junior Faculty Performance Appraisal in General Internal Medicine. Academic Medicine. 2002; 77: 458-459.
6. Kiely SC, Sipe K, Orav EJ, McMahon K, Shannon R, O'Donnell WJ. Impact of a Health System Financial Reorganization on a Group of Medical Residents. Acad. Med. 2003; 78:45-53.

7. Kiely, SC, Gryzbicki DM, Sepulveda A, Capitano M, Toborowsky E. Evaluation of Chronic Abdominal Complaints in a Haitian Population. Journal of Health Care for the Poor and Underserved. 2004; 15: 183-192.
8. Kiely SC, Berns S, Gryzbicki, DM. Physicians and Scientists Experience in the White House Fellows Program. *In progress.*
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(Revised: 6/2011)

EXHIBIT 2

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PATIENT CENSUS REPORT # 12
CONNECTICUT HOSPITAL ASSOCIATION
September 2011 vs 2010
CORONARY ANGIOPLASTY PROCEDURES

Year-to-Date: October 1 Thru September 30

	----Inpatient Procedures----				----Outpatient Procedures----				----Total Procedures----			
FACILITY	2011	2010	NET CHANGE	% CHANGE	2011	2010	NET CHANGE	% CHANGE	2011	2010	NET CHANGE	% CHANGE
Bridgeport	294	380	-86	-22.6	175	102	73	71.6	469	482	-13	-2.7
Greenwich	38	33	5	15.2			0	0.0	38	33	5	15.2
Norwalk	62	64	-2	-3.1	0	0	0	0.0	62	64	-2	-3.1
St. Vincent's	557	972	-415	-42.7	313	52	261	501.9	870	1,024	-154	-15.0
Stamford	107	123	-16	-13.0	113	115	-2	-1.7	220	238	-18	-7.6
HSA 1 TOTAL	1,058	1,572	-514	-32.7	601	269	332	123.4	1,659	1,841	-182	-9.9
Saint Raphael	706	701	5	0.7	209	118	91	77.1	915	819	96	11.7
Yale-New Haven	1,349	1,498	-149	-9.9	3	3	0	0.0	1,352	1,501	-149	-9.9
HSA 2 TOTAL	2,055	2,199	-144	-6.5	212	121	91	75.2	2,267	2,320	-53	-2.3
L&M	70	81	-11	-13.6	0	0	0	0.0	70	81	-11	-13.6
HSA 3 TOTAL	70	81	-11	-13.6	0	0	0	0.0	70	81	-11	-13.6
Dempsey	331	506	-175	-34.6	147	5	142	2,840.0	478	511	-33	-6.5
Hartford	1,247	1,143	104	9.1	22	8	14	175.0	1,269	1,151	118	10.3
HCC	131	112	19	17.0	0	0	0	0.0	131	112	19	17.0
Saint Francis	1,878	2,072	-194	-9.4	59	51	8	15.7	1,937	2,123	-186	-8.8
HSA 4 TOTAL	3,587	3,833	-246	-6.4	228	64	164	256.3	3,815	3,897	-82	-2.1
Danbury	318	296	22	7.4	107	110	-3	-2.7	425	406	19	4.7
Saint Mary's	271	269	2	0.7	2		2	0.0	273	269	4	1.5
Waterbury	373#	362#	11	3.0	0	0	0	0.0	373#	362	11	3.0
HSA 5 TOTAL	962	927	35	3.8	109	110	-1	-0.9	1,071	1,037	34	3.3
CT GRAND TOTAL	7,732	8,612	-880	-10.2	1,150	564	586	103.9	8,882	9,176	-294	-3.2

Hospital-specific data accompanied with the # symbol is estimated.

Please refer to the Qualifying Conditions section at the end of this report for additional information.

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PATIENT CENSUS REPORT # 12
CONNECTICUT HOSPITAL ASSOCIATION
September 2010 vs 2009
CORONARY ANGIOPLASTY PROCEDURES

Year-to-Date: October 1 Thru September 30

	----Inpatient Procedures----				----Outpatient Procedures----				----Total Procedures----			
FACILITY	2010	2009	NET CHANGE	% CHANGE	2010	2009	NET CHANGE	% CHANGE	2010	2009	NET CHANGE	% CHANGE
Bridgeport	380	427	-47	-11.0	102	104	-2	-1.9	482	531	-49	-9.2
Greenwich	33	41	-8	-19.5			0	0.0	33	41	-8	-19.5
Norwalk	64	16	48	300.0	0	0	0	0.0	64	16	48	300.0
St. Vincent's	972	1,008	-36	-3.6	52	44	8	18.2	1,024	1,052	-28	-2.7
Stamford	123	138	-15	-10.9	115	121	-6	-5.0	238	259	-21	-8.1
HSA 1 TOTAL	1,572	1,630	-58	-3.6	269	269	0	0.0	1,841	1,899	-58	-3.1
Saint Raphael	703	739	-36	-4.9	116	62	54	87.1	819	801	18	2.2
Yale-New Haven	1,498	1,394	104	7.5	3	2	1	50.0	1,501	1,396	105	7.5
HSA 2 TOTAL	2,201	2,133	68	3.2	119	64	55	85.9	2,320	2,197	123	5.6
L&M	81	77	4	5.2	0	0	0	0.0	81	77	4	5.2
HSA 3 TOTAL	81	77	4	5.2	0	0	0	0.0	81	77	4	5.2
Dempsey	506	448	58	12.9	5	0	5	0.0	511	448	63	14.1
Hartford	1,143	1,029	114	11.1	8	4	4	100.0	1,151	1,033	118	11.4
HCC	112	47	65	138.3	0	0	0	0.0	112	47	65	138.3
Saint Francis	1,118	1,299	-181	-13.9	33	38	-5	-13.2	1,151	1,337	-186	-13.9
HSA 4 TOTAL	2,879	2,823	56	2.0	46	42	4	9.5	2,925	2,865	60	2.1
Danbury	296	332	-36	-10.8	110	36	74	205.6	406	368	38	10.3
New Milford		10	-10	-100.0			0	0.0	0	10	-10	-100.0
Saint Mary's	269	210	59	28.1			0	0.0	269	210	59	28.1
Waterbury	362	362	0	0.0	0	0	0	0.0	362	362	0	0.0
HSA 5 TOTAL	927	914	13	1.4	110	36	74	205.6	1,037	950	87	9.2
CT GRAND TOTAL	7,660	7,577	83	1.1	544	411	133	32.4	8,204	7,988	216	2.7

Hospital-specific data accompanied with the # symbol is estimated.

Please refer to the Qualifying Conditions section at the end of this report for additional information.

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PATIENT CENSUS REPORT # 12
CONNECTICUT HOSPITAL ASSOCIATION
September 2009 vs 2008
CORONARY ANGIOPLASTY PROCEDURES

Year-to-Date: October 1 Thru September 30

	----Inpatient Procedures----				----Outpatient Procedures----				----Total Procedures----			
FACILITY	2009	2008	NET CHANGE	% CHANGE	2009	2008	NET CHANGE	% CHANGE	2009	2008	NET CHANGE	% CHANGE
Bridgeport	427	580	-153	-26.4	104	41	63	153.7	531	621	-90	-14.5
Greenwich	41	41	0	0.0		0	0	0.0	41	41	0	0.0
Norwalk	12	0	12	0.0	0	0	0	0.0	12	0	12	0.0
St. Vincent's	1,008	1,167	-159	-13.6	44	40	4	10.0	1,052	1,207	-155	-12.8
Stamford	138	46	92	200.0	121	2	119	5,950.0	259	48	211	439.6
HSA 1 TOTAL	1,626	1,834	-208	-11.3	269	83	186	224.1	1,895	1,917	-22	-1.1
Saint Raphael	739	866	-127	-14.7	62	20	42	210.0	801	886	-85	-9.6
Yale-New Haven	2,692	2,374	318	13.4	8	13	-5	-38.5	2,700	2,387	313	13.1
HSA 2 TOTAL	3,431	3,240	191	5.9	70	33	37	112.1	3,501	3,273	228	7.0
L&M	77	29	48	165.5	0	0	0	0.0	77	29	48	165.5
HSA 3 TOTAL	77	29	48	165.5	0	0	0	0.0	77	29	48	165.5
CT Children's	0	1	-1	-100.0	0	0	0	0.0	0	1	-1	-100.0
Dempsey	447	507	-60	-11.8	0	0	0	0.0	447	507	-60	-11.8
Hartford	1,029	1,105	-76	-6.9	4	6	-2	-33.3	1,033	1,111	-78	-7.0
HCC	47	49	-2	-4.1	0	0	0	0.0	47	49	-2	-4.1
Saint Francis	1,299	1,260	39	3.1	38	12	26	216.7	1,337	1,272	65	5.1
HSA 4 TOTAL	2,822	2,922	-100	-3.4	42	18	24	133.3	2,864	2,940	-76	-2.6
Danbury	332	340	-8	-2.4	36	0	36	0.0	368	340	28	8.2
New Milford	10	10	0	0.0		0	0	0.0	10	10	0	0.0
Saint Mary's	210	239	-29	-12.1		0	0	0.0	210	239	-29	-12.1
Waterbury	362	291	71	24.4	0	0	0	0.0	362	291	71	24.4
HSA 5 TOTAL	914	880	34	3.9	36	0	36	0.0	950	880	70	8.0
CT GRAND TOTAL	8,870	8,905	-35	-0.4	417	134	283	211.2	9,287	9,039	248	2.7

Hospital-specific data accompanied with the # symbol is estimated because the hospital did not submit information for the current month.
Please refer to the Qualifying Conditions section at the end of this report for additional information.

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PATIENT CENSUS REPORT # 12
CONNECTICUT HOSPITAL ASSOCIATION
September 2011 vs 2010
CARDIAC CATHETERIZATION PROCEDURES

Year-to-Date: October 1 Thru September 30

	----Inpatient Procedures----				----Outpatient Procedures----				----Total Procedures----			
FACILITY	2011	2010	NET CHANGE	% CHANGE	2011	2010	NET CHANGE	% CHANGE	2011	2010	NET CHANGE	% CHANGE
Bridgeport	480	623	-143	-23.0	394	345	49	14.2	874	968	-94	-9.7
Greenwich	190	164	26	15.9	80	103	-23	-22.3	270	267	3	1.1
Norwalk	154	139	15	10.8	26	54	-28	-51.9	180	193	-13	-6.7
St. Vincent's	984	1,188	-204	-17.2	800	600	200	33.3	1,784	1,788	-4	-0.2
Stamford	227	269	-42	-15.6	319	330	-11	-3.3	546	599	-53	-8.8
HSA 1 TOTAL	2,035	2,383	-348	-14.6	1,619	1,432	187	13.1	3,654	3,815	-161	-4.2
Saint Raphael	768	968	-200	-20.7	889	950	-61	-6.4	1,657	1,918	-261	-13.6
Yale-New Haven	1,993	2,132	-139	-6.5	922	981	-59	-6.0	2,915	3,113	-198	-6.4
HSA 2 TOTAL	2,761	3,100	-339	-10.9	1,811	1,931	-120	-6.2	4,572	5,031	-459	-9.1
Backus	124	113	11	9.7	189	209	-20	-9.6	313	322	-9	-2.8
L&M	364	485	-121	-24.9	289	271	18	6.6	653	756	-103	-13.6
Middlesex	110	135	-25	-18.5	209	294	-85	-28.9	319	429	-110	-25.6
HSA 3 TOTAL	598	733	-135	-18.4	687	774	-87	-11.2	1,285	1,507	-222	-14.7
CT Children's	1	3	-2	-66.7	7	14	-7	-50.0	8	17	-9	-52.9
Dempsey	337	450	-113	-25.1	392	332	60	18.1	729	782	-53	-6.8
Hartford	2,096	2,040	56	2.7	1,048	1,252	-204	-16.3	3,144	3,292	-148	-4.5
HCC	1,040	812	228	28.1	839	717	122	17.0	1,879	1,529	350	22.9
Rockville (ECHN)	0	0	0	0.0	0	11	-11	-100.0	0	11	-11	-100.0
Saint Francis	2,011	2,238	-227	-10.1	1,431	1,711	-280	-16.4	3,442	3,949	-507	-12.8
HSA 4 TOTAL	5,485	5,543	-58	-1.0	3,717	4,037	-320	-7.9	9,202	9,580	-378	-3.9
Danbury	367	386	-19	-4.9	463	534	-71	-13.3	830	920	-90	-9.8
Saint Mary's	428	428	0	0.0	299	327	-28	-8.6	727	755	-28	-3.7
Waterbury	678#	608	-30	-4.9	272#	317	-45	-14.2	850#	925	-75	-8.1
HSA 5 TOTAL	1,373	1,422	-49	-3.4	1,034	1,178	-144	-12.2	2,407	2,600	-193	-7.4
CT GRAND TOTAL	12,252	13,181	-929	-7.0	8,868	9,352	-484	-5.2	21,120	22,533	-1,413	-6.3

Hospital-specific data accompanied with the # symbol is estimated.

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PATIENT CENSUS REPORT # 12
CONNECTICUT HOSPITAL ASSOCIATION
September 2010 vs 2009
CARDIAC CATHETERIZATION PROCEDURES

Year-to-Date: October 1 Thru September 30

	Inpatient Procedures				Outpatient Procedures				Total Procedures			
FACILITY	2010	2009	NET CHANGE	% CHANGE	2010	2009	NET CHANGE	% CHANGE	2010	2009	NET CHANGE	% CHANGE
Bridgeport	623	629	-6	-1.0	345	373	-28	-7.5	968	1,002	-34	-3.4
Greenwich	164	190	-26	-13.7	103	124	-21	-16.9	267	314	-47	-15.0
Norwalk	139	118	21	17.8	54	53	1	1.9	193	171	22	12.9
St. Vincent's	1,188	1,395	-207	-14.8	600	578	22	3.8	1,788	1,973	-185	-9.4
Stamford	269	286	-17	-5.9	330	358	-28	-7.8	599	644	-45	-7.0
HSA 1 TOTAL	2,383	2,618	-235	-9.0	1,432	1,486	-54	-3.6	3,815	4,104	-289	-7.0
Saint Raphael	968	1,080	-112	-10.4	946	821	125	15.2	1,914	1,901	13	0.7
Yale-New Haven	2,132	2,123	9	0.4	981	1,002	-21	-2.1	3,113	3,125	-12	-0.4
HSA 2 TOTAL	3,100	3,203	-103	-3.2	1,927	1,823	104	5.7	5,027	5,026	1	0.0
Backus	113	127	-14	-11.0	209	260	-51	-19.6	322	387	-65	-16.8
L&M	485	432	53	12.3	271	299	-28	-9.4	756	731	25	3.4
Middlesex	135	142	-7	-4.9	294	269	25	9.3	429	411	18	4.4
HSA 3 TOTAL	733	701	32	4.6	774	828	-54	-6.5	1,507	1,529	-22	-1.4
CT Children's	3	10	-7	-70.0	14	26	-12	-46.2	17	36	-19	-52.8
Dempsey	447	424	23	5.4	332	320	12	3.8	779	744	35	4.7
Hartford	2,040	1,837	203	11.1	1,252	1,131	121	10.7	3,292	2,968	324	10.9
HCC	812	936	-124	-13.2	717	736	-19	-2.6	1,529	1,672	-143	-8.6
Rockville (ECHN)	0	0	0	0.0	11	14	-3	-21.4	11	14	-3	-21.4
Saint Francis	1,806	1,759	47	2.7	1,188	1,156	32	2.8	2,994	2,915	79	2.7
HSA 4 TOTAL	5,108	4,966	142	2.9	3,514	3,383	131	3.9	8,622	8,349	273	3.3
Danbury	386	392	-6	-1.5	534	527	7	1.3	920	919	1	0.1
New Milford		35	-35	-100.0		33	-33	-100.0	0	68	-68	-100.0
Saint Mary's	428	434	-6	-1.4	327	289	38	13.1	755	723	32	4.4
Waterbury	608	681	-73	-10.7	317	278	39	14.0	926	959	-34	-3.5
HSA 5 TOTAL	1,422	1,542	-120	-7.8	1,178	1,127	51	4.5	2,600	2,669	-69	-2.6
CT GRAND TOTAL	12,746	13,030	-284	-2.2	8,825	8,647	178	2.1	21,571	21,677	-106	-0.5

Hospital-specific data accompanied with the # symbol is estimated.
Please refer to the Qualifying Conditions section at the end of this report for additional information.

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PATIENT CENSUS REPORT # 12
CONNECTICUT HOSPITAL ASSOCIATION
September 2009 vs 2008
CARDIAC CATHETERIZATION PROCEDURES

Year-to-Date: October 1 Thru September 30

	-----Inpatient Procedures-----				-----Outpatient Procedures-----				-----Total Procedures-----			
FACILITY	2009	2008	NET CHANGE	% CHANGE	2009	2008	NET CHANGE	% CHANGE	2009	2008	NET CHANGE	% CHANGE
Bridgeport	629	817	-188	-23.0	373	265	108	40.8	1,002	1,082	-80	-7.4
Greenwich	190	164	26	15.9	124	130	-6	-4.6	314	294	20	6.8
Norwalk	83	79	4	5.1	74	64	10	15.6	157	143	14	9.8
St. Vincent's	1,395	1,516	-121	-8.0	578	588	-10	-1.7	1,973	2,104	-131	-6.2
Stamford	286	308	-22	-7.1	358	252	106	42.1	644	560	84	15.0
HSA 1 TOTAL	2,583	2,884	-301	-10.4	1,507	1,299	208	16.0	4,090	4,183	-93	-2.2
Saint Raphael	1,080	1,131	-51	-4.5	821	920	-99	-10.8	1,901	2,051	-150	-7.3
Yale-New Haven	2,076	1,890	186	9.8	992	941	51	5.4	3,068	2,831	237	8.4
HSA 2 TOTAL	3,156	3,021	135	4.5	1,813	1,861	-48	-2.6	4,969	4,882	87	1.8
Backus	127	102	25	24.5	260	213	47	22.1	387	315	72	22.9
L&M	432	334	98	29.3	299	343	-44	-12.8	731	677	54	8.0
Middlesex	142	152	-10	-6.6	269	315	-46	-14.6	411	467	-56	-12.0
HSA 3 TOTAL	701	588	113	19.2	828	871	-43	-4.9	1,529	1,459	70	4.8
CT Children's	10	7	3	42.9	26	46	-20	-43.5	36	53	-17	-32.1
Dempsey	424	497	-73	-14.7	320	370	-50	-13.5	744	867	-123	-14.2
Hartford	1,837	2,045	-208	-10.2	1,131	1,122	9	0.8	2,968	3,167	-199	-6.3
HCC	936	844	92	10.9	736	777	-41	-5.3	1,672	1,621	51	3.1
Rockville (ECHN)	0	0	0	0.0	14	21	-7	-33.3	14	21	-7	-33.3
Saint Francis	1,759	1,879	-120	-6.4	1,156	1,170	-14	-1.2	2,915	3,049	-134	-4.4
HSA 4 TOTAL	4,966	5,272	-306	-5.8	3,383	3,506	-123	-3.5	8,349	8,778	-429	-4.9
Danbury	392	334	58	17.4	527	456	71	15.6	919	790	129	16.3
New Milford	35	68	-33	-48.5	33	85	-52	-61.2	68	153	-85	-55.6
Saint Mary's	434	416	18	4.3	289	243	46	18.9	723	659	64	9.7
Waterbury	681	615	66	10.7	278	258	20	7.8	959	873	86	9.9
HSA 5 TOTAL	1,542	1,433	109	7.6	1,127	1,042	85	8.2	2,669	2,475	194	7.8
CT GRAND TOTAL	12,948	13,198	-250	-1.9	8,658	8,579	79	0.9	21,606	21,777	-171	-0.8

Hospital-specific data accompanied with the # symbol is estimated because the hospital did not submit information for the current month.
Please refer to the Qualifying Conditions section at the end of this report for additional information.

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EXHIBIT 3

Cardiac Catheterization Volumes, FY2009 - FY2011

Greenwich Hospital Service Area[1]

Town	Area	Fiscal Year 09			Fiscal Year 10			Fiscal Year 11		
		NY Hosp[2]	CT Hosp[3]	Total NY & CT	NY Hosp[2]	CT Hosp[3]	Total NY & CT	NY Hosp[2]	CT Hosp[3]	Total NY & CT
Darien	Connecticut	1	31	32	4	27	31	4	33	37
Greenwich	Connecticut	17	131	148	25	113	138	22	118	140
New Canaan	Connecticut	4	48	52	3	29	32	3	21	24
Norwalk	Connecticut	12	284	296	12	269	281	11	210	221
Stamford	Connecticut	18	329	347	25	291	316	32	244	276
Weston	Connecticut	2	15	17	5	22	27	3	15	18
Westport	Connecticut	11	61	72	5	68	73	4	52	56
Wilton	Connecticut	3	33	36	5	45	50	6	30	36
Connecticut Town Subtotal		68	932	1000	84	864	948	85	723	808
Armonk	New York	17		17	23	1	24	18		18
Bedford	New York	20		20	22	1	23	11	1	12
Bedford Hills	New York	23		23	23		23	24	1	25
Harrison	New York	41	3	44	36	5	41	52	7	59
Hartsdale	New York	42		42	42		42	37	1	38
Katonah	New York	28	1	29	29		29	23	2	25
Larchmont	New York	45	3	48	48	2	50	37	3	40
Mamaroneck	New York	60	6	66	63	4	67	61	5	66
Mount Kisco	New York	53		53	42		42	38	1	39
Mount Vernon	New York	208	2	210	211	3	214	223	1	224
New Rochelle	New York	268	7	275	285	1	286	241	6	247
Port Chester	New York	70	48	118	65	49	114	79	38	117
Pound Ridge	New York	9	3	12	12	2	14	11	2	13
Purchase	New York	13	2	15	3		3	10	1	11
Rye	New York	44	17	61	29	11	40	34	13	47
Scarsdale	New York	95	1	96	85		85	104	1	105
South Salem	New York	13	9	22	15	7	22	11	4	15
West Harrison	New York	40		40	32	2	34	29	1	30
White Plains	New York	246	6	252	194	8	202	216	6	222
New York Town Subtotal		1335	108	1443	1259	96	1355	1259	94	1353
Total		**1403**	**1040**	**2443**	**1343**	**960**	**2303**	**1344**	**817**	**2161**

ICD-9-CM Procedure Codes: 37.21-37.23

(1) Service Area defined by Applicants
(2) Source data obtained from SPARCS. Analysis prepared by DataGen- HANYS Solutions
(3) Source data obtained from Connecticut Hospital Association (CHA) CHIME database. Analysis prepared by Health Strategies & Solutions, Inc.

Coronary Angioplasty (PCI), FY2009 - FY2011

Greenwich Hospital Service Area[1]

Town	Area	Fiscal Year 09			Fiscal Year 10			Fiscal Year 11		
		NY Hosp[2]	CT Hosp[3]	Total NY & CT	NY Hosp[2]	CT Hosp[3]	Total NY & CT	NY Hosp[2]	CT Hosp[3]	Total NY & CT
Darien	Connecticut	2	15	17	2	12	14	4	18	22
Greenwich	Connecticut	16	74	90	15	59	74	8	68	76
New Canaan	Connecticut	1	35	36	3	22	25	3	14	17
Norwalk	Connecticut	7	185	192	5	206	211	5	123	128
Stamford	Connecticut	13	150	163	20	139	159	18	103	121
Weston	Connecticut	0	12	12	4	19	23	1	10	11
Westport	Connecticut	6	53	59	7	54	61	2	37	39
Wilton	Connecticut	2	27	29	2	41	43	2	13	15
Connecticut Town Subtotal		47	551	598	58	552	610	43	386	429
Armonk	New York	7		7	14	1	15	11	2	13
Bedford	New York	16		16	8	1	9	6	1	7
Bedford Hills	New York	13		13	13		13	6	1	7
Harrison	New York	18	3	21	24	3	27	31	4	35
Hartsdale	New York	28		28	29		29	33	1	34
Katonah	New York	23	1	24	14		14	16		16
Larchmont	New York	27	2	29	35		35	22	1	23
Mamaroneck	New York	29	4	33	39	2	41	35	3	38
Mount Kisco	New York	30	1	31	20		20	23	1	24
Mount Vernon	New York	109	2	111	81	1	82	103		103
New Rochelle	New York	164	4	168	186	1	187	158	3	161
Port Chester	New York	45	23	68	41	28	69	44	14	58
Pound Ridge	New York	8	1	9	9	3	12	8	1	9
Purchase	New York	8		8	0		0	6	1	7
Rye	New York	23	9	32	17	9	26	19	7	26
Scarsdale	New York	61		61	54		54	58		58
South Salem	New York	10	9	19	9	6	15	7	1	8
West Harrison	New York	30		30	19	1	20	28	1	29
White Plains	New York	136		136	104	3	107	112	4	116
New York Town Subtotal		785	59	844	716	59	775	726	46	772
Total		**832**	**610**	**1442**	**774**	**611**	**1385**	**769**	**432**	**1201**

ICD-9-CM Procedure Codes: 00.66, 36.03, 36.04, 36.06, 36.07 and 36.09.□

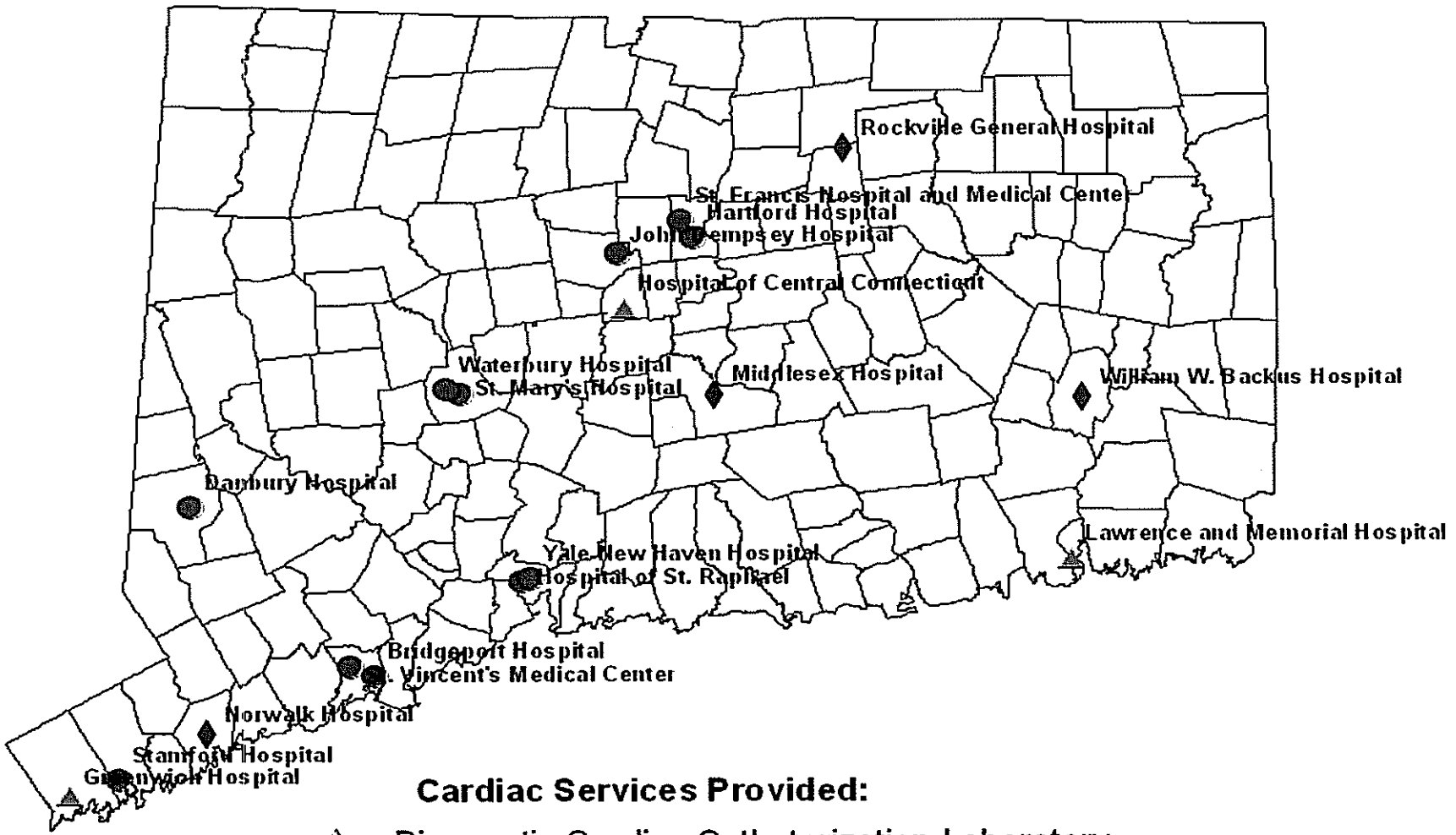
(1) Service Area defined by Applicants

(2) Source data obtained from SPARCS. Analysis prepared by DataGen- HANYS Solutions

(3) Source data obtained from Connecticut Hospital Association (CHA) CHIME database. Analysis prepared by Health Strategies & Solutions, Inc.

EXHIBIT 4

Cardiac Services in Connecticut
January 2011



Cardiac Services Provided:

- Diagnostic Cardiac Catheterization Laboratory
- Primary Angioplasty for Myocardial Infarction (Emergency Angioplasty)
- Full Service (Emergency and Elective Angioplasty and Open Heart Surg

ce: State of CT, DPH Certificate of Need Database

EXHIBIT 5

Coronary Angioplasty By Admissic

Westchester Town	Hosp #	Hospital	Total	Greenwich Hospital Service Area Total
White Plains	000306	White Plains Hospital Center	47	47
Greenburgh	000306	White Plains Hospital Center	20	
Harrison	000306	White Plains Hospital Center	12	12
Scarsdale	000306	White Plains Hospital Center	11	11
Mamaroneck	000306	White Plains Hospital Center	10	10
Rye	000306	White Plains Hospital Center	7	
New Rochelle	000306	White Plains Hospital Center	6	6
Eastchester	000306	White Plains Hospital Center	4	
Brewster	000306	White Plains Hospital Center	3	
Bronx	000306	White Plains Hospital Center	2	
Mount Vernon	000306	White Plains Hospital Center	3	3
North Castle	000306	White Plains Hospital Center	2	
Boynton Beach	000306	White Plains Hospital Center	1	
Brooklyn	000306	White Plains Hospital Center	1	
Campbell Hall	000306	White Plains Hospital Center	1	
Carmel	000306	White Plains Hospital Center	1	
Jersey City	000306	White Plains Hospital Center	1	
Lake Peekskill	000306	White Plains Hospital Center	1	
Mount Pleasant	000306	White Plains Hospital Center	1	
Myrtle Beach	000306	White Plains Hospital Center	1	
Ridgefield	000306	White Plains Hospital Center	1	
Spring Valley	000306	White Plains Hospital Center	1	
Yonkers	000306	White Plains Hospital Center	3	
Cortlandt	000306	White Plains Hospital Center	2	
Haverstraw	000306	White Plains Hospital Center	1	
Poughkeepsie	000306	White Plains Hospital Center	1	
Port Chester	000306	White Plains Hospital Center	3	3
West Harrison	000306	White Plains Hospital Center	3	3
Larchmont	000306	White Plains Hospital Center	2	2
Purchase	000306	White Plains Hospital Center	2	2
Armonk	000306	White Plains Hospital Center	2	2
Hartsdale	000306	White Plains Hospital Center	9	9
		Total	165	110

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EXHIBIT 6

White Plains Hospital

Susan Fox
Executive Vice President
Tel (914) 681-1237
Fax (914) 681-2902
sfox@wphospital.org

July 11, 2012

Sharon Kiely, M.D.
Senior Vice President of Medical Affairs, Chief Medical Officer
The Stamford Hospital
190 West Broad Street
Stamford, CT 06902

Re: Certificate of Need Application; Docket No. 12-31748-CON
Yale-New Haven Hospital and Greenwich Hospital
Proposal to Establish an Elective Angioplasty Program
Without Onsite Surgical Backup at Greenwich Hospital

Dear Dr. Kiely:

It is our understanding that Stamford Hospital will be opposing the above Certificate of Need ("CON") Application on the grounds that, among other things: (i) there is no clear public need for another elective angioplasty ("PCI") program in the Fairfield County/Westchester County service area identified at page 24 of the CON; (ii) it will not improve the quality, accessibility and cost-effectiveness of health care in the region and (iii) it will result in an unnecessary duplication of existing services. White Plains Hospital ("WPH") agrees on all counts.

As you know, WPH serves almost all of the Westchester County towns identified by the Applicants and was approved by the New York Department of Health to begin providing elective PCI procedures to patients in January of 2010. The approval resulted in WPH becoming the second hospital in Westchester County (the other being the Westchester Medical Center in Valhalla) to provide this service. One of the principal aims of our program was to provide local access to PCI for residents of our service area, many of whom had traditionally received such care at New York City hospitals, and we have been successful in that effort.

In fiscal year 2010 and with the support of the New York Presbyterian Health System, a total of 126 PCIs (92 elective and 24 emergency) were performed at WPH. In fiscal year

2011, 290 PCIs were performed at WPH (250 elective and 40 emergency). In calendar year 2012, we have begun to experience a volume shift connected with a change in referral patterns by a large cardiology practice in our area; however, year-to-date we have maintained our PCI volume.

It is WPH's view that the service area identified by Yale and Greenwich in their CON Application is already well-served by a host of high quality PCI programs, including our own. Our data also indicates that the market for PCI services in the service area is not growing to any significant degree. This being the case, we share Stamford's concerns that the establishment of yet another elective PCI program in the service area could further dilute volumes for existing providers and make it more difficult for hospitals like ours to attain the volumes recommended in the clinical literature to help maintain proficiency and assure quality.

Our elective PCI program presently has capacity to serve the needs of the community and we are not aware of any backlog of cases in our service area that would indicate patients are not receiving timely care. I would also note that in the recent past we know of two hospitals that serve Westchester County residents – Sound Shore Medical Center in New Rochelle and St. John's Riverside Hospital in Yonkers – that have been unsuccessful in attempts to gain regulatory approval from the New York Department of Health to provide elective angioplasty services. We believe this is a further indication that the need of area residents for this service is being adequately met.

Sincerely,

Susan Fox

Executive Vice President

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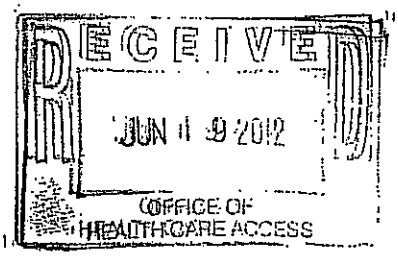
EXHIBIT 7

LAWRENCE & MEMORIAL HOSPITAL

June 18, 2012

Lisa Davis
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capital Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134



RE: Certificate of Need Application to Establish and Operate an Elective Angioplasty Program at Lawrence + Memorial Hospital in New London, CT

Dear Deputy Commissioner Davis:

Enclosed is the original Certificate of Need Application to establish and operate an elective angioplasty program at Lawrence + Memorial Hospital in New London, CT. Also enclosed are four copies of the application and a CD of the scanned application and documents in MS format.

We are filing this application with the support of Yale-New Haven Hospital and Yale School of Medicine, but they are not co-applicants.

I look forward to working with you and your staff during the review process.

Please do not hesitate to contact me at (860) 442-0711, extension 2073, if you have any questions regarding this application.

Sincerely,

Crista Durand, Vice President
Strategic Planning, Marketing, & Business Development

cc: Shraddha Patel, Director of Business Development & Planning

Lawrence + Memorial Hospital
365 Montauk Avenue, New London, CT 06320

Establish and Operate an Elective Angioplasty Program at Lawrence + Memorial Hospital

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III	Public Notice Evidence	3-6
IV	Hospital Affidavit	7
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	Attachments	
	A. Letters of Support	54-83
	B. "2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: Executive Summary" and "The Current Status and Future Direction of Percutaneous Coronary Intervention Without On-Site Surgical Backup: An Expert Consensus Document from SCAI"	84-125
	C. "Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery"	126-161
	D. Other Relevant Articles, Studies, or Reports	162-312
	E. Demographic Information	313-352
	F. Policies & Procedures for PCI Procedure	353-376
	G. Results of 2007 Community Needs Assessment	377-397
	H. SCAI Requirements for Elective PCI without On-Site Surgery & L+M Compliance	398-401
	I. Transfer Protocol and Agreement, YNHH Backup Surgery Policy, and L+M/YNHH Agreement for Primary PCI Program	402-471

Lawrence + Memorial Hospital
365 Montauk Avenue, New London, CT 06320

Establish and Operate an Elective Angioplasty Program at Lawrence + Memorial Hospital

Table of Contents (continued)

Exhibit	Item	Page(s)
	Attachments (continued)	
J.	**Letter from Local Emergency Medical Services (EMS) & Guideline for Rapid Transport of Patients Requiring Urgent Surgery**	472-474
K.	**Connecticut Department of Public Health New Mandate Regarding STEMI Patients**	475-477
L.	**New Policy Guideline from Backus EMS Regarding Transfer of Patients with STEMI to Facility Capable of Performing Primary PCI**	478-479
M.	**Curriculum Vitae** • Bruce Cummings, President and Chief Executive Officer • Daniel Rissi, MD, Vice President and Chief Medical & Clinical Operations Officer • Lugene Inzana, Vice President and Chief Financial Officer • Pamela Kane, Vice President, Physician Practice Management • Brian Cambi, MD, Medical Director of Primary Angioplasty Program at L+M • Max Gorski, Director of Cardiology • Gerry Mulholland, Manager of Cath Lab	480-491
N.	**National Cardiovascular Data Registry Measures for L+M**	492-498
O.	**Documentation of Non-Profit Status**	499-504
P.	**Hospital License**	505
Q.	**Financial Attachments I and II**	506-509
R.	**Financial Attachment Assumptions**	510
S.	**Rate Schedule**	511-518

Application Checklist

Instructions:

1. Please check each box below, as appropriate; and
2. The completed checklist *must* be submitted as the first page of the CON application.

☒ Attached is the CON application filing fee in the form of a certified, cashier or business check made out to the "Treasurer State of Connecticut" in the amount of $500.

For OHCA Use Only:

Docket No.: 12-31768-Con Check No.: 288995
OHCA Verified by: SU Date: 7/19/12

☒ Attached is evidence demonstrating that public notice has been published in a suitable newspaper that relates to the location of the proposal, 3 days in a row, at least 20 days prior to the submission of the CON application to OHCA. (*OHCA requests that the Applicant fax a courtesy copy to OHCA (860) 428-7053, at the time of the publication)*

☒ Attached is a paginated hard copy of the CON application including a completed affidavit, signed and notarized by the appropriate individuals.

☒ Attached are completed Financial Attachments I and II.

☒ Submission includes one (1) original and four (4) hard copies with each set placed in 3-ring binders.

Note: A CON application may be filed with OHCA electronically through email, if the total number of pages submitted is 50 pages or less. In this case, the CON Application must be emailed to ohca@ct.gov.

Important: For CON applications(less than 50 pages) filed electronically through email, the singed affidavit and the check in the amount of $500 must be delivered to OHCA in hardcopy.

☒ The following have been submitted on a CD

1. A scanned copy of each submission in its entirety, including all attachments in Adobe (.pdf) format.
2. An electronic copy of the documents in MS Word and MS Excel as appropriate.

CON Application Filing Fee

LAWRENCE & MEMORIAL HOSPITAL

DATE: 05/29/12
L010882 CHECK NO: 288995

INVOICE NO.	DATE	DESCRIPTION	GROSS AMT	DISCOUNT	NET AMOUNT
APPLICATION	05/24/12		500.00	0.00	500.00

PUBLISHER'S CERTIFICATE

State of Connecticut
County of New London, ss. New London

Personally appeared before the undersigned, a Notary Public within and for said County and State, Mary Labasi, Legal Adverising Clerk, of The Day Publishing Company Classifieds dept, a newspaper published at New London, County of New London, state of Connecticut who being duly sworn, states on oath, that the Order of Notice in the case of

13461 Lawrence & Memorial Hospital is applying for a Certi

A true copy of which is hereunto annexed, was published in said newspaper in its issue(s) of

04/30/2012, 05/01/2012, 05/02/2012

Cust: L&M HOSPITAL
Ad #: d00387493

Mary Labasi

Subscribed and sworn to before me

This Wednesday, May 02, 2012

Maryellen Solinsky

Notary Public

My commission expires 5/31/14

13461
Lawrence & Memorial Hospital is applying for a Certificate of Need pursuant to section 19a-638 of the general statutes. The proposal is to establish and operate an elective angioplasty program at Lawrence & Memorial Hospital located at 365 Montauk Avenue, New London, CT 06320. The total capital expenditure for the project is $0.

Southeastern Connecticut's largest source of online and print classifieds.

community classifieds



To advertise your business, call 860-701-1200

Waterford Road, on May 7, 2012, at 7:30 P.M. and will reconvene in the Town Hall Auditorium, 15 Rope Ferry Road, Waterford, on May 8 and again on May 9 at 7:30 P.M., with final action on May 9, 2012, for the following reasons:

1. To consider and act upon the General Fund Budget, which includes both Board of Education and General Government budgets for the Fiscal Year July 1, 2012 through June 30, 2013, as recommended by the Board of Finance, and as may be modified by the determination of the Representative Town Meeting.
2. To establish the due date(s) for tax payments due thereon.

Copies of the budget and RTM review schedule are available from the Office of the Town Clerk, 15 Rope Ferry Road, Waterford.

Dated at Waterford, Connecticut, this 25th day of April, 2012.

Thomas J. Dembek
RTM Moderator

13419

DOCKET NO: KNLCV126012759S SUPERIOR COURT
SOUND BREEZE OF GROT JUDICIAL DISTRICT OF
V. NORWICH/NEW LONDON
GARDINER, CATHERINE ET AL AT NEW LONDON
4/9/2012

ORDER

ORDER REGARDING:
03/28/12 102.00 MOTION FOR ORDER OF NOTICE
Judicial Notice (JDNO) was sent regarding this order.
The foregoing, having been considered by the court, is hereby:
ORDER: GRANTED
Upon motion, it appearing to and being found by the subscribing authority that notice of the institution of this action most likely to come to its attention is as herein ordered:
Ordered, that the notice of the institution of said action be given to Catherine A. Gardiner, by a proper officer causing a true and attested copy of this order to be published in the New London Day once a week for two successive weeks, the second publication commencing on or before May 8, 2012.

415995
Judge: JAMES J. DEVINE
A True Copy
Attest: /S/
J. Martin State Marshal

13451

LEGAL NOTICE
TO THE RESIDENTS OF THE TOWN WATERFORD

EQUAL OPPORTUNITY IN HOUSING IS THE LAW!

The Town of Waterford supports Fair Housing as a right for all its citizens. The Town's Fair Housing Plan is available at the Town Hall, First Selectman's Office —or by calling 860-444-5804

LONDON, CT 06320-6117 have filed an application placarded 04/30/2012 with the Dept. of Consumer Protection for a RESTAURANT LIQUOR PERMIT for the sale of alcoholic liquor on the premises at 385 BANK ST., NEW LONDON, CT 06320-5525. The business will be owned by: ASG GROUP, LLC. Entertainment will consist of the following: Acoustics (Not Amplified). Objections must be filed by: 06/10/2012.
ANDREW C BELL

13461

Lawrence & Memorial Hospital is applying for a Certificate of Need pursuant to section 19a-638 of the general statutes. The proposal is to establish and operate an elective angioplasty program at Lawrence & Memorial Hospital located at 365 Montauk Avenue, New London, CT 06320. The total capital expenditure for the project is $0.



Announcements

Notes of Interest



CT SCRAP: Will buy your scrap steel, copper & aluminum. 33 Pequot Rd, Uncasville 860-848-3366



Low Monthly Payments! Call Nancy 860-536-4931

Automobiles

Acura CL — 1999 v tec 2 dr coupe white at sunroof, good condition runs good many new parts needs a little tlc runs an drives $1700 860 501 4592

Audi S4 — 2000 5 speed, turbo, awd quattro silver, leather loaded, too many new parts to list driven daily $ 2500 860 501 4592

Buick Park — Avenue 2000 sedan, 6-cyl. Tan w/tan interior, 6-disk CD. Keyless entry. Compass. Floor mats. New battery. New brakes. Original owner. Low mileage (92,600). $5,200.00 Auto. Heated mirrors. 91,600 Call 860-884-3677

Jeep Grand — Cherokee 2000 limited 4x4 4.0 6cyl, white, leather, sunroof, 130 k at, quadra trac nice jeep, needs a little tlc, runs good, $2700 860 501 4592

Mercedes — CLK 350 Cabrilo Convertible. 2007. $25,000. Metallic blue, grey leather interior, black top. 1 owner. Always garaged. 860-535-1845

Motorcycles

all eletric — moped thomson pink and white moped new has to be picked up groton ct pink moped for sale 700 or best offer name mona number 860-701-8516

pink and — wite moped all eletric 675 or best offer 860-7018516

Motorcycles/ ATVs/Bikes

Extra Clean 2000 Harley — FLHT 33K miles, w/lots of extras, charger, lift & Jack cover $15,000 860-537-4235



To perform equipment set ups and the delivery of oxygen to customer homes. Commercial Drivers License (CDL) with Hazmat endorsement preferred. Competitive salary with excellent benefit package including health, dental, vision, life insurance, and 401K. EOE. For consideration apply in person to: 70 Howard Street New London, CT 06320 or Fax your resume to: 860-442-9940

General Help

CUSTOMER SERVICE - Full Time. Will Train. Flexible Schedule. Excellent Pay. Interviews being held now. Call 860-859-0541

Customer Service — Kellogg Marine, a division of Brunswick Corp. has a full-time CSR position available in our Engine Parts Group. To view requirements and responsibilities and to apply please visit www.Brunswick.com, click on Careers and search by requisition #5423. An Equal Opportunity Employer.

Customer Service Positions avail immediately for all shifts. Must be computer literate and dependable! Fun, fast-paced office off I-95, next to train station. Pd training/great hrly rate Call today or Email: adinthepaper@gmail.com or 860-388-1007

House Painting Firm — wants to interview hard-working painters. All skill levels welcome. MysticRiverPaintworks.com 860-535-4415

KENNEL HELP — Full Time. Must be able to work weekends & holidays. Experience preferred, benefits available. Email to: joanndooley@sbcglobal.net

Landscapers — Experience a must. Job levels ranging from mowers/general maintenance to experienced ma-

Premium Pet LICENSE REQUIRED Call 1-888-713-6020

WANTED LIFE AGENTS: Earn $500 a Day. Great Agent Benefits. Commissions Paid Daily. Liberal Underwriting. Leads. Leads. Leads. LIFE INSURANCE LICENSE REQUIRED Call 1-888-713-6020



Animal/pets

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American Bully Pitbull Puppies — UKC & ABKC reg. DOB 4/13/12. 1st shots. $1500-$2500. 860-367-3011

Labrador Retriever — Puppies. AKC. 1st shots, Vet Checked, Chocolate & Black. $650. 860-884-5040



Boats/marinas

Boats

19 Boston — Whaler, Outrage 1991, Center console, powered by 130hp 4 stroke Yamaha outboard. Comes with single axel trailer. Great for fishing and recreation. Stable and powerful. Whole package in fair to good condition. Stored indoors. Asking $8,500. Contact Mat at 860-245-5816.



ASSORTED UNIFORMS WITH PATCHES $55 OBO 401-596-1314

BOY SCOUTS — 1970'S ASSORTED UNIFORMS WITH PATCHES $55 OBO 401-596-1314

Columbia Grafonola — Oak floor model. Excellent condition, works great. Vintage records included. $700 860-303-7682

DOUBLE BED — SOLID CHERRY HEADBOARD FOOTBOARD AND SIDE RAILS $75.00 860-536-7441

GIRL SCOUTS — 1970'S BACKPACK + MESSKIT $55 OBO 401-596-1314

Key Hole — saw qty (10) and (6) regular hand saws some have nice detail in the wooden handel. All for $40.00 860 287-0339

Naval Uniform — Cracker-Jacks, Pants & Jacket. Divers, Vietnam + Other Patches. Very Good+ Cond. $85. 860.917.6364

ORIGINAL UNPUBLISHED — PHOTO CIRCA 1920'S, FOOTBALL PLAYER, V.G.COND $135 OBO 401-596-1314

ORIGINAL UNPUBLISHED — PHOTO CIRCA 1920'S, FOOTBALL PLAYER, V.G.COND $135 OBO 401-596-1314

Playboy Magazine — Collection 300 Magazines Excellent Condition 1970-2009 $3 each or $75 for all. 860-861-1598

Star Wars — 1977-79 Action figures, ships, electronic + R2D2, voice activated Darth Vader mask, misc $150 860-303-7682

TWA ROYAL — AMBASSADOR DINNERWARE SERVICE BY ROSENTHAL 10 PC ASSORTED. $500 OBO 401-596-1314

Victorian style — chair mahogany, wood carvings on back, upholstered seat and rollers on front legs. $150 860-303-7682

VINTAGE DECANTER — GERMAN VERY

Building & Contracting

Independent Carpentry Pro. Repairs, Decks, Sheetrock, Home Inspections/Radon Servicing SE CT since 1984 860-235-0506 Reg#511619

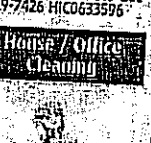
Excavation / Demolition

Ellinwood Landscaping, Land&lots cleared, logging, land reclamation, corn, snow plowing, tree& brush removal Call 860-912-2225

Flooring / Resurfacing

Ceramic tile, vinyl, carpet, hardwood professionally installed. Your material or mine. Tim Bartlett 860-319-7426 HIC0633596

House / Office Cleaning



HOUSE CLEANING — Done to perfection and details. Bonded/Insured. Good price and references. PLEASE CALL FOR A FREE ESTIMATE. Natalia/Juliana (860) 304-7865 / (860) 294-6292

Landscaping Service



A&D LANDSCAPING

Landscaping Service

Sparkle Lake Services — Lawncare, cleanups, mulch & more. Will beat any price. 20 years in business. 860-917-4873.

Lawncare & Gardening

A&A Services — All lawn and Property Maintenance. Mowing, Mulch, hedge trimming & more. Senior Discount. 860-823-0452

Best Mowing, Lawncare, Treework & Cleanups. Lic & Ins. 860-861-5941 or 860-848-4219. Residential/Commercial

ELLINWOOD LANDSCAPING & LAWNCARE. Senior Discounts & 20% off all new seasonal contracts! Full Service, Commercial & Residential. Lawn Mowing, Fertilizing, Hedge Trimming & Mulching. Lic#60369, 860-912-2225

Lawn Mowing — Groton, Ledyard, Mystic, Gales Ferry Area. Free estimates. (860)326-5128

TIM'S LAWN CARE Mowing, General Yard Work Serving E. Lyme, New London & Waterford Call: 860-287-0644

Masonry & Stonework

Sasoli's Masonry, LLC Stone Walls, Chimneys, Fire Place, Sidewalk, Patio, Steps, Outdoor Kit Llc & Ins. # HIC 0618942 FREE Est. 203-598-2524

Painting/Papering

JOHN IRVIN'S DISCOUNT PAINTING Spring Cleanups — FREE Estimates. Ref Available. Call 860-857-4755

Remodeling

ROOMS RENEWED, LLC Specializing in Custom Bathroom Remodeling & Tile work. LIC #0621800 Ask for Mark 860-867-7224

Roofing

ERICSEN Contracting LLC Roofing, Siding, Sheetrock! #602807 References 447-2318 or 460-7143 Call now Free Same Day Estimates

J&R General Roofing, Siding, Windows & Gutters. Lowest Prices Guaranteed Lic#0902784. 860-599-1087 jrgeneralllc.com

JAMES SALLS ROOFING Roofing, Siding & Repairs No job too small! Lic #578787, 860-235-0341

Pawcatuck Roofing Co. Trusted for over 66 years. Competitive Quality Roofs. Call: 860-599-1024 Pawcatuckroofing.com

Tree Service

Anthony's Tree Removal — Licensed #0633737 & Insured. We remove any tree. Bucket truck service. Free Est. Call 860-625-6633

DELIA TREE SERVICE 27 Yrs Exp. Firewood Stump Grinding, Fully Insured, Free Estimates. 860-464-0211

E.J. TREE SERVICE. No Tree Too Large / Small. Free Estimates. Land Clearing, Firewood, Insured Lic#0610990. 860-464-2032

STEBBINS DISCOUNT TREE SERVICE & STUMP GRINDING, LLC Estimates & Insured. 860-739-0116 / 860-961-9119

Year Round Tree Work — Owner operated tree service. Tree removals, tree trimming & pruning. Climbing & Bucket Truck services. All jobs cleaned up. Lic#

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AMOUNT OF $3,133,070 FOR THE FISCAL YEAR BEGINNING...

Those voting in favor of said item will vote "YES", and those voting against said item will vote "NO".

The April 30, 2012 Annual Town Budget Meeting will then reconvene at the Stonington Town Hall on Tuesday, May 8, 2012 at 8:30 p.m. to consider and record the vote.

Dated at Stonington, Connecticut this 20th day of April, 2012.

/s/
Edward Haberek Jr, First Selectman
/s/
George Crouse, Selectman
/s/
Glee McAnanly, Selectman

13469

TOWN OF WATERFORD
NOTICE OF PUBLIC HEARING
Public Protection & Safety Standing Committee of the RTM
Monday, May 7, 2012
7:00 P.M.
Waterford Public Library

The Public Protection and Safety Standing Committee of the Representative Town Meeting will hold a public hearing on Monday, May 7, 2012, at 7:00 P.M., in the Waterford Public Library, 49 Rope Ferry Road, to consider proposed amendments to Section 2.82.100, Waterways Regulations, of Chapter 2.82, Harbor Management Commission, of the Waterford Code of Ordinances, relative to the use of waters and facilities under the jurisdiction of the harbor management commission.

Copies of the proposed amendments are available from the office of the Town Clerk, 15 Rope Ferry Road, Waterford, CT.

Following the public hearing the PP&S Committee will hold a meeting to consider the outcome of said hearing and act upon recommendations to the Representative Town Meeting at a Special Meeting at 7:30 P.M. the same evening.

Timothy Condon
PP&S Committee Chair

13386

NOTICE OF HEARING

All are encouraged to attend. The hearing is accessible to the handicapped. Any disabled persons requiring special assistance or non-English speaking persons should contact Ms. Heather McNeil, ADA Coordinator, at 860-395-3190 at least five days prior to the hearing.

The Town of Old Saybrook promotes fair housing and makes all programs available to low- and moderate-income families regardless of age, race, color, religion, sex, national origin, sexual preference, marital status, or handicap.

Equal Opportunity/Affirmative Action

13461

Lawrence & Memorial Hospital is applying for a Certificate of Need pursuant to section 19a-638 of the general statutes. The proposal is to establish and operate an elective angioplasty program at Lawrence & Memorial Hospital located at 365 Montauk Avenue, New London, CT 06320. The total capital expenditure for the project is $0.

Automotive



Antique & Classic Cars

FERRARI MARKET — LETTER BACK ISSUES,1981-1990,VG.COND.$10EA,OR$7 50EA FOR 10 OR

Mopeds

pink and — wlte moped all eletric 675 or best offer 860-7018516

Motorcycles & Bicycles

Extra Clean 2000 Harley — FLHT 33K miles, w/lots of extras, charger, lift & jack cover $15,000.860-537-4235



HONDA VFR800FI — Interceptor 2003, 2003 Honda Vfr800 Interceptor, Original Adult Owner, Garage Kept, Dealer Maintained, Never Dropped/Damaged, 980 original miles, Spotless VIN History Report available upon request, OEM Color-matched Locking Hard Sad-

Drivers

DRIVER/SERVICE REPRESENTATIVE
Lincare in New London, CT is looking to add a Driver to their existing team of Service Representatives. Responsibilities include driving the company vehicle to perform equipment set ups and the delivery of oxygen to customer homes. Commercial Drivers License (CDL) with Hazmat endorsement preferred. Competitive salary with excellent benefit package including health, dental, vision, life insurance, and 401K. EOE. For consideration apply in person to: 70 Howard Street, New London, CT 06320 or Fax your resume to: 860-442-9940

General Help

Customer Service — Kellogg Marine, a division of Brunswick Corp, has a full-time CSR position available in our Engine Parts Group. To view requirements and

don Law Firm, P.C., P.O. Drawer 1430, New London, CT 06320 or email resume to Reardonlaw@aol.com

Instruction / Training / Tutoring

CNA TRAINING — 2 weeks-days or 10 weeks-eves. ETWN, 88 Howard St, New London860-447-8673



financial

Business Opportunities

WANTED LIFE AGENTS: Earn $500 a Day. Great Agent Benefits. Commissions Paid Daily. Liberal Underwriting. Leads, Leads, Leads. LIFE INSURANCE LICENSE REQUIRED Call 1-888-713-6020

WANTED LIFE AGENTS: Earn $500 a Day. Great Agent Benefits. Commissions Paid Daily. Liberal Underwriting. Leads, Leads, Leads. LIFE INSURANCE LICENSE REQUIRED Call 1-888-713-6020

WANTED LIFE AGENTS: Earn $500 a Day. Great

Oregon Scientific — Handheld NOAA weather radios. Brand New. Auto scan,alert features. (2). $ 20.00ea. 860-884-3014

Quantum Marine — Air Purifier,120VAC. (Ozone generator),kills mold/odors. $225 860 464 8301

Safety Harnesses — (2) W/tethers. Top quality,new condition.$55 ea. 860 464 8301

Slipper Springs — 500lb cap./spring. New 1 set. Radius end: 24-5/8" x 4" H arch. $30.00/set. 860-884-3014

Steams Navr — Ultra 1F Inflatable Automatic/manual PFDs(2). Type II. Gray and blue. W/O harness. $150ea. 860-884-3014



merchandise

Antiques / Collectibles / Art

ANTIQUE INSULATORS,GLASS,ASS'T. — EX.PAPERWEIGHT/GIFT.$1 5EA.OR 10 FOR $100.401-596-1314

Antique Key — Maker makes keys for old cars &

ORIGINAL UNPUBLISHED — PHOTO,CIRCA 1920'S, FOOTBALL PLAYER, V.G.COND.$135 OBO.401-596-1314

Star Wars — 1977-79 Action figures,ships,electronic R2D2,voice activated Darth Vader mask,misc.$150 860-303-7682

TWA ROYAL — AMBASSADOR DINNERWARE SERVICE BY ROSENTHAL,10 PC ASSORTED. $500 OBO. 401-596-1314

Victorian style — chair mahogany, wood carvings on back, upholstered seat and rollers on front legs. $150 860-303-7682

Vintage Bottles — 5 Vintage 7 Up Bottles With Caps. 1970s. Various Sizes & Designs. 7oz. 12oz. Pint. $15. 860.917.6364

VINTAGE DECANTER — GERMAN, VERY ORNATE/DECORATIVE. 1950-1960, $75 OBO. 401-596-1314

Vintage Dietzgen — Drafting Set Germany Excell. Cond. $45 (860)442-3504

Vintage Two-Man — Buck Saw Wood handles,no rust,5 ft $38 (860)422-3504

Wooden pulleys — various sizes qty. (10) $10.00 each would like to sell all for $90.00. 860 287-0339/860 572-9256.

Wooden Softball — and T ball bats, approx. 15 $ $3.00 each or all for $25.00 860 287-0339/860 572-9256.

Acer AO533 — netbk, 1.66GHz, 2GB, 160GB, 3USB2.SD, cam, 10.1" wide, 802.11n, Win7Ult, Office07, $200. 860-941-9331

CompactFlash SanDisk — Extreme Memory Card (NEW) 16GB (860)739-6372 $55

COMPUTER KEYBOARD,DURABRAND,NEW — IN BOX.$15.401-596-1314

COMPUTER MONITOR,DELL,15" — FLAT SCREEN,VERY GOOD CONDITION. $45 OBO 401-596-1314

Custom Pentium — 4 desktop, 2GHz, 1GB, 40GB, combo, 4 usb 2.0, XpPro SP3; Office03, more!, $100, 860-941-9331

Dell 5650 — 100 watt 5.1 surround sound speakers with subwoofer, phenominal sound for just $75, 860-941-9331

HP Mini — 110-3098nr netbook, 1.66GHz, 2GB, 160GB, 3USB2.SD, cam, 10.1" wide, Win7Ult, Office07, $225. 860-941-9331

OSP Design — Computer Work Station-Hi Tech Black w/steel frame-pull out keyboard shelf-very nice-$85-860-941-8954

Floor Coverings

Rug-wool,8'X 12' — w/fringe.Greens and cream colors,pics on line. $125.00 Exc Cond.860-535-1759

Brushed Nickel. $20. Photo on TheDay.com

LIVING RM — CHAIR -corduroy-mustard; colored-excellent condition-$100-860-941-8954

Mahogany Computer Desk, Chair & printer — Good Cond. $95 for all. Call 860-739-2462

Mattress -Queen. — Pillow top with box. New in plastic, never used. Cost $799 sell $279 860-244-9544

New beds — 1 wood full size sleigh bed, 1 twin girls bed complete w/ armoire, used portable crib.860-625-3639

Storage Ottoman-Fabric/castors,needs — a cover, but good condition. See pics online.$45.00,860-535-1759

Triple Dresser w/mirror — and Men's dresser for $250; both solid oak & good condition. 860-442-1741

TV/DVD STAND — dark cherry-24" X 24"-very nice-$25-860-941-8954

Equipment/Supplies

Air Conditioner-Kenmore — w/remote,8,000BTU. Used 2 seasons.Fits standard window.$100.00,860-535-1759

Bedspread-1 full/queen. — 100% coton.Blue/Cream check.See pics online.Never Used.$15.00,860-535-1759

BRUNO'S Washers: $150, Dryers: $125, Frigs: $150, Stoves: $125 BEST DEALS! 349 Bank St., New London Call 860-439-1998

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Community

...from the streetline of Pickerel Cove Trail.

Case 12-15 – Joyce A. Nasin, 26 Champion Road, request for variances to allow construction of a single-family dwelling on vacant lot.

Dated at Old Lyme, Connecticut this 2nd day of May, 2012.

Susanne Stutts, Chairman

P6494
Court of Probate, Southeastern CT Regional Probate District. Notice to Creditors. ESTATE of Kenneth F. Kuzmich (12-00250) The Hon. Nicholas F. Keppler, Judge of the Court of Probate, Southeastern CT Regional Probate District, by decree dated April 27, 2012, ordered that all claims must be presented to the fiduciary at the address below. Failure to promptly present any such claim may result in the loss of rights to recover on such claim. Jill A. Milkovitsch, Clerk. The fiduciary is: William Smith, c/o Brendan P. McKeever, Esq., McKeever & McKeever, P.C., 81 Pennsylvania Avenue, PO Box 514, Niantic, CT 06357-0517

13477
Liquor Permit – Notice of Application
This is to give notice that I, DAVID J FERREIRA, 53 WHITTLE ST, MYSTIC, CT 06355 Have filed an application placarded 04/24/2012 with the Department of Consumer Protection for a CAFE LIQUOR PERMIT for the sale of alcoholic liquor on the premises at 1598 ROUTE 12 GALES FERRY CT 06335 The business will be owned by: WICKED PISSA LLC (THE) Entertainment will consist of: Acoustics (Not Amplified), Disc Jockeys, Karaoke Objections must be filed by: 05/04/2012 DAVID J FERREIRA

P6496
Court of Probate, Southeastern CT Regional Pro-

13461
Lawrence & Memorial Hospital is applying for a Certificate of Need pursuant to section 19a-638 of the general statutes. The proposal is to establish and operate an elective angioplasty program at Lawrence & Memorial Hospital located at 365 Montauk Avenue, New London, CT 06320. The total capital expenditure for the project is $0.

P6498
Court of Probate, District of New London. Notice to Creditors. ESTATE OF Marian M. Cochrane (12-00181) The Hon. Matthew H. Greene, Judge of the Court of Probate, New London Probate District, by decree dated April 26, 2012, ordered that all claims must be presented to the fiduciary at the address below. Failure to promptly present any such claim may result in the loss of rights to recover on such claim. Eileen Bagwell, Clerk. The fiduciary is: George Cochrane, 45 Colonial Drive, Waterford, CT 06385

announcements

Lost & Found

Reward – Cannon DSLR camera in bag with accessories. I left it on the

Heavy Equipment

– John Deere 2009 4105 4x4 compact tractor. 41hp, hydrostatic. 183 hours. Comes with front loader and belt last box. Very clean – homeowner use. $16500 or best offer call 860 625 0232

Mopeds

all eletric – moped thompson pink and white moped new has to be picked up groton ct pink moped for sale 700 or best offer name mona number 860-701-8516

pink and – wite moped all eletric 675 or best offer 860-7018516

Motorcycles/ATVs/Dirt Bikes

Extra Clean 2000 Harley – FLHT, 33K miles, w/lots of extras, charger, lift & jack cover $15,000 860-537-4235



HONDA VFR800FI – Interceptor, 2003, 2003 Honda Vfr800 Interceptor, Original Adult Owner, Garage Kept, Dealer Maintained, Never Dropped/Damaged, 980 original miles, Spotless VIN History Report available upon request, OEM Color-matched Locking Hard Saddlebags w/ Liners included, Bike is like new, showroom condition $5000 Cash Firm OAKDALE CT Andy SOLD!

Honda – XR50 – 2002, Includes helmet and size 5 riding boots! Excellent condition $750.00

Call 860-859-0541

Customer Service Positions – avail immediately for all shifts. Must be computer literate and dependable! Fun, fast-paced office off I-95, next to train station. Pd training/great hrly rate – Call today or Email: adinthepaper@gmail.com or: 860-388-1007

Full Time Cleaners – – for janitorial account in Groton Must speak English & have own transportation. 1st shift. Call 203-925-6116

Housekeeper needed for spring cleanup. May result in weekly employment. Call between 7am & 3pm Call 401-219-0426

KENNEL HELP – Full Time. Must be able to work weekends & holidays. Experience preferred, benefits available. Email to: joanndooley@sbcglobal.net

TREE CLIMBER – Top Pay for top Climber. Experienced only need apply. Call 860-466-0711

Homes for Sale/Rentals

KENNY HOMEMAKER & COMPANION
Now hiring someone with own transportation. Bilingual a plus for housekeeping and companionship for elders. Full/Part Time. $8.50/hr Call 860-985-5638 or apply at www.kenny-homeservices.com

Human Services

Transitional Coach – Part Time, 2nd Shift, Weekends. Group home for males, exp preferred. Resumes to: Executive Director, 38 Thames St, Groton, CT 06340 EOE AA

Lost & Found/Personals

Full/Part Time & Per Diem Physical Therapist & Physical Therapist Asst. IN-HOUSE Rehab Dept. Excellent benefits and work schedule

Full/Part Time & Per Diem RN Supervisor

Fax Resume: HR Dept Attn: Denise A. (860) 437-2378

Beechwood Rehabilitation and Nursing Center 131 Vauxhall St, New London, CT 06320

Painting/Paperhng

PAINTERS WANTED – Experienced & own transportation necessary. Call: 860-434-9540 x1 Or Fax: 860-434-3356

Retail

LAYSVILLE HARDWARE – stock and sales associate, lifting of 60lbs or more required. Apply in person or mail resume to 121 Boston Post Rd Old Lyme 06371

Career & Vocational Training

FREE TRAINING - Income-Eligible. MS Office/Clerical, Culinary, CNA, Employment Prep. OIC @ 860-447-1731.

Financial

Business Opportunities

tank & motorstand. Nice cond. $600. 860-941-9322

Swampscott Dory. Built in 1997, 16', copper riveted, oars & trailer, make offer. 860-867-6821

Marine

DOCK SLIP RENTALS – Starting at $500 Don's Dock, Stonington, CT 860-535-0077 www.dons-dock.com

Parts/Supplies – Marine

Aluminum rocket – launcher. New, 4 rodholders-80/130 class, Black. Bulkhead mounted. 36"long $ 200.00 860-884-3014

Blue Sea – New Dual Circuit mini battery switch. 350Amp cap. Battery combine feature. $ 30.00 860-884-3014

Boating equipment – dock box, boat fenders sailboat hardware teak products new cruising guide sailing directions for world cruisers brass equipment BOB 860-303-3000

Cabela's Downrigger – 6lb weights. New. Black, ball front, rear keel design. (2) $ 20.00ea. 860-884-3014

Electronic Horns – hi-lo Aqua signal. New. Drop in forward facing with Stainless covers. $50. 860-884-3014

Evinrude Tilt – / Trim gauge. New. 2" diameter. Tech series. Black finish. $ 25. 860-884-3014

Hi-Lo Table – 36" square drop leaf teak formica top ex.condition. $250. 860 464 8301

Linewinder – – New, Cyclone. Portable. 120/12volt. Load, bait casters small med spinning reels. $ 175. 860-884-3014

Mistaro Survival – Anti

Pop-Up Camper Skamper – 17X – 1993 White. Good Cond. Gas stove, refrig, AC/Heat. $350.00/BO 860-446-9161

Clothing

3/4 beaver – coat, 12-14, excellent, yearly stored. $500 or best offer, 860-389-4767

Coal, Wood & Fuels

1 Cord Wood – $100. You must pick-up! Split and Seasoned. Please Call 860-447-2427 After 3PM

Approx. 2 cords of wood – Seasoned, cut & split. Under cover. You pick up. $150. Call 860-460-6208

FIREWOOD – Cut, Split & Delivered. All Year Long. Seasoned Or Green. Call: 860-886-2146

Computers

Acer – AO533 – netbk, 1.66GHz, 2GB, 160GB, 3USB2, SD, cam, 10.1" wide, 802.11n, Win7Ult, Office07, $200. 860-941-9331

Custom Pentium – 4 desktop, 2GHz, 1GB, 40GB, combo, 4 usb 2.0, XpPro SP3, Office03, morel, $100. 860-941-9331

Dell 5650 – 100 watt 5.1 surround sound speakers with subwoofer, phenominal sound for just $75. 860-941-9331

Desk – Chair-Solid – Oak,Swivel, adjustable, on wheels.Exc Cond.$100.00 See pics online.860-535-1759

Desk – Modular units with desk and file, chairs. Call 860-625-3639

Dining rm set – Henredon, buffet w/slate top, rolling cart, table w/2 leaves & pads, 6 chairs, ex! cond, $1,200. 860-848-1824

Dining Room Set – Cherry Table & 6 chairs, lighted china closet, buffet. $350/all. 860-434-8165

dresser maple – childrens like new $200 860-608-0857 picture available

Futon full – size, wood frame Mission style, cover and 3 rig pillows, like new, $150 call 860-535-9986

LIVING RM – CHAIR – corduroy-mustard colored-excellent condition-$100-860-941-6954

Mahogany Computer Desk Chair, & printer – Good Cond. $95 for all – Call 860-739-2462

New beds – 1 wood full size sleigh bed. 1 twin girls bed complete w/armoir, used portable crib.860-625-3639

Storage Ottoman-Fabric/castors,needs – a cover, but good condition. See pics online $45.00,860-535-1759

Triple Dresser w/mirror – and Men's dresser for $250, both solid oak & good condition. 860-442-1741

Black-Asking $250.00 Call 860-434-3161

KitchenAid Slide – in Electric Range – glass top. Asking $225.00 Call 860-434-3181

MIRROR-large(30"X42") – walnut stained frame-very nice – $40-860-941-6954

MIRROR-large(30"X42") – walnut stained frame-very nice – $40-860-941-6954

PICTURE FRAME – "ME AND MY BIG BROTHER" LIKE NEW CONDITION. $7.00 - CALL 860-599-2304

Samsung stainless – Washer/dryer pedestals new, still in box bought $256.00 each sell $300.00 pair OBO Moving must sell call: 860-912-2616

Lawn/Garden & Tools

Arborvitae – Privacy plants. 4' green giants. Dug fresh when ordered, area grown. $25 each. 860-848-7676

ARBORVITAES SPRING SALE! 7 1/2' Dark Green Beautiful Privacy Borders. Delivered & Planted. Only: $64.99 ea. 7.5' $85.00/ea 860-712-5359 ctirees.com

Corona Heavy – Duty 2" Loppers. Long handles, compound mechanical action. Good condition. $ 25. 860-884-3014

55gallon plastic – Drums (4). Brand New – Closed head. 2-2" outlets with plugs. $60.00ea. 860-884-3014

Sears Professional – Deluxe Mechanics Tool Cart. Brand New. Black. 2 ball bearing draws. 43" x 16". $ 200.00 860-884-3014

Medical Supplies

Hospital Mattress – and walker. $25.00 each. 860-4426041

Lift Chair – In GREAT cond, Sage Green. Paid $425, Asking $200. Call 860-204-9810

Wheelchair – – Invacare 9000 w/extra features, used 3 months. $1800. Call 860-442-6041

Musical Instruments

BFlat Clarinet – W/Brilhart Mouthpiece, Brand New Ligatura, Cork Grease, Reeds, Cloth & Case. $85. 860.917.6364

CB Drum – set, all you need to start playing-perfect for a beginner. $250. cash only Please call 860-535-2120

Office/Skilled Employment

Antonio Stradivari – – A Stradivari Advertisement & Informational B&W Framed Print. $5. Call 860.917.6364

Check out our Business Services

AFFIDAVIT

Applicant: **Lawrence + Memorial Hospital**

Project Title: **Establish and Operate an Elective Angioplasty Program at Lawrence + Memorial Hospital**

I, Bruce Cummings, President and Chief Executive Officer of Lawrence + Memorial Hospital being duly sworn, depose and state that Lawrence + Memorial Hospital's information submitted in this Certificate of Need Application is accurate and correct to the best of my knowledge.

Signature

5/24/12
Date

Subscribed and sworn to before me on 24, May 2012

Notary Public/Commissioner of Superior Court

My commission expires:

Karen M. Santacroce
Notary Public, State of Connecticut
My Commission Expires Sept. 30, 2012

State of Connecticut
Office of Health Care Access
Certificate of Need Application

Instructions: Please complete all sections of the Certificate of Need ("CON") application. If any section or question is not relevant to your project, a response of "Not Applicable" may be deemed an acceptable answer. If there is more than one applicant, identify the name and all contact information for each applicant. OHCA will assign a Docket Number to the CON application once the application is received by OHCA.

Docket Number:	
Applicant:	Lawrence + Memorial Hospital
Contact Person:	Ms. Shraddha Patel
Contact Person's Title:	Director of Business Development & Planning
Contact Person's Address:	365 Montauk Avenue, New London, CT 06320
Contact Person's Phone Number:	(860) 442-0711 x. 5185
Contact Person's Fax Number:	(860) 444-3716
Contact Person's Email Address:	spatel@lmhosp.org
Project Town:	New London, CT
Project Name:	Establish and Operate an Elective Angioplasty Program at Lawrence + Memorial Hospital
Statute Reference:	Section 19a-638, C.G.S.
Estimated Total Capital Expenditure:	$0

1. Project Description: Establishment of Cardiac Services

a. Please provide a narrative detailing the proposal.

Response:
Lawrence + Memorial Hospital (L+M) is a not-for-profit 280-bed acute care hospital located in New London, Connecticut. L+M proposes to establish and operate an elective angioplasty program to address local health care needs, improve quality of care in the community L+M serves, reduce health care costs, and improve the patient experience. Angioplasty, or percutaneous coronary intervention (PCI), is a procedure used to open blocked or narrowed coronary arteries. PCI is lifesaving in patients with acute ST-segment elevation myocardial infarction (STEMI) and has been shown to improve quality of life when performed electively in appropriate patients. The proposed program would build upon L+M's primary (or emergency) PCI program (approved by OHCA in Docket Number: 04-30297-CON) and would employ the same high quality cardiac interventionalists, equipment, staff, and facilities. In continuation of L+M's active emergency PCI service, the proposed program will be developed at L+M and supported by a collaborative relationship with Yale-New Haven Hospital (YNHH) and Yale School of Medicine (YSM).

In its early days, PCI carried a significant risk of complication including a 5-7% risk of requiring emergency cardiac surgery. During these years, PCI was performed exclusively at large tertiary care hospitals, often with a surgical team on "standby". The past three decades have seen significant technical and pharmacologic advances in PCI that have lowered complication rates to < 1% and the need for emergency cardiac surgery to 0.3%. Angiographic and procedural success rates have also improved for similar reasons. In low risk patients, the efficacy and safety endpoints are even better.

These observations led many to raise the possibility of performing elective PCI cases at hospitals without on-site cardiac surgery. Emergency PCI for acute heart attack patients is already performed at such hospitals but elective PCI at these facilities has not been widely accepted as standard practice. Despite this, there are many health care centers nationally that have been performing such procedures and reports of their favorable experiences are cited throughout the medical literature. In addition, the practice has been very common in Europe for years. Recently there have been well done, randomized controlled trials presented at national conferences and published in the literature that lend credence to such "off-site" PCI programs and have led to a change in the American College of Cardiology/American Heart Association (ACC/AHA) guidelines for PCI. The latest guidelines now give a Class IIb level of recommendation to such elective PCI programs without on-site cardiac surgery provided that "appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection."

Embracing these changes and bringing elective PCI to L+M would have a significant impact on the quality of care delivered to the patients of southeastern Connecticut. Currently, the common practice is to perform diagnostic angiography at L+M. Should

the patient require a PCI, they are typically transferred to YNHH or another facility with cardiac surgery capabilities for their elective PCI procedure.

Prior to the transfer, the arterial access catheter, which had been placed in an artery in the groin for the diagnostic procedure, is sewn in place. This leads to a prolonged time laying flat in bed and results in multiple transfers with an indwelling arterial sheath[1]. The transfer process for the patient is burdensome and can lead to addition risk. It typically occurs in the following sequence:

1. Patient receives diagnostic procedure at L+M and, if an elective PCI is required, is transferred from L+M cath lab procedure table to hospital stretcher.
2. Patient is transferred from hospital stretcher to ambulance stretcher.
3. Patient rides ~50 miles in ambulance to YNHH.
4. Patient is transferred from ambulance stretcher to YNHH bed.
5. When the YNHH cath lab is available, patient is transferred from YNHH bed to YNHH cath lab procedure table and the procedure is completed.

Once on the procedure table at YNHH, the existing femoral artery sheath is then exchanged for a sterile one. This process of multiple transfers between beds and stretchers and sheath exchanges can lead to an increase in vascular complications and infections as well as significant patient discomfort that would otherwise be avoided if the entire procedure had been completed at L+M. Furthermore, YNHH is a significant distance for most L+M patients and their families causing a significant emotional and financial burden due to the travel distance between L+M and YNHH. The facilities closest to L+M that provide elective PCI are located within large cities which can be difficult to navigate and are prone to heavy traffic. These factors make travel particularly stressful. Plus the costs of parking and potential family loss of work time visiting the patient contribute to the burden.

An ideal "off-site" elective PCI center must meet several important parameters. The center has to provide emergency PCI for a high volume of STEMI patients with quality metrics on par with national benchmarks. The center should have a well established relationship with a tertiary care facility and have mechanisms in place for the rapid communication and transport of unstable patients. An effective elective PCI program should be a collaborative effort between the tertiary facility and the community hospital and be under the leadership of an experienced operator with appropriate procedure volumes and low complication rates. Also, strict patient selection criteria should be instituted so only low risk patients undergo elective PCI procedures. L+M and YNHH (through its Heart & Vascular Center) are ideally suited to develop such a collaborative model. Together, the sites have already been providing emergency PCI services to the patients of southeastern Connecticut and western Rhode Island since May of 2008. The average annual emergency PCI volume is 78 cases and quality metrics are on par or exceed national benchmarks. The Medical Director of the Primary Angioplasty Program at L+M is five years post-fellowship training and has performed over 500 PCIs with high success and low complication rates. The Medical Director is also Assistant Professor at YSM and all other interventional cardiologist physicians that cover the L+M's primary

[1] Indwelling sheath is defined as a catheter left in the body, either temporarily or permanently.

PCI program are on faculty at YSM. Historically, communication and emergent transport with YNHH when needed has been seamless.

Much has changed in the world of PCI since its inception in the 1980's. Advances in medicine and technology have made these procedures safer and more successful. Recent experimental evidence has demonstrated the safety and feasibility of developing elective PCI programs at community hospitals without on-site cardiac surgery which has led to a significant change in the ACC/AHA guidelines. The patients of southeastern Connecticut are exactly the kind of cohort who stands to gain the greatest benefit from these changes. As the only PCI program in the region, L+M in collaboration with YNHH is ideally suited to advance the level of cardiac care in the region and help usher in these changes.

b. Provide letters that have been received in support of the proposal.

Response:
Please refer to Attachment A for letters received in support of the proposal. Letters were submitted by both L+M and YSM physicians. According to the letters of support, elective PCI at L+M would:

- Improve access for southeastern Connecticut residents to needed cardiac services
- Improve quality of cardiac care delivered to service area patients
- Improve continuity of care
- Reduce the burden to patients associated with travel for "out-of-market" post-procedure and follow-up care

In addition, the letters of support propose that L+M is an appropriate location for elective PCI for the following reasons:

- L+M's emergent PCI program is well-established and has excellent outcomes
- L+M is equipped to accommodate elective PCI cases (i.e., the infrastructure is already in place (e.g., YNHH/YSM physicians, facilities, equipment, staff))
- Recently published medical literature supports elective PCI without on-site cardiac surgery
- L+M's cardiac diagnostic capability enables accurate assessment of patient risk to ensure the appropriateness of elective PCI without on-site surgical backup. Furthermore the immediate transfer of images from the L+M catheterization lab to YNHH would allow for real-time feedback from multiple interventional cardiologists to ensure proper patient selection.
- If a complication does arise, L+M's long-standing partnership with YNHH permits the rapid transport of patients that require urgent surgery

2. Clear Public Need

a. Explain why there is a clear public need for the proposal. Provide evidence that demonstrates this need.

Response:
The establishment of an elective PCI program at L+M supports a system-wide strategy to improve the health of the communities L+M serves.

The current proposal is submitted out of a desire at L+M to support the needs of its service area population and stems from a preponderance of evidence that support new practice guidelines which have demonstrated the feasibility of elective PCI without on-site cardiac surgery capabilities. This proposal is driven by the following overriding principles:

I. Elective PCI at facilities without on-site cardiac surgery has been proven safe and effective
II. Local access to elective PCI is needed for L+M service area residents
III. Elective PCI at L+M will improve quality and continuity of care, reduce health care costs, and improve the patient experience

Additional detail regarding the principles that justify the need for L+M to establish an elective PCI program is provided below.

I. Clear Public Need Factor
Elective PCI at facilities without on-site cardiac surgery has been proven safe and effective.

The efficacy of elective PCI without on-site cardiac surgery is substantiated by medical research and evidenced by market trends including:

- New clinical practice guidelines from the ACC/AHA
- Published data from medical literature
- Increased number of states that allow elective PCI without on-site cardiac surgery
- Increased cardiologist support for elective PCI without on-site cardiac surgery

Further elaboration on these points is provided below.

New Clinical Practice Guidelines from the ACC/AHA
In November 2011, The American College of Cardiology Foundation (ACCF), the American Heart Association (AHA), and the Society for Cardiovascular Angiography and Interventions (SCAI) released their "2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention" (please refer to Attachment B for the entire report). Of significance, the 2011 practice guidelines raised the indication for elective PCI without on-site cardiac surgery from Class III ("should not be performed") to Class IIb ("may be considered") based upon the results of several landmark studies.

Specifically, the 2011 practice guidelines state that, "elective PCI can be performed at hospitals without on-site cardiac surgery backup with a high success rate, low in-hospital mortality rate, and low rate for emergency coronary artery bypass graft (CABG)." In order for a successful implementation, the 2011 practice guidelines note that elective PCI may be considered in hospitals without on-site surgery provided that:

- Appropriate planning for program development has been accomplished
- Rigorous clinical and angiographic criteria are used for proper patient selection
- The clinical operators possess strong PCI experience and expertise, and
- The program clearly fills a void in the health care needs of the community.

L+M meets each of the criteria listed above as will be discussed in this application. To summarize, much of the program development for elective PCI without on-site surgery has been accomplished as part of L+M's existing emergency PCI program including (please refer to Section 2d for details):

- A well established relationship with tertiary partner YNHH/YSM
- A process for the rapid transfer of patients requiring urgent surgery to YNHH
- Highly experienced YSM Medical Director and interventionalists
- Fully equipped facilities, including two catheterization laboratories that can accommodate emergent or elective PCI procedures; each lab is capable of immediate transfer of images from L+M to YNHH and real-time audio/video communication with YNHH interventionalists or cardiac surgeons as needed
- Highly experienced catheterization lab staff and inpatient nurses
- Data collection mechanisms for quality assurance
- Participation in national PCI registry for the purpose of benchmarking
- Access to education resources through partnership with YNHH

L+M will adhere to strict patient selection criteria recommended by SCAI in determining which patients are eligible to receive elective PCI at L+M (please refer to Section 2d). Per SCAI, non-high risk patients are the best candidates for elective PCI without on-site cardiac surgery and, therefore, L+M will only perform procedures on these patient types.

The clinical operators of L+M's existing PCI program will be the same clinical operators of the elective program. These physicians are all on faculty at YSM and have significant experience performing both emergent and elective procedures at YNNH and emergent procedures at L+M. As recommended by SCAI guideline statements, L+M's program Medical Director is five years post-fellowship and has performed over 500 procedures to date. Also, L+M's geographic location makes it an ideal candidate for elective PCI services as there are no other providers of this service within a 60 minute drive of L+M. Section 2a and Section 2biii of this application demonstrate the need for cardiac services in the community L+M serves and the existing void of elective PCI in the region.

Of note, the November 2011 practice guidelines for PCI also raised the indication for primary PCI without on-site cardiac surgery from Class IIb ("may be considered") to Class IIa ("is reasonable to perform"). Prior to this update, L+M received OHCA approval and had been completing primary PCI procedures while the practice was clinically recommended as Class IIb. Since Class IIb is now the indication for elective PCI without on-site cardiac surgery, L+M is confident it can perform these procedures successfully as it is a supported clinical practice and L+M meets the criteria for successful implementation as noted above. A copy of the 2007 Expert Consensus from SCAI for Cardiovascular Angiography and Interventions is included in Attachment B.

This document confirms the classification of emergent PCI without on-site cardiac surgery as Class IIb prior to the November 2011 update.

Published Data from Medical Literature

In addition to the studies supporting the latest 2011 ACCF/AHA/SCAI Guidelines for PCI, several notable reports confirm the appropriateness of elective PCI without on-site cardiac surgery. This medical research has demonstrated that patient mortality and morbidity outcomes for elective PCI, as well as the risk of complications requiring urgent surgery, are not significantly different at facilities with or without on-site cardiac surgery backup. Summaries of key studies and articles analyzing this issue are provided below:

C-PORT E Trial

The John Hopkins University randomized, controlled trial entitled the Atlantic Cardiovascular Patient Outcomes Research Team Elective (C-PORT E) was initiated in April 2006 and completed in March 2011. The study was designed to determine whether the safety and benefits of angioplasty are the same at hospitals that perform angioplasty either with or without open heart surgery backup. Patients who entered the study had a cardiac catheterization at a hospital without a cardiac surgery program. If they needed angioplasty, they were then randomized to either stay at the hospital without cardiac surgery for their procedure or to be transferred to a hospital with cardiac surgery. For every four patients, three stayed at the hospital without cardiac surgery for their elective PCI procedure and one was transferred to a facility with on-site surgery.

To be a participant in the study, patients needed to fit certain requirements including:

- Age > 18 years
- Significant coronary artery disease (CAD) ≥ 50% stenosis that requires PCI
- Not high risk
- Stable CAD or an acute coronary syndrome
- Lesion had to be considered treatable at the hospital without on-site surgery before randomization

Participants were excluded if:

- Patient had an acute myocardial infarction with ST-segment elevation
- Patient had an ejection fraction of less than 20%
- Patient required PCI of an unprotected lesion in the left main coronary artery
- Patient considered high risk

Institutional requirements for facilities participating in the study included:

- Primary or emergent PCI programs available 24 hours a day/7 days a week
- Ability to perform minimum of 200 PCIs per year (the sum of emergent and elective); "ramp up" of cases were allowed so that 100 PCI procedures were required in first year, increasing to 200 in second year

- Formal agreement with tertiary hospital partner for receipt of emergency transfers
- Formal agreement with properly equipped transfer partner (e.g., ambulance, helicopter) with anticipated response time within 30 minutes
- Formal PCI development program (includes detailed care plans and pathways, order sets, and logistics and the training of staff in the care of patients undergoing PCI)
- Interventionalists that complete ≥ 75 angioplasty cases per year (the sum of emergent and elective) which is the minimum number to maintain clinical competence

Between April 2006 and March 2011, 99,479 patients at participating study hospitals had a diagnostic catheterization. Of the 76.1% who provided consent to participate in the trial, 21,165 were judged to require PCI after the diagnostic procedure. Of this total, 2,298 or 10.9% were excluded because they were judged to be at too high a risk for study participation (i.e., they were too high risk to complete elective PCI without on-site surgery). Therefore, 18,867 patients were eligible to be part of the study; however, 18,548 actually participated (319 patients pulled out of the study and did not undergo PCI).

Outcomes measured in the CPORT-E study included 6-week mortality and 9-month incidence of major adverse cardiac events. According to study results published in the March 2012 edition of The New England Journal of Medicine (NEJM) (please refer to Attachment C for the full article), "PCI performed at hospitals without on-site cardiac surgery was non-inferior to PCI performed at hospitals with on-site cardiac surgery with respect to mortality at 6 weeks and major adverse cardiac events at 9 months." Mortality rates were nearly identical 6 weeks post-procedure at just below 1%. At nine months post-procedure, similar to the six-week mortality results, patients fared about the same regardless of whether PCI was completed at a facility with or without on-site surgery. At 9 months, the death rate was the same for both groups at 3% and incidence of Q-wave myocardial infarction was also the same for both groups at 3%. Emergency surgery was only required in 23 of the 18,548 cases (or 0.1% of the cases) and occurred more frequently at hospitals with on-site surgical backup.

The comparable medical and safety outcomes between hospital types suggest that PCI is safe to perform at hospitals without on-site cardiac surgery within the bounds established by the CPORT-E trial. Of note is that prior to the release of the CPORT-E results, the ACCF/AHA/SCAI practice guidelines for PCI had already raised the indication for elective PCI without onsite surgery. Although CPORT-E was not considered for this update, results of the trial support the reclassification.

Meta-Analysis Published in the Journal of the American Medical Association
In December 2011, a large meta-analysis published in the Journal of the American Medical Association (JAMA) presented further evidence of the safety of PCI without on-site surgery (please refer to Attachment D for the full article). The

analysis reviewed 15 controlled studies of both primary and non-primary PCI performed at centers with and without on-site surgery between 1990 and 2009. In all, the analysis included 124,074 patients who underwent primary PCI for STEMI and 914,288 patients who underwent non-primary PCI. Similar to CPORT-E, this analysis determined that PCI performed at centers without on-site surgery had similar outcomes as compared to centers with on-site surgery backup. According to the study, the rate of in-hospital mortality for elective PCI was 1.4% for sites without on-site surgery compared to 2.1% for sites with on-site surgery. The incidence of emergency cardiac surgery at centers without on-site surgery was found to be low. The observed rate was 0.2% for elective PCI cases. Due to the large number of patients evaluated and the quality of studies included, authors of the meta-analysis believe the study is an important addition to the growing amount of literature supporting elective PCI without on-site surgery.

The American College of Cardiology Study Published in the Journal of the American College of Cardiology

In 2009, a study published in the Journal of the American College of Cardiology (JACC) analyzed data from the ACC-National Cardiovascular Data Registry (ACC-NCDR) (please refer to Attachment D for the full article). The results showed that patients who received elective or emergency PCI at hospitals without on-site surgery had no difference in procedural success, morbidity, rates of emergency surgery, or mortality, compared to patients receiving the same procedure at hospitals with on-site surgery. These outcomes were observed despite the fact that sites without on-site surgery maintained lower annual PCI volumes and had higher proportion of patients presenting with acute myocardial infarction. The observed unadjusted procedural outcomes from the study are shown in Table A below:

Table A: Procedure Outcomes for Elective PCI Patients by Site Type

Outcome	Site Without On-Site Surgery (n = 6,802)	Site With On-Site Surgery (n = 268,312)
PCI Procedure Success	6,438 (95%)	250,923 (94%)
Total Complications	345 (5.1%)	14,692 (5.5%)
Overall Mortality	54 (0.8%)	2,025 (0.8%)
Emergency CABG	12 (0.2%)*	753 (0.3%)
Mortality after Emergency CABG	1/10 (10.0%)*	83/753 (11.0%)

*Note: study showed figures of 12 and 10 emergency CABG procedures. The reason for this discrepancy is unclear.

Similar to the meta-analysis results published in JAMA in December 2011, there were very low rates of emergency cardiac surgery observed after elective PCI regardless of whether surgery was available on-site. Of note in this analysis was the mortality rate after cardiac surgery when urgent surgery was required. Mortality was similar despite that for sites without on-site surgery, a patient transfer was involved to move the patient to a tertiary facility with cardiac surgery capabilities. This study indicates that on-site surgery backup is not required to optimize patient

outcomes and confirms elective interventions can be performed safely at facilities without on-site surgery.

MASS COMM Trial
The MASS COMM trial, currently in progress, is a randomized controlled study designed to compare the acute safety and long term outcomes among Massachusetts hospitals with and without on-site cardiac surgery for patients treated with elective PCI. The study began in June 2006 and is expected to be completed by June 2012 (final data collection). Ten Massachusetts community hospitals who lack on-site surgery are participating. Similar to the CPORT-E trial, outcomes will be measured at various intervals post-procedure and compared to outcomes at tertiary facilities with on-site surgery. The trial is jointly sponsored by Massachusetts community hospitals and the Massachusetts Department of Health. Although data from this study is yet to be published, the MASS COMM trial is another demonstration of studies underway designed to evaluate whether on-site cardiac surgery is essential for patient safety and optimal outcomes during and after elective PCI.

2012 ACCF/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update
In May, the 2012 ACCF/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards was published in JACC (please refer to Attachment D for full report). This latest Expert Consensus Document reiterated many of the recommendations published in the 2011 ACCF/AHA/SCAI practice guidelines for PCI. Key recommendations noted in the May 2012 document include:

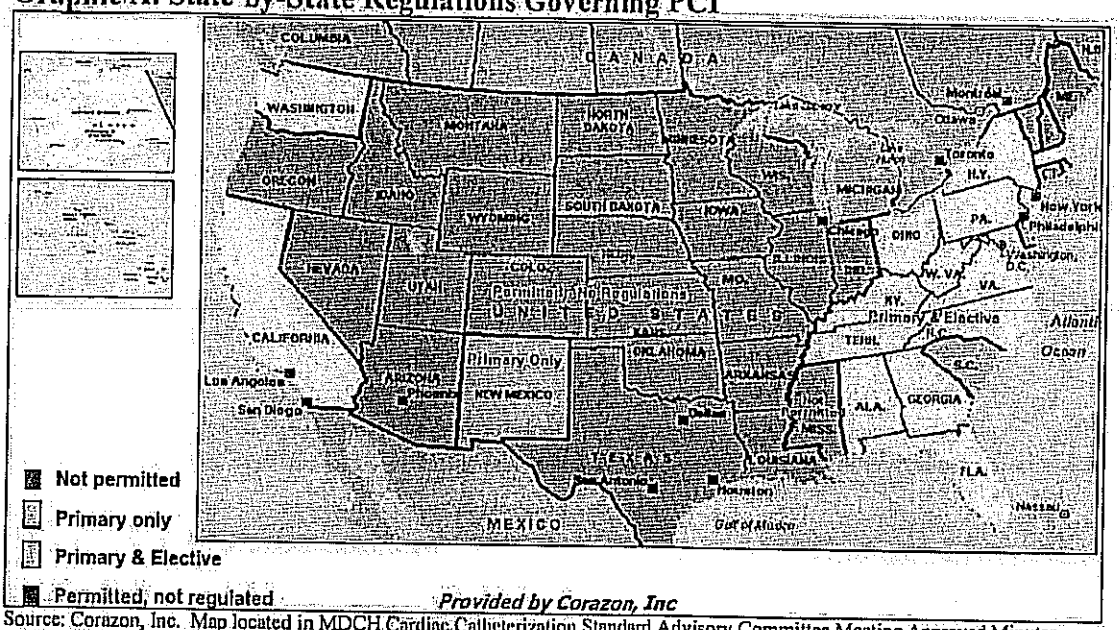
- Elective PCI without on-site surgery should be fostered in markets where access to this "higher level of cardiovascular care" is limited
- Elective PCI without on-site surgery is appropriate when patients are appropriately selected and backup precautions are in place, and
- Patients who are high risk should not undergo elective PCI without on-site cardiac surgery.

This application will demonstrate L+M's compliance with these updated guidelines.

Other
Additional studies and articles demonstrating the safety and effectiveness of elective PCI without on-site surgery are noted in Section 3e of this application and full-texts are provided in Attachment D.

Increased Number of States that Allow Elective PCI without On-Site Cardiac Surgery
The number of states that allow elective PCI procedures to be performed without on-site cardiac surgery continues to grow. As of 2010, 41 states permit elective PCI without on-site surgery with varying requirements. Graphic A depicts the regulations governing such procedures on a state-by-state basis. Four states (Maine, Vermont, Rhode Island, and Mississippi) do not permit primary or elective PCI without on-site surgery while five states, including Connecticut, allow primary PCI without on-site surgery.

Graphic A: State-by-State Regulations Governing PCI



Source: Corazon, Inc. Map located in MDCH Cardiac Catheterization Standard Advisory Committee Meeting Approved Minutes (http://www.michigan.gov/documents/mdch/12.1.10.CCSAC.Minutes_345281_7.pdf).

There has been much activity regarding regulations related to PCI without on-site surgery. Recent regulatory changes for select states include[2]:

- New York – regulatory changes signed in November 2009 allow elective PCI without on-site cardiac surgery with certain requirements and prohibit the addition of diagnostic only labs.
- Pennsylvania – in 2001, 10 programs granted exceptions to pilot both primary and elective PCI without on-site surgery. In 2009, 5 new programs approved if they qualified for the C-PORT E trial.
- Georgia – in 2005, 10 hospitals permitted to participate in national clinical trial to allow community hospitals to provide elective and emergent PCI without on-site surgery. In July 2009, 16 additional hospitals were granted approval to do primary and elective PCI without participation in the CPORT-E trial.
- California – allows primary PCI without on-site surgery and in January 2009 passed bill for pilot to allow 6 hospitals to add elective PCI without on-site surgery.
- West Virginia – in August 2008, implemented 3 tiers of service. Tier 1 must demonstrate minimum diagnostic catheterization volume; after 1 year of diagnostic catheterizations, facility can apply for primary PCI under Tier 2; after 2 years of offering primary PCI, hospitals may apply for elective PCI without on-site surgery under Tier 3.

[2] Source: MDCH Cardiac Catheterization Standard Advisory Committee Meeting Approved Minutes (http://www.michigan.gov/documents/mdch/12.1.10.CCSAC.Minutes_345281_7.pdf).

It is likely that the number of states allowing elective PCI without on-site cardiac surgery will continue to increase as more states participate in trials and demonstration projects and as more research and data supporting the practice becomes available.

Increased Cardiologist Support for Elective PCI without On-Site Cardiac Surgery
Recent surveys conducted by *theheart.org* and *U.S. News & World Report* have demonstrated that the majority of cardiologist respondents believe that elective PCI at centers without cardiac surgery on-site can be performed safely and effectively (please refer to Attachment D for survey). In fact two-thirds of respondents supported these programs.

Of those in support of elective PCI without on-site surgery, several noted the procedure had been performed "for a very long time" particularly in Europe. Wrote Dr. Henry Altszuler of Robert Wood Johnson Medical School in New Brunswick, NJ, "as a participant in the [CPORT-E] trial, I can attest to the benefits...With intelligent case selection and experienced staff and physicians, [elective PCI without on-site surgery] is a seamless process and a 'win-win' for patients and hospitals." Another respondent from Baltimore, Dr. Martin Albornoz, noted "case selection, physician experience, and careful oversight are key" to a successful elective PCI program. Yet another respondent noted that elective PCI without on-site surgery can be safe "if cases are chose carefully and there is a plan for emergent transfer to a facility with surgical support in the rare instance that there is a complication that requires urgent surgical intervention." Each of these requirements noted by the surveyed cardiologists has been addressed in L+M's program as demonstrated in this application.

Even among survey respondents who were more skeptical to elective PCI without on-site surgery, physicians noted "there are legitimate reasons to do PCI without surgery at remote hospitals where patients might not have local access." The location of a facility was a key factor to many in deciding whether a hospital should provide elective PCI without on-site cardiac surgery. As demonstrated in this application, the distances from L+M to facilities that provide elective PCI are high and can place an undue burden on patients thus making L+M an ideal candidate for elective PCI (please refer to II. Clear Public Need Factor).

II. Clear Public Need Factor

Local access to elective PCI is needed for L+M service area residents.

Local access to elective PCI is needed for L+M service area residents due to a:

- Regional lack of elective PCI providers
- Service area population with poor health statistics and health status compared to state and national averages

Further elaboration on these points is provided below.

Regional Lack of Elective PCI Providers

L+M Hospital, which is located in the town of New London, is geographically isolated from facilities that perform elective PCI procedures. There are no providers of elective PCI in L+M's service area, within New London County, or within the eastern half of the state as shown in Graphic B below (L+M service area is located within blue oval on Graphic). Currently 11 facilities are capable of performing elective PCI in Connecticut. It is clear from Graphic B that L+M's service area and the entire eastern half of Connecticut have a service gap in elective PCI.

Graphic B: Facilities in Connecticut that Offer Elective PCI

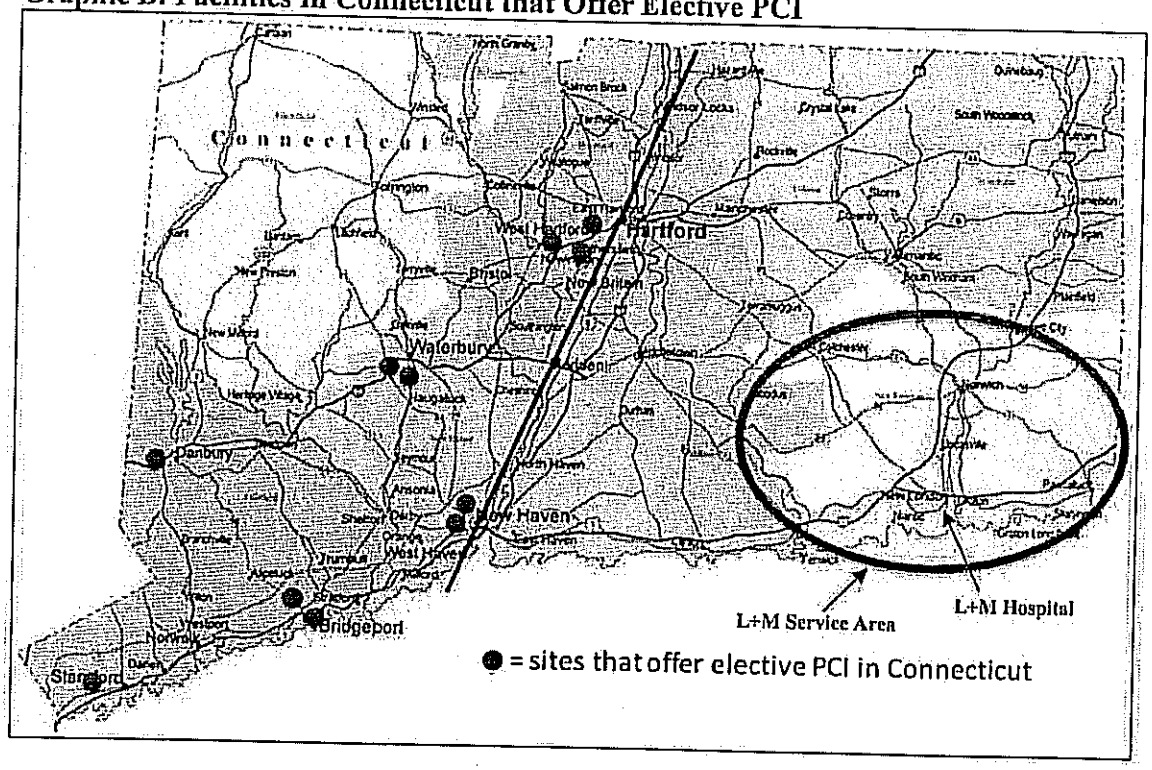


Table B below presents a tabulation of mileage and drive time estimates from L+M Hospital to the closest facilities within Connecticut and Rhode Island that provide elective PCI. Metrics were sourced from Google Maps and assume no delay during transit due to traffic or construction.

Table B: Mileage and Drive Time from Town of New London, CT to Closest Facilities that Offer Elective PCI

Hospital	City, State	Miles from Town of New London	Drive Time
YNHH	New Haven, CT	49	58
St. Francis Hospital	Hartford, CT	48	59
Hartford Hospital	Hartford, CT	49	60
Miriam Hospital	Providence, RI	61	64

Source: Google Maps.

Currently, patients must travel nearly one hour to a facility that can perform elective PCI when transferred or referred for such a procedure. As noted previously, L+M is an ideal location for elective PCI without on-site cardiac surgery due to its existing successful emergent program and infrastructure.

For some patients who require elective PCI, the distances and travel times to sites with this service are unmanageable and, therefore, care is not sought. Within L+M's service area, there are several towns whose poor socioeconomics may limit access for residents. For example, in the town of New London, where 9% of the total service area population resides, 14.3% of households live below the federal poverty line (as a comparison, 5.8% of Connecticut residents overall live below the poverty line). In addition, in the town of Norwich, which accounts for another 11% of the total service area population, 8.1% of households live below the poverty line (please refer to Attachment E for detailed demographic information). Thus, at least one-fifth of the population in L+M's proposed service area may find travel to facilities with elective PCI cost-prohibitive and therefore, may forgo necessary care. L+M's proposed elective PCI program would address the unmet demand currently experienced by these and other service area residents.

In the medical literature, distance to facilities that can perform elective PCI is a major consideration when evaluating the feasibility of offering elective PCI without on-site surgery. As noted previously, the November 2011 ACC/AHA/SCAI practice guidelines for PCI state:

> "It is only appropriate to consider initiation of a PCI program without on-site cardiac surgical backup if this program will clearly fill a void in the healthcare needs of the community. Competition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interests of the community."

Furthermore, the more recent May 2012 ACCF/SCAI Expert Consensus Document of Cardiac Catheterization Lab Standards (noted earlier) state:

> "It behooves the cardiology community to foster [elective PCI without on-site surgery] programs...when such programs improve access to a higher level of cardiovascular care than would otherwise be available."

L+M's proposed elective PCI program is in compliance with these recommendations. The Hospital's geographic isolation made it an ideal candidate for primary PCI when the program was approved by OHCA in 2006. Today, L+M remains an ideal candidate for elective PCI as not only is the Hospital still geographically isolated from elective PCI providers as depicted in Graphic B, but its emergency PCI program has experienced more than four years of success with excellent quality outcomes. With L+M's existing PCI service in place, much of the program development required to offer elective PCI is already complete and the addition of elective procedures would be seamless.

Further demonstrating the gap in cardiac services in L+M's market, according to preliminary data published by OHCA for its Statewide Health Care Facilities and Services Plan, DEMHS[3] Region 4 (eastern Connecticut), which includes L+M, The William W. Backus Hospital, Day Kimball Hospital, and Windham Hospital, has a greater demand for medical and surgical cardiac services than there is capacity to serve (please refer to Attachment D for exert from the draft report). OHCA's initial analysis indicates an unmet need for cardiac care throughout eastern Connecticut. Elective PCI at L+M can help close the service gap by shifting migration and referral patterns and allowing patients to receive necessary care locally.

Service Area Population with Poor Health Statistics and Health Status Compared to State and National Averages

New London County, which comprises most of L+M's service area, has poorer cardiovascular health than state and national averages as demonstrated in key statistics. Contributing to this fact include the high prevalence of key risk factors for cardiovascular disease and coronary heart disease in New London County, as well as the aging population and race/ethnic mix. These factors portend a high incidence of coronary heart disease in the market and an anticipated need for increased diagnostic and interventional coronary procedures such as PCI. Detailed information (e.g., incidence, prevalence, demographic data) that supports L+M's contention that elective PCI is needed in its local market is provided in Section 2b.iii of this application. Summarizing Section 2b.iii, compared to state and national averages, New London County has:

- High mortality and hospitalization rates for heart disease
- Increased prevalence of key risk factors including high blood pressure, diabetes, smoking, obesity, and physical inactivity
- High proportion of elderly residents (population aging has a relatively large effect on the incidence of heart disease and the use of cardiac-related services).
- High proportion of black non-Hispanic residents in select service area towns (this race/ethnic mix has an increased risk for cardiac-related health issues)

Despite modest population growth expected in the proposed service area overall, the factors above indicate a high demand for cardiac services in L+M's market.

III. Clear Public Need Factor

Elective PCI at L+M will improve quality and continuity of care, reduce health care costs, and improve the patient experience.

Elective PCI at L+M will improve quality and continuity of care, reduce health care costs, and improve the patient experience by:

- Minimizing the compromise to quality of care associated with "decoupled" diagnostic catheterization and elective PCI
- Increasing PCI volume at L+M, thus enhancing hospital and team experience and, in turn, quality and safety
- Reducing costs associated with patient transfers and adverse health events

[3] DEMHS=Department of Emergency Management & Homeland Security. DEMHS Region 4 includes all of New London County, all of Windham County, and part of Tolland County.

- Maintaining patients' medical home[4] and improving continuity of care
- Reducing the emotional and financial burden on patients and families

Further elaboration on these points is provided below.

Minimizing the Compromise to Quality of Care Associated with "Decoupled" Diagnostic Catheterization and Elective PCI

Coupling diagnostic cardiac catheterization and elective PCI in one patient visit is a supported clinical practice. Without the ability to perform "ad hoc" elective PCI at time of diagnostic cardiac catheterization, patients must be transferred to another facility to receive this procedure. As shown in Table C, there were 138 patients in FY 2011 who upon receiving a diagnostic cardiac catheterization at L+M were transferred the same day to YNHH or another facility to receive elective PCI. These 138 patients were candidates for transfer due to the severity of their arterial blockage; however, because these patients were stable and non-STEMI, they could not be treated at L+M as an emergent case.

Table C: L+M Diagnostic Catheterization Volume and Volume Transferred Same Day for Elective PCI

Fiscal Year	Total Diagnostic Caths	Total Patients Transferred for Elective PCI	Location of Transfer		
			YNHH	St. Francis	Hartford Hospital
2009	810	168	161	7	0
2010	858	200	198	2	0
2011	724	138	137	1	0
2012*	266	49	49	0	0

*Note: Represents actual volumes for FY 2012 through 3-1-12
Source: L+M Department of Cardiology.

The transfer process can compromise quality of care for patients requiring elective PCI. As described previously in this application, there are opportunities for infections due to multiple invasive punctures, as well as opportunities for other vascular complications including blood loss. Other consequences patients face include increased or prolonged exposure to anticoagulants and increased x-ray doses from the two separate procedures at each facility. In addition, because transferred patients are stable upon arrival at the receiving facility, they often wait several hours for their elective procedure as emergent and scheduled cases typically take priority. Transferred patients are forced to lay flat for an extended period of time due to the indwelling sheath which can cause significant discomfort, particularly for the elderly population.

If L+M were to provide elective PCI and "couple" the procedure with patients' diagnostic catheterization, a subset of the previously transferred cases would remain at L+M and the compromises to quality of care would be lessened. To further ensure high quality of care, L+M plans to adhere to strict patient selection criteria defined by SCAI (see Table I in

[4] The medical home model is designed to provide a single point of coordination for all health care, including specialists, hospital, and post-acute care. The primary care physician acts as a facilitator and coordinates all levels of care. Coordination in this model reduces fragmentation in patient care to lower costs and improve outcomes.

Section 2d). Based on the SCAI recommendations, non-high-risk patients are the best candidates for elective PCI without on-site cardiac surgery and would be the ideal cohort to receive elective PCI at L+M. Patients considered high-risk would continue to be transferred to facilities with surgical backup as they are now.

Increasing PCI Volume at L+M, Thus Enhancing Hospital and Team Experience and, in turn, Quality and Safety

Section 3c of this application outlines the incremental volume expected at L+M if the Hospital were to perform elective PCI. Proponents of elective PCI without on-site cardiac surgery argue that elective PCI is necessary to sustain and improve primary angioplasty programs. Advocates reason that added volumes would increase hospital and team experience, thus improving proficiency and the quality and safety of all PCIs performed. At 78 PCI cases per year on average, L+M's emergent PCI program is robust and its quality indicators are excellent. Although L+M's interventionalists (provided by YNHH/YSM) already have high volumes, the addition of elective PCI at L+M will increase hospital and team experience which can improve outcomes at L+M further.

Reducing Costs Associated with Patient Transfers and Adverse Health Events

Coupled diagnostic catheterization and elective PCI in the same care setting can save payers approximately $7,350 per case based on Medicare rates versus completing the procedures in a decoupled or staged fashion. This figure was provided by the Michigan Department of Community Health which in 2010 was re-evaluating its policy on hospitals providing elective PCI without on-site cardiac surgery.[5] The incremental cost associated with the decoupled procedure is attributed to duplicate testing and redundant costs for dye, catheters, surgical trays, and other supplies which are provided at each facility. In addition, according L+M internal data, the cost to payers for ground/ambulance transfers from L+M to another institution is $1,000 per trip.

For the 138 patients transferred from L+M to facilities with elective PCI in FY 2011, this equates to over $1.1 million in annual costs to payers and, in turn, the health care system overall as a result of decoupled diagnostic catheterizations and elective PCI. If L+M were to perform elective PCI, these costs would be reduced significantly as nearly 90% of patients transferred currently are non-high-risk and thus candidates to receive their elective PCI procedure at L+M (please refer to Section 3d for additional details).

Providing elective PCI at L+M would reduce the risk of infections, bleeding complications, and other adverse events associated with multiple procedures at two facilities. As noted in the previous section, multiple patient transfers, multiple invasive punctures, extended exposure to anticoagulants, and patients laying flat for an extended period of time, all pose significant health risks for patients. While the cost of transfers is substantial, the potential cost of adverse health events can be even greater. Complications can lead to extended hospital stays and increased use of health care resources (e.g., medications, nursing, physicians) both in and out of the acute care setting.

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[5] Source: MDCH Cardiac Catheterization Standard Advisory Committee Meeting Approved Minutes (http://www.michigan.gov/documents/mdch/12.1.10.CCSAC.Minutes_345281_7.pdf).

If L+M were to offer elective PCI, the potential for health complications would be mitigated resulting in reduced costs for the health care system overall.

Maintains Patients' Medical Home and Improves Continuity of Care

Elective PCI at L+M would enable patients to receive their care locally and remain with their medical home which is the recommended approach of the current health care and payment reform efforts. Patients that are transferred from L+M or referred out of the market for elective PCI often experience a disconnect from their medical home as their medical record and primary or referring physician do not easily cross hospital boundaries at this time. Key information regarding a patient's medical history can be "lost" when patients travel outside their medical home for care. The reverse is also true as pertinent medical information originating from an out-of-market facility can too easily fail to transfer to the patient's local health providers thus impacting continuity of care.

If L+M offered elective PCI, information from the Hospital's electronic medical record (EMR) could be viewed by local primary and referring physicians easily. In addition, providers at L+M Hospital including covering cardiac interventionalists would have access to test results and other key information vital to the management of a patient's health. Continuity of care, and in turn quality of care, improves as accurate health information is shared in a timely fashion. Also, offering elective PCI at L+M would enable the interventionalists performing the elective PCI procedure to also conduct the post-procedure follow-up visit, thereby further improving continuity of care and patient satisfaction.

In the case of stable CAD, or based on patient preference, uncoupling PCI from the diagnostic catheterization and performing each procedure on separate days is possible. Even in this scenario, completing both procedures locally, within a patient's medical home, has advantages. The most significant benefit is the time afforded to both the patient and patients' local physicians to communicate with one another and develop the optimum treatment path. This level of collaboration among providers is challenging when patients leave the market for elective PCI. Another benefit of uncoupled procedures provided locally is that patients and families have the opportunity to meet the performing interventionalist prior to admission, ask questions, and gain a better understanding of the procedure itself, benefits, and risks. Patients are more informed and patient's families have an opportunity to learn their role in pre- and post-procedure care.

Reducing the Emotional and Financial Burden for Patients and Families

Patients who are transferred from L+M to another facility for elective PCI often face an undue emotional and financial burden. The transfer process as described previously can be painful as patients are moved frequently from stretchers to beds to tables with an indwelling sheath in the femoral artery in their groin. Patients must lay flat for an extended period of time which can be difficult for some patients. Multiple sheath exchanges also increase the risk of infection and other complications. In addition, patients who receive their care out-of-market and become an inpatient are separated from their family and are forced to navigate unfamiliar settings and meet new physicians. Patients also incur significant costs to travel to YNHH or other facilities for necessary

post-procedure and follow-up care. Some patients who do not wish to travel often forgo this important aspect of care delivery.

For families, a financial burden exists with multiple procedures at two facilities. When patients are transferred and have their procedure completed on an inpatient basis, families incur costs of travel, parking, and hotel accommodations as needed. Plus families face a potential loss of work time when visiting the patient. The financial burden of families is incurred regardless of whether the patient was transferred to another facility or directly referred to another facility for elective PCI. Also, similar to patients, families are also forced to navigate unfamiliar settings and interact with new physicians. For both patient and families, these can be stressful situations.

If L+M provided elective PCI services, a subset of patients and, in turn, their families could remain local. Thus the emotional and financial toll inherent when care is sought out-of-market could be avoided.

b. Provide the following regarding the proposal's location:

i. The rationale for choosing the proposed service location;

Response:
L+M Hospital is the appropriate location for the proposed service as the Hospital currently offers emergency PCI and is fully equipped from a facilities and clinical standpoint to add elective PCI. The Hospital has two fully functioning, well-equipped, catheterization laboratories both capable of completing emergent PCI and the proposed elective PCI service. In addition, the PCI service is staffed by highly trained physicians from YNHH/YSM with experience performing both emergent and non-emergent PCI procedures. The proposed service would be completed as an inpatient procedure in the three year planning horizon. Supporting the inpatient service at the Hospital is a:

- Coronary Care and Telemetry Unit (25 beds) and
- Coronary Intensive Care Unit (10 beds)

Both inpatient units are staffed by highly trained nurses capable of managing care for patients undergoing PCI. As noted in Attachment F, the Education Plan for Non-Emergent Angioplasty will improve and maintain staff competency for all personnel related to the PCI program. The process outlined in the Education Plan encompasses varied learning methodologies including self learning modules, formal lectures, clinical experience at YNHH as needed, observation, vendor-sponsored in-services, and dry run simulations for the cath lab and post-procedure units.

The addition of elective PCI would augment L+M's existing cardiovascular program which includes:

- Cardiac Catheterization (diagnostic procedures including right and left heart catheterizations; 2,400 procedures completed between FY 2009 and FY 2011)
- Primary or Emergency PCI (program approved by OHCA (Docket #04-30297-CON) and more than 300 procedures completed since program inception)
- Interventional Radiology Laboratory

- Pacemaker Insertions and Evaluation
- Implantable Cardiac Defibrillator (ICD) Insertions and Evaluation
- Vascular and Thoracic Surgery
- Cardiac Rehabilitation
- Cardiac Imaging Services including CT (64-slice scanner) and MRI (3.0 Tesla scanner)
- Stress Testing (Exercise and Echocardiogram)
- Nuclear Cardiac Imaging (Stress, Rest, Pharmacologic)
- Event Monitoring
- Echocardiography
- 24-Hour Holter Monitoring and 30-Day Event Monitoring
- Tilt Table Testing
- Electrocardiography (EKG)
- Outpatient Cardiovascular Care and Prevention Programs including Smoking Cessation, Weight Management Programs, and Nutrition Services

ii. The service area towns and the basis for their selection;

Response:
The service area for the proposed service includes the Hospital's existing primary and secondary service area towns. They include:

Primary service area (PSA): East Lyme, Groton, Ledyard, Lyme, Montville, New London, Old Lyme, Stonington, North Stonington, and Waterford

Secondary service area (SSA): Bozrah, Colchester, Franklin, Griswold+Lisbon, Old Saybrook, Preston, Norwich, Salem, Voluntown, and Westerly (RI)

As demonstrated in Section 3a of this application, the majority of L+M's emergent PCI cases originate from L+M's existing PSA and SSA. In FY 2011, nearly 80% of L+M's PCI patients resided in towns within the Hospital's PSA or SSA. A similar draw is expected for the proposed elective PCI service.

iii. The population to be served, including specific evidence such as incidence, prevalence, or other demographic data that demonstrates need;

Response:
The population to be served by this proposal includes residents in the service area towns listed above. Both state and New London County health statistics indicate a high need for cardiovascular services, including elective PCI, in the market served by L+M. According to "The Burden of Cardiovascular Disease in Connecticut; 2010 Surveillance Report," a report issued by the Connecticut Department of Health (CT DPH):

- Cardiovascular disease[6] (CVD) is the leading cause of death in the state overall and for residents aged 85+; CVD is the 2nd leading cause of death for residents aged 65-84
- CVD accounted for one-third of all Connecticut resident deaths in 2008
- Coronary heart disease[7] accounted for 49% of all CVD deaths
- 18% of all hospital discharges in Connecticut are due to CVD; approximately 26% of CVD hospitalizations are due to coronary heart disease
- $2.2 billion was billed for CVD hospitalizations in Connecticut in 2008 (approximately 34% of CVD charges are for coronary heart disease)
- Premature mortality rates[8] for coronary heart disease are significantly higher for the black non-Hispanic population compared to rates for the white non-Hispanic and Hispanic populations
- Key risk factors for CVD and coronary heart disease include:
    - High blood pressure, high blood cholesterol, cigarette smoking, diabetes, obesity, and physical inactivity
    - Increasing age
    - Race/ethnicity (age-adjusted mortality rates are highest for the black non-Hispanic population compared to white non-Hispanic and Hispanic populations)
    - Family history of heart disease

As noted in the CT DPH report, cardiovascular health is of great public concern statewide as CVD and coronary heart disease are major drivers of deaths, hospital utilization, and health care costs in Connecticut. More locally to L+M, cardiovascular health is as significant an issue because regional statistics for prevalence of risk factors, hospitalization rates, and other key metrics are worse than statewide and national averages.

In 2007, a community health assessment was completed for the local market of L+M. This assessment compared key health statistics in New London County[9] to statewide and national statistics. According to the analysis, New London County fares worse than both state and/or national data in several key risk factors for cardiovascular disease outlined previously including percent of residents with high blood pressure, percent of residents who smoke, percent of residents with diabetes, percent of residents who are obese, and percent who are relatively inactive (please refer to Table D and Attachment G for a summary of the findings). In the same community health assessment, key statistics including admission rates and mortality rates for cardiovascular disease were also analyzed. According to the assessment, New London County residents have a higher hospital admission rate and mortality rate than the state overall for residents who had an acute myocardial infarction (AMI) (please refer to Table D). In addition, mortality rates for heart disease are higher in New London County than state averages for both residents

[6] Cardiovascular diseases are diseases of the circulatory system, which includes myocardial infarction, ischemic heart disease, valvular heart disease, peripheral vascular disease, arrhythmias, high blood pressure and stroke.
[7] Coronary heart disease is a form of heart disease resulting from impaired circulation in one or more coronary arteries.
[8] Premature mortality is defined as the "years of potential life lost before age 75."
[9] New London County comprises most of L+M's service area.

aged 45-64 and those aged 65+. For years, L+M has been focusing on prevention including outreach programs designed to help residents manage their weight, and health and exercise programs designed to encourage physical fitness. For its own employees, L+M offers weight management programs and smoking cessation classes. While these efforts have demonstrated success, the community health assessment revealed a true local need for cardiac care as key risk factors are more prevalent and as a result, mortality and admission rates are higher than state averages.

Table D: Health Status Profile from Community Health Assessment

	New London County	Connecticut	United States
Risk Factors			
% with High Blood Pressure	25.1	23.8	25.5
% Smokers	24.5	16.5	20.6
% Diabetes Age 18+	8.7	6.5	7.3
% Obese	24.1	20.1	24.4
% Limited Activity	23.8	15.1	NA
% Sedentary	21.9	21.2	23.8
Cardiac Statistics			
AMI Hospital Admission Rate	175.3	129.9	NA
AMI Mortality Rate	47.8	44.2	58.7
Heart Disease Mortality Age 45-64	122.2	110.1	NA
Heart Disease Mortality Age 65+	1,518.1	1,496.3	NA

Source: Community Health Assessment for New London County, Connecticut (May 11, 2007).

Another study completed by the Robert Wood Johnson Foundation (RWJF) in 2012 evaluated the health of communities and ranked New London County as 5th of 8 counties in the state of Connecticut in health outcomes and health factors. In fact, New London County ranked 5 or 6 out of 8 counties in all health categories including mortality, morbidity, health behaviors, clinical care, social and economic factors, and physical environment. Key statistics from the study that relate to cardiac health are listed in Table E.

Table E: Health Status Profile from RWJF Study

	New London County	Connecticut	United States Benchmark
Health Behaviors			
Adult Smoking	19%	16%	14%
Adult Obesity	24%	23%	21%
Clinical Care			
Primary Care Physicians	1,098:1	729:1	631:1
Preventable Hospital Stays	70	63	49

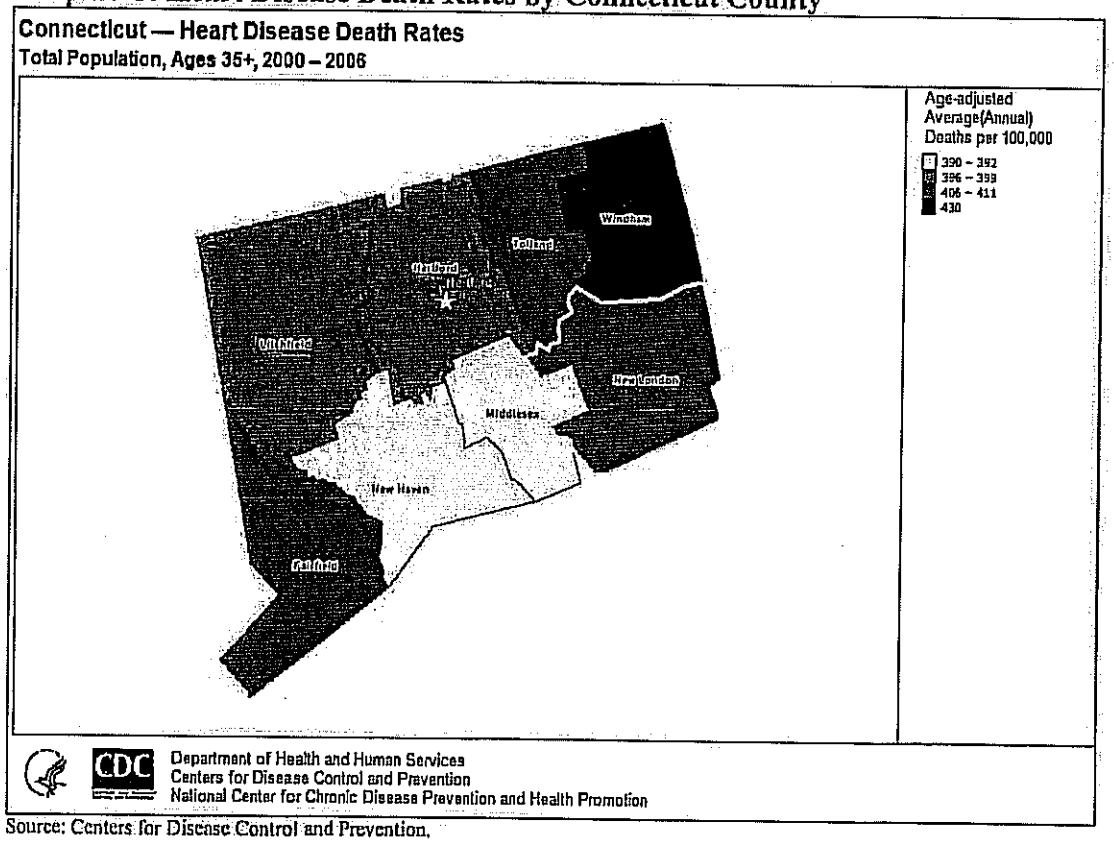
Source: Robert Wood Johnson Foundation, County Health Rankings & Roadmaps (http://www.countyhealthrankings.org/#app/).

Similar to the 2007 community needs health assessment, the study from RWJF demonstrates that smoking and obesity, key risk factors for heart disease, remain a

serious issue in New London County. In addition, the ratio of population to primary care physicians is very high in the County. Lack of access to primary care can negatively impact the health of a community as treatment for needed services can be delayed or not sought at all. Residents with CVD or coronary heart disease can remain undiagnosed without an adequate base of primary care to order diagnostics or refer patients to cardiologists. Lack of primary care can lead to worsening health status and can contribute to the RWJF's other finding of an increased number of preventable hospital stays in New London County compared to state and national averages.

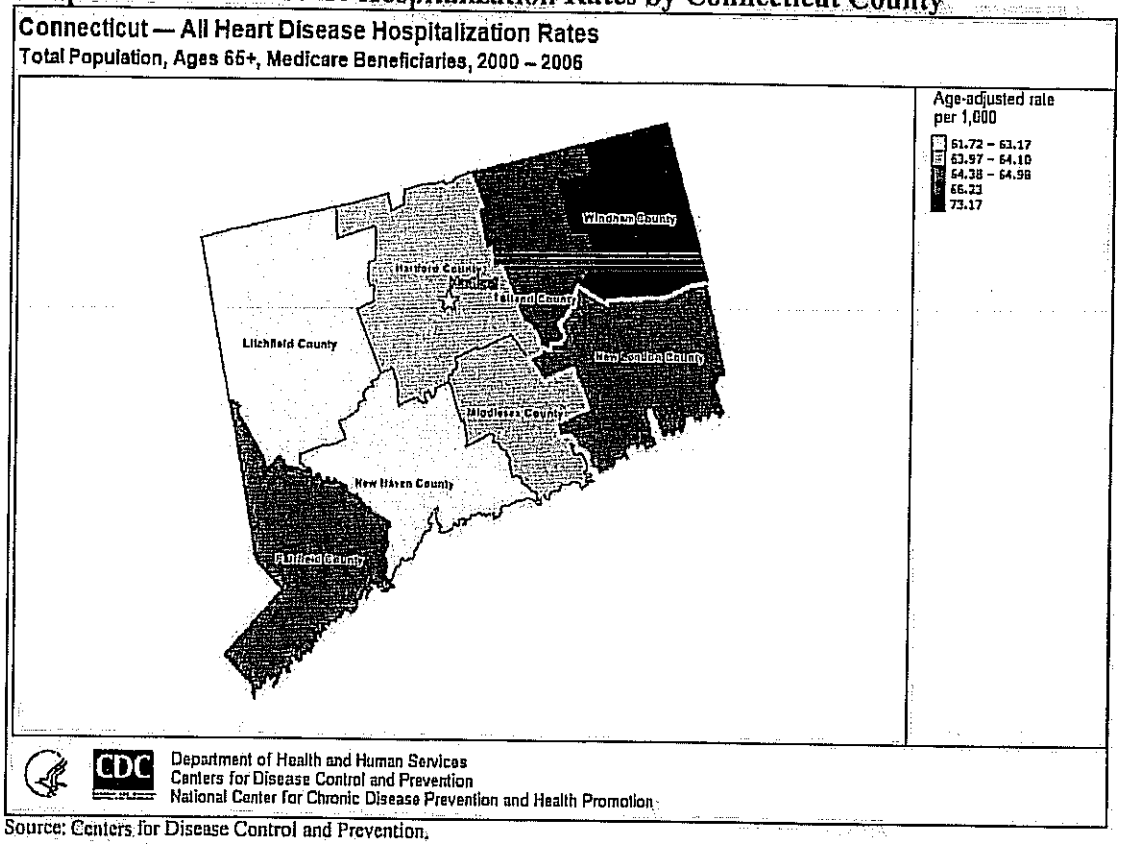
Furthermore, according to data provided by the Centers for Disease Control and Prevention (CDC), New London County has a higher heart disease death rate and hospitalization rate than most other counties in the state. Graphics C and D display this and further demonstrate that cardiac services such as elective PCI is much needed in New London County and the proposed service area.

Graphic C: Heart Disease Death Rates by Connecticut County



Source: Centers for Disease Control and Prevention.

Graphic D: Heart Disease Hospitalization Rates by Connecticut County



Source: Centers for Disease Control and Prevention.

As noted earlier, another key risk factor for CVD and coronary heart disease is increasing age. The total service area population was 291,068 in 2010 and is expected to increase to 295,830 by 2015. While the overall population is expected to increase only modestly at 1.6%, the rate of growth in the older age cohorts (65+) is expected to be much higher at nearly 11% (please refer to Table F and please refer to Attachment E for detailed demographic information).

Table F: L+M Total Service Area Population Statistics

Age Cohort	2010	2015	% Change
0-44	170,507	165,257	-3.1%
45-54	45,925	45,447	-1.0%
55-64	33,181	39,230	18.2%
65-74	20,345	24,084	18.4%
75-84	14,473	14,225	-1.7%
85+	6,637	7,587	14.3%
Total	**291,068**	**295,830**	**1.6%**
% Age 45+	41.4%	44.1%	
% Age 65+	14.2%	15.5%	
% Age 85+	2.3%	2.6%	

Source: Claritas.

By 2015, 15.5% of the total service area population will be over age 65. According to Claritas, in the state of Connecticut, 15.4% of the population will be aged 65+ in 2015 and 14.3% of the nation's population will be aged 65+. Therefore, the local market of L+M is older proportionately compared to the state and nation. Since the risk and rate of CVD and coronary heart disease increases with age, the demand for cardiac services such as PCI is likely higher on a per person basis in the local market of L+M.

Race and ethnicity also play a key role in CVD and coronary heart disease prevalence and incidence. As noted earlier, the black non-Hispanic population has a higher mortality rate compared to white non-Hispanic and Hispanic populations. Within L+M's service area, four zip codes that represent 30% of the total population in 2015 (zip codes: 06320, 06340, 06357, and 06382)[10], have a higher proportion of residents that are black non-Hispanic compared to the statewide proportion of 9.7% (please refer to Attachment E for L+M service area definition by zip code and for information on race/ethnicity by service area town). Each of the four zip codes is located within L+M's PSA. Due to this race/ethnic mix, the corresponding need for cardiac services may be higher compared to other markets in the state.

In summary, given the high rate of growth in the older population, the higher proportion of residents aged 65+, the higher proportion of black non-Hispanic residents in select service area towns, and the poorer health statistics and behaviors locally, this translates into an increased demand for cardiac services including interventional procedures in the market served by L+M. Elective PCI at L+M would help meet the existing and potentially growing community need.

iv. How and where the proposed patient population is currently being served;

Response:
Patients that reside within L+M's service area must migrate from the local community to receive elective PCI services. As previously discussed, patients who receive a diagnostic catheterization at L+M and require PCI the same day are transferred to YNHH or another facility for this procedure.

Because L+M does not currently provide elective PCI, some patients migrate from the local community for their entire interventional care, including both diagnostic catheterization and PCI. This often occurs when patients prefer care in one setting rather than decoupled procedures and multiple sites of service.

The Connecticut Hospital Association (CHA) collects inpatient data from its member facilities including L+M. A limitation of the data is that volume is not separated into emergent versus elective cases. However, according to CHA's inpatient data set[11], in FY 2011, 9% of PCI cases in the proposed service area occurred at L+M (these would all be emergent cases). In the same year, 73% of PCI volume from the service area migrated to

[10] Zip code and town as follows: 06320 New London, 06340 Groton, 06357 Niantic, and 06382 Uncasville.
[11] Data based on analysis of the following ICD-9 codes: 0066 PTCA OR CORONARY ATHER, 3604 INTRCORONRY THROMB INFUS, 3609 REM OF COR ART OBSTR NEC, 3603 OPEN CORONRY ANGIOPLASTY, 3606 INS NONDRUG ELUT COR ST, 3607 INS DRUG-ELUT CORONRY ST).

YNHH while 9% migrated to St. Francis Hospital and 9% to Hartford Hospital (YNHH, St. Francis Hospital, and Hartford Hospital cases include both emergent and elective procedures). Based on the CHA data, YNHH is the preferred service location for many service area residents and is a key referral source for local referring physicians. Although the CHA data set does not separate emergent from elective cases, regardless of case type, YNHH receives the large majority of PCI volume from the proposed service area.

v. All existing providers (name, address, services provided) of the proposed service in the towns listed above and in nearby towns;

Response:
There are no providers of elective PCI in the proposed service area towns listed previously or in nearby towns.

vi. Describe existing referral patterns in the area to be served by the proposal; and

Response:
There are two cardiology practices located within L+M's PSA, both employed by L+M Physician Association (L+MPA). One practice is located in New London and includes two cardiologists. The second practice is located in Waterford and includes eight cardiologists. The primary referral source for elective PCI for these local cardiologists is YNHH. YNHH is the primary source regardless of whether patients are transferred to YNHH from L+M's catheterization lab or are directly referred to YNHH for their entire cardiac interventional care.

Within L+M's SSA, there are eleven cardiologists located in Norwich that are affiliated with Backus Hospital. Similarly, the majority of patients who require elective PCI are referred to YNHH; however, in L+M's SSA, St. Francis Hospital and Hartford Hospital are the receiving facilities for a small portion of elective PCI cases particularly in service area towns that are relatively close to the town of Hartford such as Colchester.

vii. The effect of the proposal on existing providers, explaining how current referral patterns will be affected by the proposal.

Response:
If L+M were to add elective PCI to its service complement, there would be an increase in PCI cases at L+M, and a reduction in cases migrating to YNHH and these other facilities. L+M anticipates a shift in referral patterns as local physicians within the proposed service area would refer patients to L+M for their patients' elective PCI procedures so long as the patient meets strict selection criteria. Letters of support for the proposed program received from local referring physicians are included in Attachment A.

As demonstrated in Section 3d, L+M's projected elective PCI volume is expected to be generated through a shift cases from YNHH to L+M. In Years 1 to 3, L+M projected approximately 70-135 elective cases thus only a minimal impact is expected on YNHH's total volumes. In FY 2011, YNHH completed 1,350 emergent and elective PCI

procedures (volumes per the CHA September 2011 Patient Census Report). If 70-135 elective cases shift from YNHH to L+M, the impact to YNHH would be minimal as the facility would complete 1,215-1,280 cases per year which is more than enough volume to maintain a high quality and safe service. Since L+M is not expecting elective volume to shift from St. Francis Hospital or Hartford Hospital to L+M, impacts to these facilities' volumes would be non-existent.

c. Explain why the proposal will not result in an unnecessary duplication of existing or approved health care services.

Response:
The proposal will not result in an unnecessary duplication of existing or approved health care services as there are no providers of elective PCI in the proposed service area or nearby towns. In fact, L+M is the only provider of emergency PCI in its service area and in New London County and is well-equipped to make the transition to elective PCI as program development (e.g., physicians, facilities, staffing, and equipment) is already in place.

d. The record in this docket will include, in addition to other materials, the American College of Cardiology/American Heart Association (ACC/AHA) practice guidelines. The Applicants may submit any comments in response to this evidence, which they deem appropriate.

Response:
The 2011 ACC/AHA practice guidelines are included as Attachment B. As stated in Section 2a of this application, the revised guidelines released in November 2011 support L+M's intent to add elective PCI services to its service complement. The guidelines clearly state that elective PCI may be considered in hospitals without on-site surgery provided that:

- Appropriate planning for program development has been accomplished
- Rigorous clinical and angiographic criteria are used for proper patient selection
- The program maintains experienced operators with complication rates and outcomes equivalent or superior to national benchmarks
- The program will clearly fill a void in the healthcare needs of the community

Due to L+M's existing emergency PCI program, much of the planning for program development of a strong elective PCI service is already complete. In the November 2011 practice guideline, SCAI lists its "Expert Consensus Document for Personnel and Facility Requirements for PCI Programs without On-Site Surgical Backup" as well as its "Expert Consensus Document Requirements for Off-Site Surgical Backup." The SCAI requirements from the 2011 ACC/AHA practice guidelines are included in Tables G and H.

Table G: SCAI Expert Consensus Document Personnel and Facility Requirements for PCI Programs without On-Site Surgical Backup

Table 5. SCAI Expert Consensus Document Personnel and Facility Requirements for PCI Programs Without On-Site Surgical Backup

Experienced nursing and technical laboratory staff with training in interventional laboratories. Personnel must be comfortable treating acutely ill patients with hemodynamic and electrical instability.
On-call schedule with operation of laboratory 24 h/d, 365 d/y.*
Experienced coronary care unit nursing staff comfortable with invasive hemodynamic monitoring, operation of temporary pacemaker, and management of IABP. Personnel capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary.
Full support from hospital administration in fulfilling the necessary institutional requirements, including appropriate support services (e.g., respiratory care, blood bank).
Written agreements for emergency transfer of patients to a facility with cardiac surgery. Transport protocols should be developed and tested a minimum of 2 times per year.
Well-equipped and maintained cardiac catheterization laboratory with high-resolution digital imaging capability and IABP equipment compatible with transport vehicles. The capability for real-time transfer of images and hemodynamic data (via T-1 transmission line) as well as audio and video images to review terminals for consultation at the facility providing surgical backup support is ideal.
Appropriate inventory of interventional equipment, including guide catheters, balloons, and stents in multiple sizes; thrombectomy and distal protection devices; covered stents; temporary pacemakers; and pericardiocentesis trays. Pressure wire device and IVUS equipment are optimal but not mandatory. Rotational or other atherectomy devices should be used cautiously in these facilities because of the greater risk of perforation.
Meticulous clinical and angiographic selection criteria for PCI (Tables 6 and 7).
Performance of primary PCI as the treatment of first choice for STEMI to ensure streamlined care paths and increased case volumes. Door-to-balloon times should be tracked, and <90 min outlier cases should be carefully reviewed for process improvement opportunities.
On-site rigorous data collection, outcomes analysis, benchmarking, quality improvement, and formalized periodic case review.
Participation in a national data registry where available, such as the ACC NCDR in the United States.

*Required for U.S. facilities but may not be possible for all facilities worldwide.
ACC indicates American College of Cardiology; IABP, intra-aortic balloon pump; IVUS, intravascular ultrasound; NCDR, National Cardiovascular Data Registry; PCI, percutaneous coronary intervention; SCAI, Society for Cardiovascular Angiography and Interventions; and STEMI, ST-elevation myocardial infarction.
Adapted with permission from Dehmer et al. [352].

Source: "2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention." (Included as Attachment B).

Table H: SCAI Expert Consensus Document Requirements for Off-Site Surgical Backup

Table 6. SCAI Expert Consensus Document Requirements for Off-Site Surgical Backup

1. Interventional cardiologists establish a working relationship with cardiac surgeons at the receiving facility.
2. Cardiac surgeon must have privileges at the referring facility to allow review of treatment options as time allows.
3. Cardiac surgeon and receiving hospital agree to provide cardiac surgical backup for urgent cases at all hours and for elective cases at mutually agreed hours.
4. Surgeon and receiving facility ensure that patients will be accepted based on medical condition, capacity of surgeon to provide services at the time of request, and availability of resources. If this cannot be ensured before the start of an elective procedure, the case should not be done at this time.
5. Interventional cardiologists must review with surgeons the immediate needs and status of any patient transferred for urgent surgery.
6. Hospital administrations from both facilities endorse transfer agreement.
7. Transferring and receiving facilities establish a rigorous protocol for rapid transfer of patients, including the proper personnel with appropriate experience.
8. A transport provider is available to begin transport within 20 min of the request and provide vehicle/helicopter with necessary life-sustaining equipment, including IABP and monitoring capability.
9. Transferring physician obtains consent for surgery from patient or appropriate surrogate.
10. Initial informed consent for PCI discloses that the procedure is being done without on-site surgical backup and acknowledges the possibility of risks related to transfer. The consent process should include the risk of urgent surgery (approximately 0.3%) and state that a written plan for transfer exists.
11. As part of the local continuous quality improvement program, a regular review of all patients transferred for emergency surgery with the outcome of surgery and identification of any improvement opportunities.

IABP indicates intra-aortic balloon pump; PCI, percutaneous coronary intervention; and SCAI, Society for Cardiovascular Angiography and Interventions.
Adapted with permission from Dehmer et al. [352].

Source: "2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention." (Included as Attachment B).

L+M and its off-site surgical backup partner, YNHH, meet the criteria set forth in Tables G and H. Please refer to Attachment H for a listing of the SCAI requirements and information on how L+M and/or YNHH comply.

SCAI has developed strict patient selection criteria (clinical and angiographic) for patients to be eligible for elective PCI without on-site cardiac surgery. The guidelines were published in the November 2011 report noted earlier (and included as Attachment B). L+M plans to complete elective PCI procedures only on patients deemed to be non-high-risk from a patient risk and lesion risk standpoint in Year 1 of program operation. In Years 2 and 3 of operation, L+M plans to complete elective PCI procedures only on patients deemed to be non-high-risk from a patient risk standpoint and either non-high risk or high-risk from a lesion standpoint. Please refer to Table I for details on how SCAI defines non-high-risk and high-risk (please refer to Attachment F for L+M policy regarding patient selection criteria):

Table I: SCAI Requirements for Patient and Lesion Selection for Nonemergency PCI at Hospitals without On-Site Cardiac Surgery

Table 8. SCAI Expert Consensus Document Requirements for Patient and Lesion Selection and Backup Strategy for Nonemergency PCI by Experienced Operators at Hospitals Without On-Site Cardiac Surgery

Patient risk: expected clinical risk in case of occlusion caused by procedure

High patient risk: Patients with any of the following:

- Decompensated congestive heart failure (Killip Class 3) without evidence for active ischemia, recent CVA, advanced malignancy, known clotting disorders
- LVEF <25%
- Left main stenosis (≥50% diameter) or 3-vessel disease unprotected by prior bypass surgery (>70% stenoses in the proximal segment of all major epicardial coronary arteries)
- Single-target lesion that jeopardizes >50% of remaining viable myocardium

Lesion risk: probability that procedure will cause acute vessel occlusion

Increased lesion risk: lesions in open vessels with any of the following characteristics:

- Diffuse disease (>2 cm in length) and excessive tortuosity of proximal segments
- More than moderate calcification of a stenosis or proximal segment
- Location in an extremely angulated segment (>90%)
- Inability to protect major side branches
- Degenerated older vein grafts with friable lesions
- Substantial thrombus in the vessel or at the lesion site
- Any other feature that may, in the operator's judgment, impede successful stent deployment

Aggressive measures to open CTOs are also discouraged because of an increased risk of perforation.

Strategy for surgical backup based on lesion and patient risk:

- **High-risk patients with high-risk lesions** should not undergo nonemergency PCI at a facility without on-site surgery.
- **High-risk patients with non–high-risk lesions:** Nonemergency patients with this profile may undergo PCI, but confirmation that a cardiac surgeon and operating room are immediately available is necessary.
- **Non–high-risk patients with high-risk lesions** require no additional precautions.
- **Non–high-risk patients with non–high-risk lesions** require no additional precautions. Best scenario for PCI without on-site surgery.

CTO indicates chronic total occlusion; CVA, cerebrovascular accident; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; and SCAI, Society for Cardiovascular Angiography and Interventions.

Adapted with permission from Dehmer et al. (352).

Source: "2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention." (Refer to Attachment B for entire report).

L+M's strict patient selection criteria for Year 1 of operation and in Years 2 and 3 are reflected in the volume projections in Section 3 of this application. As noted in Table I, non-high-risk patients with non-high-risk lesions are the best candidates for PCI without on-site surgery. For this reason, L+M plans to isolate its initial patients to those that fall under this category. In Years 2 and 3, L+M will expand its clinical reach to non-high-risk patients with high-risk lesions as "no additional precautions" are required by SCAI to complete procedures on these patient types.

High-risk patients with either non-high-risk or high-risk lesions would be transferred to another facility with on-site cardiac surgery for elective PCI as they are currently.

For non-emergent patients that receive a diagnostic catheterization at L+M and whose results indicate the need for a PCI immediately, L+M will utilize its digital imaging capability to transmit angiograms to YNHH which can be viewed real-time by multiple interventional cardiologists at YNHH to ensure proper patient selection and confirm if a patient is indeed a candidate for elective PCI at L+M. Interventionalists at L+M will utilize existing information from the patient's medical record to help inform their decision on whether the patient needs to be transferred for their elective PCI. Only patients that meet the strict patient selection criteria will be candidates for elective PCI at L+M the same day as their diagnostic catheterization.

L+M's PCI program will be covered by experienced operators from YNHH/YSM who are capable of performing both primary and elective PCI. The experience and competency of these physicians have resulted in patient outcomes at L+M and YNHH that are comparable to or better than national benchmarks. Also, as shown in Section 2a of this application, an elective PCI program at L+M will clearly fill a void in the health care needs of the community as there are no providers of this service in eastern Connecticut and New London County residents clearly require cardiac services as demonstrated in health statistics and demographic data.

e. If applicable to the proposal (e.g. establishment of cath lab without a cardiac surgical program), provide a copy of a signed agreement between the Applicant and a tertiary care facility. Identify patient selection guidelines, the process and protocols involved in the transfer of a patient requiring cardiac surgery, and joint quality assurance reviews and joint training.

Response:
A copy of the Transfer Protocol and Agreement between L+M and YNHH can be found in Attachment I. Attachment I also includes the agreement between L+M and YNHH to provide primary PCI. The Medical Director and other interventionalists that provide coverage for the primary PCI program at L+M will also perform elective PCI at L+M. Attachment F includes policies related to patient selection guidelines, the process and protocols involved in the transfer of a patient requiring cardiac surgery, and the process and protocols for joint quality assurance reviews and training between L+M and YNHH. Attachment I also includes the YNHH Department of Surgery surgical backup policy to the L+M elective PCI program.

f. Has the Applicant held any discussions with the local emergency medical service ("EMS") regarding the proposed service? Describe.

Response:
L+M's Emergency Medical Service (EMS) Coordinator has held discussions with local emergency transport personnel regarding L+M's proposal to establish an elective PCI program. Consistent with SCAI's requirement outlined in Table H, local emergency transport (including ground/ambulance transport from American Ambulance Service, Inc. and Life Star Ground Transportation and air/helicopter transport from Life Star Air Medical Transportation) will provide patient transport within 20 minutes once notified of

the need by L+M (please refer to Attachment J for a letter from American Ambulance Service, Inc. confirming this timeframe). Adhering to this transit time will ensure the rapid transfer of patients to a facility with cardiac surgery should a complication arise from an elective PCI procedure. YNHH is the preferred surgical facility to receive such patients as outlined in the agreement located in Attachment I. The guideline outlining the process for emergent transport of an elective PCI patient is in Attachments F and J.

According to the JACC 2009 study of off-site PCI providers referenced earlier, the global standard from "initial decision to transport" to "actual time of initiating [emergency] CABG at the receiving surgical center" is 90 minutes (the JACC study is included in Attachment D).[12] With logistics coordination in place, L+M is well equipped to meet this standard. In accordance with the guideline outlining the process for emergency transport, the interventionalist will determine the most appropriate form of transport for the patient. In a situation when urgent surgery is needed, the likely mode of transport for patients will be air transportation through Life Star. According to L+M's EMS Coordinator, the average time to L&M once Life Star is contacted is 12 minutes[13] and the average travel time from L+M to YNHH is 20 minutes.

3. Projected Volume

a. In table format, provide historical volumes (three full years and the current year-to-date) for each Applicant by service; by zip code; by inpatient/outpatient; and by unique physician identifier as applicable to the proposal.

Response:

Historical volume for primary or emergent PCI at L+M is shown in the table below. All volume was completed as inpatient procedures.

Total Primary PCI Cases at L+M*

	FY 2009	FY 2010	FY 2011	FY 2012**
Primary PCI	78	81	74	44

*Note: All volume completed as inpatient procedures. **Note: Represents actual volumes for FY 2012 through 3-21-12
Source: L+M Department of Cardiology.

Total Primary PCI Cases at L+M by Zip Code (sorted high to low on FY 2011)

Zip Code	Town	L+M Service Area	FY 2009	FY 2010	FY 2011	FY 2012*
06340	Groton	PSA	10	16	11	10
06320	New London	PSA	14	18	10	6
06355	Mystic	PSA	7	13	7	2
06385	Waterford	PSA	9	5	6	5
06357	Niantic	PSA	5	4	6	4
06339	Ledyard	PSA	2	5	4	
06335	Gales Ferry	PSA	2	4	3	5
06382	Uncasville	PSA	2	1	2	1
06371	Old Lyme	PSA	2	2	2	

[12] According to the 2007 Expert Consensus from SCAI, the goal is <120 minutes between decision for surgery and initiation of urgent surgery (a copy of the Expert Consensus is included in Attachment B).
[13] 12 minute timeframe includes 6 minutes of flight preparation and 6 minutes travel time from Life Star helicopter holding site in Norwich to L+M.

48195	Other	Other			2	
01151	Other	Other			2	
06370	Oakdale	PSA	1	1	1	2
06333	East Lyme	PSA	1	3	1	
06378	Stonington	PSA	4	2	1	
06379	Pawcatuck	PSA	2	1	1	
06334	Bozrah	SSA			1	
02891	Westerly	SSA	1		1	
06360	Norwich	SSA			1	1
10541	Other	Other			1	
06390	Other	Other			1	
06040	Other	Other			1	
06525	Other	Other			1	
02813	Other	Other			1	
05855	Other	Other			1	
84108	Other	Other			1	
06488	Other	Other			1	
07307	Other	Other			1	
06374	Other	Other			1	
12477	Other	Other			1	
06037	Other	Other			1	
06375	Quaker Hill	PSA	3	1		1
06359	N. Stonington	PSA	1	1		
06376	South Lyme	PSA	1			
06475	Old Saybrook	SSA		1		
06351	Jewett City	SSA	2			
06420	Salem	SSA	2			1
06365	Preston	SSA				1
11753	Other	Other		1		
40324	Other	Other		1		
07628	Other	Other		1		
06423	Other	Other	1			
34957	Other	Other	1			
06450	Other	Other	1			
02368	Other	Other	1			
06489	Other	Other	1			
11757	Other	Other	1			
01602	Other	Other	1			
06720	Other	Other				1
02833	Other	Other				1
05354	Other	Other				1
02808	Other	Other				1
02916	Other	Other				1
Total			**78**	**81**	**74**	**44**

*Note: Represents actual volumes for FY 2012 through 3-21-12. Source: L+M Department of Cardiology.

Total Primary PCI Cases at L+M by Unique Physician Identifier (sorted high to low on FY 2011)

Physician Identifier	FY 2009	FY 2010	FY 2011	FY 2012*
A	32	39	28	21
B	0	8	14	8
C	4	12	14	2
D	10	7	9	5
E	9	5	8	6
F	0	0	1	0
G	1	0	0	0
H	22	10	0	2
Total	**78**	**81**	**74**	**44**

*Note: Represents actual volumes for FY 2012 through 3-21-12
Source: L+M Department of Cardiology.

b. If applicable, for the most recently completed fiscal year, identify the number of:

i. Patients with a diagnosis of ST-segment elevation acute myocardial infarction (AMI) that presented at the Hospital's emergency room.

Response:
In FY 2011, there were 74 patients that presented to L+M's emergency department with a diagnosis of STEMI. There were 205 total patients that presented with acute myocardial infarction.

ii. Doses of thrombolytic medication, issued through its pharmacy, to patients with a diagnosis of AMI.

Response:
In FY 2011, thrombolytic medication was not issued to patients who presented at the L+M emergency department with a diagnosis of AMI. Rather than issue thrombolytic medication, patients with STEMI were transferred to L+M's catheterization lab for emergent PCI which is the preferred treatment for patients.

c. In table format, provide projected volumes (three full years) for each Applicant by service; by inpatient/outpatient; and by unique physician identifier as applicable to the proposal.

Response:
Historical and projected volume for PCI at L+M is shown in the table below.

	FY 2009	FY 2010	FY 2011	FY 2012*	Year 1 FY 2013	Year 2 FY 2014	Year 3 FY 2015
Primary PCI	78	81	74	44	89	89	89
Elective PCI	-	-	-	-	73	130	135
Total	**78**	**81**	**74**	**44**	**162**	**219**	**224**

*Note: Represents actual volumes for FY 2012 through 3-21-12. Source: L+M Department of Cardiology.

Projected PCI Volumes at L+M by Inpatient/Outpatient is shown in the table below.

	Year 1 FY 2013	Year 2 FY 2014	Year 3 FY 2015
Inpatient PCI	162	219	224
Outpatient PCI	0	0	0
Total	**162**	**219**	**224**

Projected PCI Volume at L+M by Unique Physician Identifier is shown in the table below.

Physician Identifier	Year 1 FY 2013	Year 2 FY 2014	Year 3 FY 2015
A	78	105	108
B	23	29	30
C	15	24	24
D	17	23	24
E	23	32	32
F	1	1	1
G	1	1	1
H	4	4	4
Total	**162**	**219**	**224**

d. Provide a detailed description of all assumptions used in the derivation/calculation of the projected volumes.

Response:

L+M's future volumes include projected increases in emergency PCI cases and new volume from elective PCI procedures. Elective PCI cases are expected to be performed during weekdays (excluding holidays) during normal business hours (7:30am - 4pm). L+M will continue to accept emergent PCI cases 24 hours a day, 365 days per year. Justification for the projected volumes is outlined below.

Assumptions for Projections for Primary PCI

L+M anticipates an increase in emergency PCI cases due to an updated policy instituted by the CT DPH earlier this year. On January 23, 2012, DPH Commissioner, Jewel Mullen, MD, issued the "DPH Policy Guidance for STEMI patients" (please refer to Attachment K). The intent of the guidelines was two-fold. The first goal was to ensure timely diagnosis of STEMI in the field by EMS personnel. The second goal was to increase the likelihood that patients will be transported for treatment for PCI within 90 minutes of first medical contact. The guidelines instituted require that for patients with a prehospital-diagnosed STEMI, EMS transport the patient directly to a hospital capable of performing primary PCI if that hospital is less than 30 minutes of travel time away. For L+M, the impact is increased emergency PCI volume originating from towns whose EMS formerly transported patients to other facilities.

In response to this Policy Guidance, on January 26, 2012, Backus Hospital's EMS Coordinator issued a directive noting that all prehospital STEMI patients diagnosed in the

field in Norwich and south are under 30 minutes of L+M and should be transferred to L+M for primary PCI (please refer to Attachment L). Based on this directive, L+M anticipates 15-20 incremental patients transported to L+M for emergency PCI. This figure was generated as currently 60 patients with STEMI from this area are being transferred to YNHH from the Backus EMS for emergent PCI according to YNHH data sources. According to L+M's Medical Director, experience has shown that 30% of emergency department visits for STEMI come from field application (i.e. EMS). Thus L+M predicts 15-20 incremental patients to L+M. The projections in the table above include conservatively 15 additional emergency PCI procedures in FY 2013, FY 2014, and FY 2015 compared to FY 2011 totals due to the updated DPH policy.

Assumptions for Projections for Elective PCI

To determine the number of elective cases that L+M could perform with the addition of elective PCI services, L+M:

- Completed a chart review of FY 2011 patients who received a diagnostic catheterization at L+M and were then transferred to another facility to receive elective PCI. An assessment was completed to determine which subset of these patients were eligible to receive elective PCI at L+M in Year 1 of operation.
- Utilized the CPORT-E trial patient selection process to determine the patients eligible to receive elective PCI at L+M in Year 2 of operation.
- Utilized market demographic information to project Year 3 volumes.

Year 1 Projections

According to data provided by YNHH, over a 12 month period between 2011 and 2012, 146 patients were transferred from L+M or directly referred from an L+M service area physician to YNHH for elective PCI. As noted earlier in this application, in FY 2011, 138 patients were transferred from L+M to YNHH for elective PCI immediately following the patient's diagnostic catheterization at L+M. Thus, 8 patients were directly referred to YNHH for diagnostic catheterization and elective PCI. A key factor influencing these direct referrals include patients' preference for "coupled" procedures in one setting versus "decoupled" procedures in two settings where a transfer is involved.

The medical chart review of patients transferred from L+M to YNHH after receiving their diagnostic catheterization at L+M revealed that approximately 50% of the patients met the patient selection criteria and were eligible to receive their PCI at L+M. The patient selection criteria utilized in this chart review was very strict and only non-high-risk patients with non-high-risk lesions were considered. Applying 50% to 138 cases that are currently leaving the market results in 69 patients capable of having their elective PCI at L+M versus another facility. This figure was carried into the FY 2013 volume projection for elective cases.

For the 8 patients directly referred to YNHH for elective PCI, applying the same 50% noted above results in 4 patients capable of receiving elective PCI at L+M.

Thus, Year 1 volumes include 74 existing emergent cases (from FY 2011 data), 15 incremental emergent cases, 69 elective PCI cases previously transferred the same day as the diagnostic catheterization, and 4 elective PCI cases previously referred directly to YNHH. These volumes total 162 for FY 2013 which exceeds the minimum threshold of 100 cases required for CPORT-E trial participants in the first year of operation.

Year 2 Projections

In Year 2 of operation, it is expected that L+M will expand its patient selection criteria to include non-high-risk patients with higher-risk lesions, a patient complement similarly utilized in the CPORT-E trial. In the CPORT-E trial (referenced in Section 2a earlier), of the total patients eligible for PCI and consenting to participate in the study, 10.9% were considered high-risk after further testing and eliminated from the study. For Year 2 volume projections, L+M is assuming that, similar to the CPORT-E trial, 10.9% of the patients currently leaving the market to YNHH are high risk and therefore, ineligible to receive elective PCI at L+M. Therefore, 89.1% of patients are non-high-risk and thus eligible to receive elective PCI locally. This equates to an additional 130 patients who can receive elective PCI at L+M (146 patients transferred or referred x 89.1% = 130).

Thus, Year 2 volumes include 74 existing emergent cases, 15 incremental emergent cases (conservatively assuming no change from FY 2013 volume), and 130 elective PCI cases that were previously transferred from L+M or directly referred outside the market. These volumes total 219 for FY 2014.

Year 3 Projections

Growth between Year 2 and Year 3, albeit modest growth, is expected given the service area demographics (i.e., rate of growth for 65+ population, race/ethnic mix) and the high prevalence of coronary heart disease risk factors (e.g., smoking, obesity, sedentary lifestyle) in New London County.

The 65+ age cohort is expected to increase by 2% annually between 2010 and 2015[14]. Accounting for this factor, as well as the race/ethnic mix and the poor health statistics locally, L+M conservatively anticipates a 4% increase in elective PCI cases between Years 2 and 3. This equates to 135 elective PCI at L+M (130 cases from FY 2014 x 1.04 = 135).

Thus, Year 3 volumes include 74 existing emergent cases, 15 incremental emergent cases (conservatively assuming no change from FY 2013 volume), and 135 elective PCI cases. These volumes total 224 for FY 2015.

[14] From table showing population statistics listed earlier in the application, in 2010, 41,455 residents will be aged 65+ and in 2015, 45,896 will be aged 65+. This translates into 2% annual increase in the age 65+ population.

Assumptions for Primary and Elective PCI Projections
All cases are expected to remain inpatient in the three year time horizon. Select elective cases will eventually transfer to outpatient procedures beyond the three year time horizon.

Several studies, such as CPORT-E, have indicated that programs with case totals over 200 have sufficient volume to sustain a quality and safe emergent and elective PCI program. L+M is projected to exceed 200 total cases in Year 2 of operation.

Assumptions for Projections by Physician Identifier
The projected volume in Years 1, 2, and 3 were further detailed by physician identifier. The distribution of the projected emergent PCI cases was assumed to be equal to the actual distribution experienced in FY 2012 year-to-date statistics. This assumption is based on the existing call schedule which will remain relatively unchanged in the three year planning horizon. For elective PCI cases, 50% of the cases were distributed to the Medical Director of the program who spends the majority of his clinical time at L+M and the other 50% of the cases were distributed among four other YNHH/YSM interventionalists who provide coverage at L+M in the Medical Director's absence.

e. Provide a copy of any articles, studies, or reports that support the statements made in this application justifying need for the proposal, along with a brief explanation regarding the relevance of the selected articles.

Response:
In prior sections of this application, various studies and articles were referenced in support of the proposal. Other materials supporting the statements made in this application are summarized below. Full texts are provided in Attachment D.

Title, Journal Name (if applicable), and Publication Year	Relevance
"Outcomes of Nonemergent Percutaneous Intervention With and Without On-site Surgical Backup: A Meta-Analysis" published in the American Journal of Therapeutics (2011)	Meta-analysis which demonstrated that compared to facilities with on-site surgical backup, the risk of in-hospital death, nonfatal myocardial infarction, and need of emergency CABG for elective PCI patients is similar to those facilities lacking on-site surgical backup. The article notes that technical improvements in PCI instruments and techniques have nearly diminished the need for emergency CABG during elective PCI.
"Outcomes of 1,090 Consecutive, Elective, Nonselected Percutaneous Coronary Interventions at a Community Hospital without Onsite Cardiac Surgery" published in The American Journal of Cardiology (2008)	Study evaluated efficacy and safety of elective PCI at a hospital without onsite cardiac surgery. Results demonstrated that favorable clinical outcomes can be achieved for elective PCI at a hospital without cardiac surgery if strict program requirements are

	utilized (e.g., experienced interventionalists, technicians, and nurses; transport protocol; well-equipped cath lab; and quality assurance program).
"Nonemergent Coronary Angioplasty without On-Site Surgical Backup: A Randomized Study Evaluating Outcomes in Low-Risk Patients" published in the American Heart Journal (2006)	Study evaluated the safety of performing elective PCI at a facility without on-site surgery compared to a facility with on-site surgery. Results were that the angiographic success rate was 96% at both hospitals and the number of periprocedural complications were equal at both hospitals at 0.3%. Neither hospital had a death or need for urgent transfer to cardiac surgery.
"Outcomes Following Elective Percutaneous Coronary Intervention without Onsite Surgical Backup in a Community Hospital" published in The American Journal of Cardiology (2005)	Study evaluated elective PCI outcomes at a community hospital without on-site surgery. Authors concluded that elective PCI with off-site surgical backup is feasible and safe for selected patients given a well-developed transfer plan.
"Emergency Coronary Artery Bypass Surgery for Percutaneous Coronary Interventions" published in the Journal of the American College of Cardiology (2005)	Study evaluated the changes in incidence and indications for CABG in patients undergoing PCI from 1979 to 2003. Results demonstrated that there has been a marked decrease in the incidence of patients requiring emergency surgery from 2.9% to 0.3%. Authors hypothesize that the decrease is due to improved PCI technology.
"Safety of Elective—Including "High Risk"—Percutaneous Coronary Interventions without On-Site Cardiac Surgery" published in the American Heart Journal (2004)	Study of 1,000 patients undergoing elective PCI (including "high risk" patients) at a single center. Results were 0.7% of patients required elective cardiac surgery after failed PCI, periprocedural death (within 48 hours) occurred in 0.2% of patients, and no patients required emergency cardiac surgery. Authors of study concluded that technical advances in interventional cardiology allow for safe performance of PCI in hospitals without on-site cardiac surgery.
"C-PORT E: Elective PCI Doesn't Require Surgical Backup" (2011)	Article notes that geographic location is a key factor in determining whether a site should be able to provide elective PCI without on-site surgery. Sites that have access limitations to elective PCI should be considered for elective PCI without on-site surgery.
"Survey Says: Most Cardiologists Support Elective PCI sans On-Site	Article references a survey completed by cardiologists regarding elective PCI without

CABG…with Caveats" (2011)	on-site surgery. Results were that two-thirds of respondents said that elective angioplasty at centers without cardiothoracic surgery on-site can be done safely and effectively.

f. Please identify the number of physicians that will be providing coverage for the proposed program. Explain whether the physicians will be full time with the proposed program or also providing coverage at other hospitals.

Response:
Ten YNHH/YSM physicians have privileges at L+M and provide on-call coverage for L+M's existing emergent PCI program. Similar to current conditions, these physicians will be part-time at L+M and will continue to provide coverage at YNHH. With the addition of the proposed elective PCI service, all of these physicians will be capable of performing elective PCI procedures to L+M patients. However, the vast majority of elective PCI cases are estimated to be completed by the Medical Director, and four other interventionalists who frequently provide coverage at L+M. All the interventional cardiologists involved in L+M's program are proficient and experienced at PCI.

4. Quality Measures

a. Submit a list of all key professional, administrative, clinical, and direct service personnel related to the proposal. Attach a copy of their Curriculum Vitae.

Response:
Key personnel related to the proposal are listed below. Please refer to Attachment M for each individual's Curriculum Vitae.

- Bruce D. Cummings, President and Chief Executive Officer
- Daniel Rissi, MD, Vice President and Chief Medical & Clinical Operations Officer
- Lugene Inzana, Vice President and Chief Financial Officer
- Pamela Kane, Vice President, Physician Practice Management
- Brian Cambi, MD, Medical Director of the Primary Angioplasty Program at L+M
- Max Gorski, Director, Cardiology
- Gerry Mulholland, RN, Manager, Cardiac Catheterization Lab

b. Explain how the proposal contributes to the quality of health care delivery in the region.

Response:
As noted in Section 2 of this application, the current practice of "decoupled" diagnostic catheterization and elective PCI and procedures completed at two separate facilities can lead to infections, vascular complications, as well as pain and discomfort for patients during and after the transfer process. If the procedures were "coupled" and completed entirely at L+M, these risks to patients' health and negative impacts on health care delivery can be mitigated. Medical literature clearly shows that with sound patient

selection criteria, which L+M plans to adhere to, the risk of complications for elective PCI procedures at L+M is minimal. Advances in technology have dramatically improved patient outcomes of all PCIs completed. Low risk patients can receive care locally, improving continuity of care between the hospital and local providers, and maintaining patients' medical home. The incremental volume from elective cases also poses to positively impact the entire PCI program at L+M. Generally speaking, facilities that perform more volume maintain better quality outcomes due more facility and clinical staff experience.

L+M's geographic location makes it an ideal facility to add elective PCI. L+M's existing PCI service is strong and elective PCI can be added seamlessly. The high travel distances to facilities that provide elective PCI currently put an undue burden on service area residents, particularly those who are economically disadvantaged. Elective PCI at L+M will improve access to care for these and other residents L+M plans to serve in this proposal. As demonstrated in the health statistics presented earlier, cardiac services like elective PCI are much needed in L+M's local market.

Since the beginning of L+M's primary PCI program, there have been 13 total mortalities including patients who expired due to non-cardiac deaths (e.g., neurological conditions, etc.). The 13 total deaths translate into a 4.1% mortality rate as L+M completed 316 total procedures during the same time period. According to data from the 2011 ACCF/AHA/SCAI Practice Guideline, an analysis of data from the NCDR showed an in-hospital mortality rate of 4.81% in STEMI patients. In addition, according to the large meta-analysis published in JAMA in December 2011 cited earlier, the mortality rate in patients undergoing primary PCI at sites without on-site cardiac surgery was 4.6%. This rate was derived from an assessment of 124,074 patients who underwent emergent PCI without surgical backup. Comparatively, L+M's emergent PCI program has quality statistics that are better than average. This is largely due to the quality of L+M's physicians, staff, and policies & procedures for emergency PCI. Thus, L+M would be an appropriate location to complete elective PCI given the high quality standards already in place and the fact that only select patients will be eligible for the procedure at L+M.

As noted in the Letters of Support for this proposal, "before beginning an elective PCI program, a well-run primary PCI program for acute heart attack must already be in place." L+M's primary PCI program utilizes high quality interventionalists, staff, facilities, and equipment. As a result, the program's quality and safety metrics are excellent. A door-to-balloon (D2B) time of 90 minutes or less is recommended by the ACC/AHA to minimize the amount of cardiac muscle damage during STEMI. L+M compares very well to national standards in both D2B times and percent of STEMI patients who receive PCI within 90 minutes. Data from the NCDR shown in Table J displays the latest statistics from L+M's program compared to benchmarks. Clearly, L+M's existing emergent program is operating well above standards. The proposed elective program is expected to similarly have excellent outcomes given the infrastructure in place and the strict patient selection criteria that will be utilized. The Executive Summary of the NCDR report is included as Attachment N.

Table J: National Cardiovascular Data Registry, Rolling Four Quarters ending 2011 Q4

Metric	L+M Hospital	All Hospitals 50th Percentile	All Hospitals 90th Percentile
Median time to immediate PCI for STEMI patients (in minutes)	57.0	62.5	50.0
Proportion of STEMI patients receiving immediate PCI within 90 minutes	95.2%	91.9%	100%

Note: Data includes L+M Hospital compared to rolling four quarters for all hospitals ending 2011 Q4. Aggregation date: April 16, 2012. Publish Date: May 11, 2012.

c. Identify the Standard of Practice Guidelines that will be utilized in relation to the proposal. Attach copies of relevant sections and briefly describe how the Applicant proposes to meet each of the guidelines.

Response:

As noted previously, L+M is in compliance with the recommendations outlined by SCAI in the 2011 ACCF/AHA/SCAI Practice Guidelines for PCI (please refer to Section 2d and Attachment H of this application). In addition to adhering to these recommendations, L+M will implement policies and protocols related to the proposed elective PCI program if the service is approved. Attachment F includes the following key policies and protocols relevant to the proposal:

- Non-Emergent Angioplasty Procedure Policy and Procedure (establishes procedures for the safe care of elective PCI patients)
- Non-Emergent PCI Appropriateness Audit Form (ensures compliance with SCAI recommendations for patient selection at facilities without on-site surgery)
- Education Plan for Non-Emergent Angioplasty without On-Site Surgery (prepares clinical staff to care for patients undergoing elective PCI)
- Patient Bumping Protocol (ensures primary angioplasty is available with a timeframe that meets ACC/AHA guidelines (≤ 90 minutes D2B time); bumping refers to postponement of elective procedure and not interruption of a procedure already in progress even if elective)
- Patient Transfer Procedure (provides transfer protocol should the need for urgent surgery arise)
- Quality Assurance Plan Policy and Procedure (establishes an ongoing quality assurance plan for maintaining high quality performance and providing high quality patient care through systematic, on-going evaluation of patient outcomes and process reviews)
- PCI Peer Quality Review Form (includes peer review process pursuant to CT Peer Review Immunity Statute)

The 2011 ACCF/AHA/SCAI practice guidelines for PCI recommend that every PCI program should operate a quality improvement program that routinely a) reviews quality outcomes of the entire program, b) reviews results of individual operators, c) includes risk adjustment, d) provides peer review of difficult or complicated cases, and e) performs random case reviews. The policies and protocols outlined in Attachment F

address these recommendations. Also, the practice guidelines note that every PCI program should participate in a regional or national PCI registry for the purpose of benchmarking its outcomes against national norms. L+M participates in the ACC-NCDR PCI registry for quality assurance and benchmarking for its emergent PCI program. L+M will continue to submit data to the ACC if approved for elective PCI to ensure its PCI program possesses exemplary quality outcomes.

5. Organizational and Financial Information

a. Identify the Applicant's ownership type(s) (e.g. Corporation, PC, LLC, etc.).

Response:
Corporation

b. Does the Applicant have non-profit status?
☒ Yes (Provide documentation) ☐ No

Response:
Refer to Attachment O for documentation of non-profit status.

c. Provide a copy of the State of Connecticut, Department of Public Health license(s) currently held by the Applicant and indicate any additional licensure categories being sought in relation to the proposal.

Response:
A copy of the State of Connecticut, Department of Public Health license is included as Attachment P. No additional licensure categories are being sought in relation to the proposal.

d. Financial Statements

i. If the Applicant is a Connecticut hospital: Pursuant to Section 19a-644, C.G.S., each hospital licensed by the Department of Public Health is required to file with OHCA copies of the hospital's audited financial statements. If the hospital has filed its most recently completed fiscal year audited financial statements, the hospital may reference that filing for this proposal.

Response:
Copies of the Hospital's audited financial statements for FY 2011 are on file with OHCA.

ii. If the Applicant is not a Connecticut hospital (other health care facilities): Audited financial statements for the most recently completed fiscal year. If audited financial statements do not exist, in lieu of audited financial statements, provide other financial documentation (e.g. unaudited balance sheet, statement of operations, tax return, or other set of books.)

e. Submit a final version of all capital expenditures/costs as follows:

Table 2: Proposed Capital Expenditures/Costs

Medical Equipment Purchase	$0
Imaging Equipment Purchase	
Non-Medical Equipment Purchase	
Land/Building Purchase *	
Construction/Renovation **	
Other Non-Construction (Specify)	
Total Capital Expenditure (TCE)	**$0**
Medical Equipment Lease (Fair Market Value) ***	$
Imaging Equipment Lease (Fair Market Value) ***	
Non-Medical Equipment Lease (Fair Market Value) ***	
Fair Market Value of Space ***	
Total Capital Cost (TCC)	**$0**
Total Project Cost (TCE + TCC)	**$0**
Capitalized Financing Costs (Informational Purpose Only)	
Total Capital Expenditure with Cap. Fin. Costs	$0

* If the proposal involves a land/building purchase, attach a real estate property appraisal including the amount; the useful life of the building; and a schedule of depreciation.
** If the proposal involves construction/renovations, attach a description of the proposed building work, including the gross square feet; existing and proposed floor plans; commencement date for the construction/ renovation; completion date of the construction/renovation; and commencement of operations date.
*** If the proposal involves a capital or operating equipment lease and/or purchase, attach a vendor quote or invoice; schedule of depreciation; useful life of the equipment; and anticipated residual value at the end of the lease or loan term.

Response:
This proposal will not incur any capital costs.

f. List all funding or financing sources for the proposal and the dollar amount of each. Provide applicable details such as interest rate; term; monthly payment; pledges and funds received to date; letter of interest or approval from a lending institution.

Response:
Not applicable. This proposal will not incur any capital costs.

g. Demonstrate how this proposal will affect the financial strength of the state's health care system.

Response:
As stated in Section 2a of this application, currently patients who receive a diagnostic catheterization at L+M and have a significant blockage of an artery are typically transferred to YNHH or another facility for elective PCI. The two procedures are "decoupled" and performed at two institutions. In FY 2011, 138 total patients were transferred from L+M for elective PCI. These transferred patients incurred more than

$1.1 million in costs from increased payer reimbursement and associated ambulance fees. In addition, the potential complications and infections transferred patients may experience can add significant cost to their care should an issue arise.

By allowing L+M to perform elective PCI on low risk patients with low risk lesions, the added costs of a transfer and the potential adverse impact on patient's health can be avoided. The financial strength of the state is improved as patients will be less costly to the health care system to treat if L+M is able to perform elective PCI in-house.

6. Patient Population Mix: Current and Projected

a. Provide the current and projected patient population mix (based on the number of patients, not based on revenue) with the CON proposal for the proposed program.

Table 3: Patient Population Mix

	Current** FY 2012	Year 1 FY 2013	Year 2 FY 2014	Year 3 FY 2015
Medicare*	46.9%	46.9%	46.9%	46.9%
Medicaid*	10.0%	10.0%	10.0%	10.0%
CHAMPUS & TriCare	0.0%	0.0%	0.0%	0.0%
Total Government	**56.9%**	**56.9%**	**56.9%**	**56.9%**
Commercial Insurers*	41.9%	41.9%	41.9%	41.9%
Uninsured	1.3%	1.3%	1.3%	1.3%
Workers Compensation	0.0%	0.0%	0.0%	0.0%
Total Non-Government	**43.1%**	**43.1%**	**43.1%**	**43.1%**
Total Payer Mix	**100.0%**	**100.0%**	**100.0%**	**100.0%**

* Includes managed care activity. ** New programs may leave the "current" column blank.
*** Fill in years. Ensure the period covered by this table corresponds to the period covered in the projections provided.

b. Provide the basis for/assumptions used to project the patient population mix.

Response:
The patient mix is projected to be consistent with FY 2012. The elective PCI program is expected to draw a similar age and patient mix as is currently experienced with L+M's existing emergent PCI program.

7. Financial Attachments I & II

a. Provide a summary of revenue, expense, and volume statistics, without the CON project, incremental to the CON project, and with the CON project. **Complete Financial Attachment I.** (Note that the actual results for the fiscal year reported in the first column must agree with the Applicant's audited financial statements.) The projections must include the first three full fiscal years of the project.

Response:
Please refer to Attachment Q for Financial Attachments I and II.

b. Provide a three year projection of incremental revenue, expense, and volume statistics attributable to the proposal by payer. **Complete Financial Attachment II.** The projections must include the first three full fiscal years of the project.

Response:
Please refer to Attachment Q for Financial Attachments I and II.

c. Provide the assumptions utilized in developing **both Financial Attachments I and II** (e.g., full-time equivalents, volume statistics, other expenses, revenue and expense % increases, project commencement of operation date, etc.).

Response:
Please refer to Attachment R for Financial Attachment assumptions. The proposal will not incur any costs other than the variable cost of supplies associated with the incremental volume. There are no additional staffing or capital costs associated with this proposal. To be conservative, it was assumed that all procedures were "coupled" meaning the diagnostic catheterization was completed the same day as the elective PCI procedure at L+M. Net revenue per case and expense per case were adjusted to reflect the incremental revenues and expenses from the proposal.

d. Provide documentation or the basis to support the proposed rates for each of the FYs as reported in Financial Attachment II. Provide a copy of the rate schedule for the proposed service(s).

Response:
Please refer to Attachment S for rate schedule.

e. Provide the minimum number of units required to show an incremental gain from operations for each fiscal year.

Response:
Not applicable. The project has an incremental gain in each year of operation.

f. Explain any projected incremental losses from operations contained in the financial projections that result from the implementation and operation of the CON proposal.

Response:
Not applicable. The project has an incremental gain in each year of operation.

g. Describe how this proposal is cost effective.

Response:
The proposal is cost effective as the addition of elective PCI at L+M results in no additional capital expenses or overhead costs. Existing facilities and equipment can be

utilized and no additional space is required. In fact, room utilization of L+M's existing catheterization labs will increase. Also, there is no additional staff required to achieve the volumes projected in the three year planning horizon. The only costs associated with the project are the variable costs necessary to perform the additional procedures.

L+M currently finances its PCI program through an annual fee paid to YNHH/YSM. The annual payment is in excess of $1.45 million and on a per case basis, this fee is substantial. Adding elective PCI will improve the cost effectiveness of the PCI service at L+M as volumes are projected to more than double by Year 1 of operation, reducing the cost per case.

EXHIBIT 8

Heart Disease Deaths Declining in Connecticut

Hartford – Data from the Connecticut Department of Public Health (DPH) show that mortality from heart disease has been declining in Connecticut since 1999.

Age-adjusted death rates from heart disease declined 28.7 percent in Connecticut between 1999 and 2008. The age-adjusted death rates from coronary heart disease and heart failure, two types of heart disease, also declined significantly in this time period. Coronary heart disease death rates declined 39.6 percent and heart failure death rates declined 6 percent. Nationally, the death rate from coronary heart disease declined 30.1 percent and the death rate from heart failure declined 5.5 percent between 1997 and 2006 (http://apps.nccd.cdc.gov/NCVDSS_DTM/). For more information on the decline in heart disease in Connecticut see the report The Burden of Cardiovascular Disease in Connecticut at: http://www.ct.gov/dph/heartstrokedata.

Improved control of high blood pressure and high cholesterol, a decline in the prevalence of smoking, and improvements in treatments, medications, and quality of care contributed to the decline in heart disease death rates. Despite these improvements, heart disease remains the number one cause of death in Connecticut and the United States.

The Connecticut DPH's Heart Disease and Stroke Prevention Program (HDSP) works to reduce the burden of heart disease and stroke among Connecticut's residents. For example, HDSP's Black Resident Program provides risk assessments, health education, and outreach to residents in an effort to reduce risk factors that lead to heart disease. Also, the Women's Healthy Heart Initiative is developing and conducting healthy lifestyle programs for women in Hartford, addressing risk factors for heart disease and stroke. Additionally, community-developed, culturally specific materials addressing heart disease, stroke, and diabetes in Connecticut's Hispanic population are being created. For more information on DPH programs see: http://www.ct.gov/dph/cwp/view.asp?a=3135&q=387022.

In September 2011, the Connecticut DPH announced that it will receive $493,891 in federal Affordable Care Act funds to support community prevention efforts to reduce chronic disease. This initiative, known as the Community Transformation Grant, is designed to help reduce the burden of chronic diseases, such as heart disease, stroke, diabetes, and cancer, by supporting prevention programs proven to have a positive impact on health.

The U.S. Department of Health and Human Services, in collaboration with nonprofit and private organizations, is launching Million Hearts, a national campaign with evidence-based interventions and strategies aimed at preventing 1 million heart attacks and strokes over the next 5 years (http://millionhearts.hhs.gov/about-mh.shtml).

EXHIBIT 1

William A. Gray, M.D.
Curriculum Vitae

CONTACT INFORMATION:

Address:	173 Ft. Washington Ave., 4th Floor New York, NY 10032
Telephone:	212.305.7060
Cell:	347.306.8601
Fax:	212.342.3660
Email:	wg2131@columbia.edu

EDUCATION

Undergraduate	Dickinson College Carlisle, Pennsylvania Bachelor of Science in Chemistry with Honors	1976 – 1980
Medical	Temple University School of Medicine Philadelphia, Pennsylvania Doctor of Medicine	1980 – 1984

POSTGRADUATE TRAINING

Intern/Resident in Internal Medicine Brown University/Rhode Island Hospital Providence, Rhode Island	1984 – 1987
Chief Resident in Internal Medicine Brown University/Rhode Island Hospital Providence, Rhode Island	1987 – 1988
Clinical/Research Fellow in Cardiology Brown University/Rhode Island Hospital Providence, Rhode Island	1988 – 1991
Interventional Fellow in Cardiology Brown University/Rhode Island Hospital Providence, Rhode Island	1991 – 1992

BOARD CERTIFICATION

National Board of Medical Examiners	1985
American Board of Internal Medicine	
Internal Medicine	1987
Cardiology	1991, 2001
Interventional Cardiology	1999, 2009
American Board of Vascular Medicine	
Vascular Medicine	2005
Endovascular Medicine	2005

MEDICAL LICENSURE	State of New York, License No. 236296	2005
	State of Washington, License No. 37638	1999
	Nuclear Medicine	2001
	State of New Mexico, License No. 92-234	1992
	Nuclear Medicine	1993
	State of Rhode Island, License No. 6844	1986
ACADEMIC POSITIONS	Associate Professor of Clinical Medicine Columbia University College of Physicians and Surgeons	2005 – Present
	Assistant Clinical Professor of Medicine University of New Mexico Albuquerque, New Mexico	1993 – 1999
	Clinical Instructor of Medicine Brown University Providence, Rhode Island	1987 – 1992
HOSPITAL ACTIVITIES	Director, Endovascular Services New York-Presbyterian Hospital Columbia University Medical Center New York, New York	2005 – Present
	Director, Endovascular Care Swedish Medical Center Seattle, Washington	1999 – 2005
	Board of Directors (founding member) Heart Hospital of New Mexico Albuquerque, New Mexico	1998 – 1999
	Vice-Chair, Division of Cardiology Chairman, Cardiac Clinical Operations Director, Coronary Care Units Presbyterian Hospital, Albuquerque, New Mexico	1996 – 1997 1993 – 1997 1993 – 1997
	Medical Director, Project Heart Start (Mass CPR training) Albuquerque, New Mexico	1994 – 1998
	Intern Selection Committee Brown University/Rhode Island Hospital	1987 – 1991

RELATED WORK EXPERIENCE	President, Southwest Cardiology Associates Albuquerque, New Mexico	1998 – 1999
	Director of Intervention and Research Southwest Cardiology Associates Albuquerque, New Mexico	1996 – 1999
	Emergency Physician Bergstrom Air Force Base Austin, Texas	1991 – 1992
	Medical Co-Director, Ambulatory Services Notre Dame Hospital Central Falls, Rhode Island	1988 – 1990
	Emergency Physician St. Joseph's Hospitals Providence, Rhode Island	1987 – 1992
HONORS/AWARDS	*Horace Elton Rogers Award* for Excellence in Chemistry Dickinson College	1979
	The Haffenreffer Foundation Award for Outstanding Resident in Internal Medicine Brown University/Rhode Island Hospital	1987
EDITORIAL BOARD	Journal of the American College of Cardiology, Interventions Catheterization and Cardiac Interventions Endovascular Today	
JOURNAL REVIEWER	Circulation Journal of the American College of Cardiology Journal of the American Medical Association Catheterization and Cardiac Interventions	

RESEARCH ACTIVITY

National Principal Investigator

Coronary

ZoMAXX II [Abbott Vascular]	Randomized Trial of ZoMAXX Drug-Eluting Coronary Stent vs.TAXUS Stent in Patients with de novo Coronary Disease

Endovascular

ARCHeR [Guidant]	High Surgical Risk Carotid Stent Trial using the Acculink Stent and Accunet Carotid Protection Devices
CAPTURE [Abbott Vascular]	Carotid RX ACCULINK/ACCUNET Post Approval Trial to Uncover Unanticipated and Rare Events
CAPTURE 2 [Abbott Vascular]	Carotid RX ACCULINK/ACCUNET Post-Approval Trial to Uncover Unanticipated and Rare Events: second phase
COMPLETE SE [Medtronic]	Iliac IDE single arm study
ACTIVE [Medtronic]	Iliac IDE single arm study
EMBOLDEN [WL GORE]	EMBOLic Filter in Carotid StENting for High Risk Surgical Subjects
STROLL [Cordis/Johnson &Johnson]	Smart Stent in the SFA
CHOICE [Abbott Vascular] (Executive Committee)	Carotid Stenting for High Surgical-Risk Patients
PROTECT [Abbott Vascular] (Executive Committee)	Protected Carotid Artery Stenting in Subjects at High Risk for Carotid Endarterectomy

Site Principal Investigator

Coronary

SCORES [Boston Scientific]	Radius coronary stent
TRAP trial [Microvena]	Coronary vascular filter

Endovascular

CREST– [NIH/NHLBI]	Carotid Revascularization Endarterectomy vs. Stent Trial
SAPPHIRE[Cordis/Johnson&Johnson]	Randomized High Surgical Risk carotid stent trial
ARCHER[Guidant]	High Surgical Risk Carotid Stent Trial using the Acculink stent and Accunet carotid protection device
CABERNET [EndoTex/BSC]	Carotid Artery Revascularization Using the EPI FilterWire EX and the NexStent
CREATE [eV3]	Carotid Revascularization with ev3 Arterial Technology Evolution

MAVeRIC [Medtronic/AVE]	Self-Expanding Carotid Stent System with Distal Protection In the Treatment of Carotid Stenosis
Carotid Wallstent [Schneider/BSC]	Carotid Stent vs. CEA Randomized Trial
Memotherm [BARD]	Phase I Carotid Stent Trial
CASES-PMS[Cordis/Johnson&Jonhson]	Carotid Artery Stenting with Embolic Protection Surveillance: Post Marketing Study
CAPTURE [Abbott Vascular]	Carotid RX ACCULINK/ACCUNET Post-Approval Trial to Uncover Unanticipated and Rare Events
MOBILE [Novoste]	Brachytherapy to prevent restenosis following peripheral arterial intervention
VIBRANT[WL Gore]	Viabahn vs. nitinol stents for SFA intervention
STROLL [Cordis]	Smart Stent in the SFA
CAPTURE 2 [Abbott Vascular]	Carotid RX ACCULINK/ACCUNET Post Approval Trial to Uncover Unanticipated and Rare Events: second phase
CHOICE [Abbott Vascular]	Carotid Stenting for High Surgical-Risk Patients
EMBOLDEN [WL Gore]	EMBOLic Filter in Carotid StENting for High Risk Surgical Subjects
ACTIVE [Medtronic]	Iliac IDE single arm study (balloon-expandable stent)
COMPLETE SE [Medtronic]	Iliac IDE single arm study (self-expanding stent)
PROTECT [Abbott Vascular]	Protected Carotid Artery Stenting in Subjects at High Risk for Carotid Endarterectomy
CENTRAL [CR BARD]	Crosser Enters The Right Arterial Lumen

STRUCTURAL

PROTECT AF [Atritech]	Watchman Left Atrial Appendage System for Embolic Protection in Patients with Atrial Fibrillation
PLAATO [eV3]	Percutaneous Left Atrial Appendage Transcatheter Occlusion. Using the X-Caliber System, A Feasibility Study
EVEREST 1 [evalve]	A Feasibility Study of the Edge to Edge Repair of Mitral Valve Regurgitation Using the Evalve Cardiovascular Valve Repair System
EVEREST II [evalve]	A Randomized Study of the Evalve Cardiovascular Valve Repair System Endovascular Valve Edge-to-Edge Repair Study
CardiacAssist	Percutaneous LVAD in cardiogenic shock

RESEARCH-RELATED ACTIVITIES

Co-chair, Peripheral Vascular Academic Research Consortium	2010-
Chair, Data Safety and Monitoring Biofreedrom Trial	2009-2010
Executive Committee, ACT I trial	2004-present
Interventional Management Committee, ACT I trial	2005-present
Interventional Management Committee, CREST study	2003-2008
Member, CEC Fortron AAA study	2005-2009
Chairman, CEC PLAATO study	2003-2007
BARD Memotherm Iliac Stent Trial Data Safety and Monitoring Board	1999-2001

COURSE DIRECTORSHIPS

Course Co-Director International Congress for Endovascular Specialists (iCON) Phoenix, AZ	2011
Course Co-Director International Symposium on Endovascular Therapies (ISET) Miami, FL	2011
Course Co-Director Transcatheter Cardiovascular Therapeutics (TCT) Washington, D.C.	2005-present
Program Director *The Status of Carotid Stenting* American College of Cardiology	2003 – 2005
Course Director Science Innovation Synergy (SIS) Seattle, WA	2001-2008
Chair, John Locke Conference Swedish Medical Center Seattle, WA	2000 – 2001
Wilson Lectureship Planning Committee Presbyterian Hospital, Albuquerque, New Mexico	1994 – 1997

	Co-Director, Santa Fe Symposium, Albuquerque, New Mexico	1993 – 1999
INDUSTRY EXPERIENCE		
	Scientific Advisory Board, Medtronic	2005-present
	Scientific Advisory Board, Cordis/Johnson &Johnson	2005- present
	Scientific Advisory Board, Ovalis Corporation	2005- present
	Scientific Advisory Board, CoAptus Corporation	2004 - present
	Scientific Advisory Board (chair), Pathway Medical	2004 – present
	Scientific Advisory Board, Abbott Vascular	2003 – present
	Medical Advisory Board, Rubicon Medical Corp.	2002 – 2005
	Medical Advisory Board, The Medicines Company	2003 – 2005
	Medical Director, BEACH carotid trial, Boston Scientific	2002-2004
	Consultant, Covidien	2009- present
	Consultant, Schneider USA	1997 – 1999
	Consultant, BARD USA,	1995 – 2010
	Consultant, Guidant Corporation	1999 – 2005
PATENTS	Temporary Vascular Filter Guide Wire	2002
	PFO closure devices (co-holder CoAptus corporation)	Pending
	PFO closure devices (co-holder Ovalis corporation)	Pending
DEVICE/PROCEDURE PROCTOR		
	Cordis/Johnson and Johnson Endovascular Carotid System	2005 – Present
	Guidant/Abbott Vascular Corporation Carotid System	2005 – Present
	NMT PFO device	2003-2004
	Schneider USA Carotid Stent	1997 – 1999

Johnson and Johnson Interventional Coronary Stent	1995 – 1996
Heart Technology Rotablator	1995 – 2003

SOCIETIES/OTHER AFFILIATIONS

Co-chair, SCAI Carotid and Neurovascular Committee	2010-
Member, Medical Society of the State of New York New York Country Medical Society Inc.	2010-
Member, New York County Medical Society	2010-
Board of Directors American Board of Vascular Medicine	2009-present
Fellow, Society of Cardiac Angiography and Intervention	2005-present
American College of Cardiology PVD Committee member, SCAI representative	2003-2005
American Heart Association Stroke Council	2001-present
American Heart Association New Mexico Chapter, Board of Directors	1995 – 1997
Medical Advisory Board New Mexico Emergency Medical System	1995 – 1997
Fellow, American College of Cardiology	1993-present
Member, Greater Albuquerque Medical Association	1992 – 1999
Member, American Heart Association Circulation Council	1988
Member, American College of Physicians	1987-present

Original/Peer Reviewed Articles

1. Gray WA, Capone RJ, Most AS. Unsuccessful Emergency Medical Resuscitation - Are Continued Efforts in the Emergency Department Justified? N Engl J Med 1991; 325:1393-1398.

2. Gray WA, Gewirtz H. Comparison of 99mTc-teboroxime with thallium for myocardial imaging in the presence of a coronary artery stenosis. Circulation. 1991 Oct;84(4):1796-1807.

3. Gray WA, Capone RJ, Most AS. Resuscitation after Cardiac Arrest Outside the Hospital (letter). N Engl J Med 1991; Vol. 20; 325:1495-1497.

4. Gray WA. "Nearly successful" resuscitation. Lancet. 1993 Apr 3;341(8849):866.

5. Gray WA. Prehospital resuscitation. The good, the bad, and the futile. JAMA. 1993 Sep 22-29;270(12):1471-1472.

6. Mills I, Wrenn D, Sasken H, Gray W, Bier J, Levine D, Berman S, Gilson M, Gewirtz H. Adaptive Responses of Coronary Circulation and Myocardium to Chronic Reduction in Perfusion Pressure and Flow. Am J Physiol 1994 Feb;266 (2 Pt 2):H447-457.

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8. Gray WA, DuBroff R, White H. A Common Clinical Conundrum. N Engl J Med, 1997; 336:1008-1011.

9. Gray WA, DuBroff R, White H. Carotid Stenting (letter). N Engl J Med, 1997; 337(6): 427-428.

10. Walji S, Peterson RJ, Neis P, DuBroff R, Gray WA, Benge W. Ultra-fast track hospital discharge using conventional cardiac surgical techniques. Ann Thorac Surg. 1999 Feb;67(2):363-9; discussion 369-370.

11. Gray WA, Barrett DM, Benge JW. Heart or head? N Engl J Med. 1999 Nov 4;341(19):1458-1462.

12. Wholey MH, Wholey M, Mathias K, Roubin GS, Diethrich EB, Henry M, Bailey S, Bergeron P, Dorros G, Eles G, Gaines P, Gomez CR, Gray B, Guimaraens J, Higashida R, Ho DS, Katzen B, Kambara A, Kumar V, Laborde JC, Leon M, Lim M, Londero H, Mesa J, Musacchio A, Myla S, Ramee S, Rodriquez A, Rosenfield K, Sakai N, Shawl F, Sievert H, Teitelbaum G, Theron JG, Vaclav P, Vozzi C, Yadav JS, Yoshimura SI. Global experience in cervical carotid artery stent placement. Catheter Cardiovasc Interv. 2000 Jun;50(2):160-7.

13. New G, Roubin GS, Iyer SS, Vitek JJ, Wholey MH, Diethrich EB, Hopkins LN, Hobson RW 2nd, Leon MB, Myla SV, Shawl F, Ramee SR, Yadav JS, Rosenfield K, Liu MW,

Gomez CR, Al-Mubarak N, Gray WA, Tan WA, Goldstin JE, Stack RS. Safety, efficacy, and durability of carotid artery stenting for restenosis following carotid endarterectomy: a multicenter study. J Endovasc Ther. 2000 Oct;7(5):345-352.

14. Gray WA. Successful resolution of a peripheral arterial in-stent thrombus in a patient with combined eptifibatide and thrombolytic therapy. J Invasive Cardiol. 2000 Dec;12 Suppl D:19D-20D.

15. Gray WA, White HJ Jr, Barrett DM, Chandran G, Turner R, Reisman M. Carotid stenting and endarterectomy: a clinical and cost comparison of revascularization strategies. Stroke. 2002 Apr;33(4):1063-1070.

16. Wang JC, Aucoin-Barry D, Manuelian D, Monbouquette R, Reisman M, Gray W, Block PC, Block EH, Ladenheim M, Simon DI. Incidence of aspirin nonresponsiveness using the Ultegra Rapid Platelet Function Assay-ASA. Am J Cardiol. 2003 Dec 15;92(12):1492-1494.

17. Reisman M, Gray WA. Vascular brachytherapy and the strontium vascular brachytherapy system. J Invasive Cardiol. 2003 Sep;15(9):520-522.

18. Casserly IP, Kereiakes DJ, Gray WA, Gibson PH, Lauer MA, Reginelli JP, Moliterno DJ. Point-of-care ecarin clotting time versus activated clotting time in correlation with bivalirudin concentration. Thromb Res. 2004;113(2):115-121.

19. Hanna IR, Kolm P, Martin R, Reisman M, Gray W, Block PC. Left atrial structure and function after percutaneous left atrial appendage transcatheter occlusion (PLAATO): six-month echocardiographic follow-up. J Am Coll Cardiol. 2004 May 19;43(10):1868-1872.

20. Gray WA. A Cardiologist in the Carotids. J Am Coll Cardiol. 2004 May 5;43(9):1602-1605.

21. Spencer MP, Moehring MA, Jesurum J, Gray WA, Olsen JV, Reisman M. Power m-mode transcranial Doppler for diagnosis of patent foramen ovale and assessing transcatheter closure. J Neuroimaging. 2004 Oct;14(4):342-349.

22. Reisman M, Christofferson RD, Jesurum J, Olsen JV, Spencer MP, Krabill KA, Diehl L, Aurora S, Gray WA. Migraine headache relief after transcatheter closure of patent foramen ovale. J Am Coll Cardiol. 2005 Feb 15;45(4):493-495.

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atrial fibrillation: results from the international multi-center feasibility trials. J Am Coll Cardiol. 2005 Jul 5;46(1):9-14.

25. Hara H, Virmani R, Ladich E, Mackey-Bojack S, Titus J, Reisman M, Gray W, Nakamura M, Mooney M, Poulose A, Schwartz RS. Patent foramen ovale: current pathology, pathophysiology, and clinical status. J Am Coll Cardiol. 2005 Nov 1;46(9):1768-76.

26. Gray WA. Proceedings of the TCT: endovascular interventional care evolves into multidisciplinary field. J Interv Cardiol. 2006 Jun;19(3):222-225.

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EXHIBIT 2



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Sidney C. Smith, Jr, Ted E. Feldman, John W. Hirshfeld, Jr, Alice K. Jacobs, Morton J. Kern, Spencer B. King, III, Douglass A. Morrison, William W. O'Neill, Hartzell V. Schaff, Patrick L. Whitlow, David O. Williams, Elliott M. Antman, Sidney C. Smith, Jr, Cynthia D. Adams, Jeffrey L. Anderson, David P. Faxon, Valentin Fuster, Jonathan L. Halperin, Loren F. Hiratzka, Sharon Ann Hunt, Alice K. Jacobs, Rick Nishimura, Joseph P. Ornato, Richard L. Page, and Barbara Riegel

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ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention)

WRITING COMMITTEE MEMBERS

Sidney C. Smith, Jr, MD, FACC, FAHA, *Chair*

Ted E. Feldman, MD, FACC, FSCAI*
John W. Hirshfeld, Jr, MD, FACC, FSCAI*
Alice K. Jacobs, MD, FACC, FAHA, FSCAI
Morton J. Kern, MD, FACC, FAHA, FSCAI*
Spencer B. King, III, MD, MACC, FSCAI
Douglass A. Morrison, MD, PhD, FACC, FSCAI*
William W. O'Neill, MD, FACC, FSCAI
Hartzell V. Schaff, MD, FACC, FAHA
Patrick L. Whitlow, MD, FACC, FAHA
David O. Williams, MD, FACC, FAHA, FSCAI

TASK FORCE MEMBERS

Elliott M. Antman, MD, FACC, FAHA, *Chair*
Sidney C. Smith, Jr., MD, FACC, FAHA, *Vice Chair*

Cynthia D. Adams, MSN, APRN-BC, FAHA
Jeffrey L. Anderson, MD, FACC, FAHA
David P. Faxon, MD, FACC, FAHA†
Valentin Fuster, MD, PhD, FACC, FAHA, FESC†
Jonathan L. Halperin, MD, FACC, FAHA
Loren F. Hiratzka, MD, FACC, FAHA†
Sharon Ann Hunt, MD, FACC, FAHA
Alice K. Jacobs, MD, FACC, FAHA
Rick Nishimura, MD, FACC, FAHA
Joseph P. Ornato, MD, FACC, FAHA
Richard L. Page, MD, FACC, FAHA
Barbara Riegel, DNSc, RN, FAHA

*SCAI Official Representative
†Former Task Force Member during this writing effort

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PREAMBLE

It is important that the medical profession play a significant role in critically evaluating the use of diagnostic procedures and therapies as they are introduced and tested in the detection, management, or prevention of disease states. Rigorous and expert analysis of the available data documenting relative benefits and risks of those procedures and therapies can produce helpful guidelines that improve the effectiveness of care, optimize patient outcomes, and favorably affect the overall cost of care by focusing resources on the most effective strategies.

The American College of Cardiology (ACC) and the American Heart Association (AHA) have jointly engaged in the production of such guidelines in the area of cardiovascular disease since 1980. This effort is directed by the ACC/AHA Task Force on Practice Guidelines, whose charge is to develop and revise practice guidelines for important cardiovascular diseases and procedures. The Task Force is pleased to have this guideline cosponsored by the Society for Cardiovascular Angiography and Interventions (SCAI). Experts in the subject under consideration have been selected from all three organizations to examine subject-specific data and write guidelines. The process includes additional representatives from other medical practitioner and specialty groups where appropriate. Writing groups are specifically charged to perform a formal literature review, weigh the strength of evidence for or against a particular treatment or procedure, and include estimates of expected health outcomes where data exist. Patient-specific modifiers, comorbidities, and issues of patient preference that might influence the choice of particular tests or therapies are considered, as well as frequency of follow-up and cost-effectiveness. When available, information from studies on cost will be considered; however, review of data on efficacy and clinical outcomes will be the primary basis for preparing recommendations in these guidelines.

The ACC/AHA Task Force on Practice Guidelines makes every effort to avoid any actual, potential, or perceived conflicts of interest that might arise as a result of an outside relationship or personal interest of a member of the writing panel. Specifically, all members of the writing panel are asked to provide disclosure statements of all such relationships that might be perceived as real or potential conflicts of interest. These statements are reviewed by the parent task force, reported orally to all members of the writing panel at each meeting, and updated and reviewed by the writing committee as changes occur.

The practice guidelines produced are intended to assist healthcare providers in clinical decision making by describing a range of generally acceptable approaches for the diagnosis, management, or prevention of specific diseases or conditions. These guidelines attempt to define practices that meet the needs of most patients in most circumstances. These guideline recommendations reflect a consensus of expert opinion after a thorough review of the available, current scientific evidence and are intended to improve patient care. If these guidelines are used as the basis for regulatory/payer decisions, the ultimate goal is quality of care and serving the patient's best interests. The ultimate judgment regarding care of a particular patient must be made by the healthcare provider and patient in light of all of the circumstances presented by that patient.

These guidelines were approved for publication by the governing bodies of the ACCF, AHA, and SCAI. The guidelines will be reviewed annually by the ACC/AHA Task Force on Practice Guidelines and will be considered current unless they are revised or withdrawn from distribution. The summary article and recommendations are published in the January 3, 2006 issue of the *Journal of the American College of Cardiology*, the January 3, 2006 issue of *Circulation*, and the January 2006 issue of *Catheterization and Cardiovascular Interventions*. The full-text guideline is posted on the World Wide Web sites of the ACC (www.acc.org), the AHA (www.americanheart.org), and the SCAI (www.scai.org). Copies of the full text and the executive summary are available from the ACC, AHA, and the SCAI.

Elliott M. Antman, MD, FACC, FAHA
Chair, ACC/AHA Task Force on Practice Guidelines

1. INTRODUCTION

The ACC/AHA Task Force on Practice Guidelines was formed to gather information and make recommendations about appropriate use of technology for the diagnosis and treatment of patients with cardiovascular disease. Percutaneous coronary interventions (PCIs) are an important group of technologies in this regard. Although initially limited to balloon angioplasty and termed percutaneous transluminal coronary angioplasty (PTCA), PCI now includes other new techniques capable of relieving coronary narrowing. Accordingly, in this document, implantation of intracoronary stents and other catheter-based interventions for treating coronary atherosclerosis are considered components of PCI. In this context, PTCA will be used to refer to those studies using only balloon angioplasty, whereas PCI will refer to the broader group of percutaneous techniques. These new technologies have impacted the effectiveness and safety profile initially established for balloon angioplasty. Moreover, additional experience has been gained in the use of adjunctive pharmacological treatment with glycoprotein (GP) IIb/IIIa receptor antagonists and the use of bivalirudin, thienopyridines, and drug-eluting stents (DES). In addition, since publication of the guidelines in 2001, greater experience in the performance of PCI in patients with acute coronary syndromes and in community hospital settings has been gained. In view of these developments, an update of these guidelines

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is warranted. This document reflects the opinion of the ACC/AHA/SCAI writing committee charged with updating the 2001 guidelines for PCI (1).

Several issues relevant to the Writing Committee's process and the interpretation of the guidelines have been noted previously and are worthy of restatement. First, PCI is a technique that has been continually refined and modified; hence, continued, periodic guideline revision is anticipated. Second, these guidelines are to be viewed as broad recommendations to aid in the appropriate application of PCI. Under unique circumstances, exceptions may exist. These guidelines are intended to complement, not replace, sound medical judgment and knowledge. They are intended for operators who possess the cognitive and technical skills for performing PCI and assume that facilities and resources required to properly perform PCI are available. As in the past, the indications are categorized as class I, II, or III on the basis of a multifactorial assessment of risk and expected efficacy viewed in the context of current knowledge and the relative strength of this knowledge.

These classes summarize the recommendations for procedures or treatments as follows:

Class I: Conditions for which there is evidence for and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.

Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.

Class IIb: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful.

In addition, the weight of evidence in support of the recommendation is listed as follows:

- Level of Evidence A: Data derived from multiple randomized clinical trials or meta-analyses.
- Level of Evidence B: Data derived from a single randomized trial or nonrandomized studies.
- Level of Evidence C: Only consensus opinion of experts, case studies, or standard-of-care.

A recommendation with level of evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Even though randomized trials are not available, there may be a very clear clinical consensus that a particular test or therapy is useful and effective.

In instances where recommendations of class III, level of evidence C, occur, it is recognized that the bases of these recommendations are opinion and the consensus of the writing group. In this setting, it is not unreasonable for clinical trials to be conducted to further investigate the validity of this consensus opinion. The schema for classification of recommendations and level of evidence is summarized in Table 1, which also illustrates how the grading system provides an estimate of the size of the treatment effect and an estimate of the certainty of the treatment effect.

The committee conducted comprehensive searching of the scientific and medical literature on PCI, with special emphasis on randomized controlled trials and meta-analyses published since 2001. In addition to broad-based searching on PCI, specific targeted searches were performed on the following subtopics: catheter-based intervention, stents (drug-eluting and bare-metal), cardiac biomarkers (e.g., creatine kinase and troponins), pharmacological therapy (aspirin, thienopyridines, GP IIb/IIIa inhibitors, heparin, and direct thrombin inhibitors), special populations (women, patients with diabetes, elderly), coronary artery bypass grafting (CABG), high-risk PCI, quality, outcomes, volume, left main PCI (protected and unprotected), distal embolic protection, intravascular ultrasound (IVUS), fractional flow reserve (FFR), vascular closure, and secondary prevention/risk factor modification. The complete list of keywords is beyond the scope of this section. The committee reviewed all compiled reports from computerized searches and conducted additional searching by hand. Literature citations were generally restricted to published manuscripts appearing in journals listed in Index Medicus. Because of the scope and importance of certain ongoing clinical trials and other emerging information, published abstracts were cited when they were the only published information available. Additionally, the Committee reviewed and incorporated recommendations and/or text from published ACC/AHA or SCAI documents to maintain consistency, as appropriate.

Initially, this document describes the background information that forms the foundation for specific recommendations. Topics fundamental to coronary intervention are reviewed, followed by separate discussions relating to unique technical and operational issues. This format is designed to enhance the usefulness of this document for the assessment and care of patients with coronary artery disease (CAD). Formal recommendations for the use of PCI according to clinical presentation are included in Section 5. A clear distinction is drawn between the emergency use of PCI for patients with ST-segment elevation myocardial infarction (STEMI), termed "primary PCI," and all other procedures, which are included under the term "elective PCI" (see Section 4.2 for further discussion).

This committee includes cardiologists with and without involvement in interventional procedures, and a cardiac surgeon. This document was reviewed by 2 official reviewers nominated by ACC; 2 official reviewers nominated by AHA;

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"Estimate of Certainty (Precision) of Treatment Effect"
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Table 1. Applying Classification of Recommendations and Level of Evidence

	"Size of Treatment Effect"		
	Class IIa ***Benefit >> Risk*** ***Additional studies with focused objectives needed*** **IT IS REASONABLE to perform procedure/administer treatment**		
Level A *Multiple (3-5) population risk strata evaluated** *General consistency of direction and magnitude of effect*	• **Recommendation in favor of treatment or procedure being useful/effective** • **Some conflicting evidence from multiple randomized trials or meta-analyses**		
Level B *Limited (2-3) population risk strata evaluated**	• **Recommendation in favor of treatment or procedure being useful/ effective** • **Some conflicting evidence from single randomized trial or non-randomized studies**		
Level C *Very limited (1-2) population risk strata evaluated**	• **Recommendation in favor of treatment or procedure being useful/ effective** • **Only diverging expert opinion, case studies, or standard-of-care**		
Suggested phrases for writing recommendations †	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/ beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown /unclear/uncertain or not well established	is not recommended is not indicated should not is not useful/effective/beneficial may be harmful

*Data available from clinical trials or registries about the usefulness/efficacy in different sub-populations, such as gender, age, history of diabetes, history of prior MI, history of heart failure, and prior aspirin use. A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Even though randomized trials are not available, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

†In 2003, the ACC/AHA Task Force on Practice Guidelines developed a list of suggested phrases to use when writing recommendations. All recommendations in this guideline have been written in full sentences that express a complete thought, such that a recommendation, even if separated and presented apart from the rest of the document (including headings above sets of recommendations), would still convey the full intent of the recommendation. It is hoped that this will increase readers' comprehension of the guidelines and will allow queries at the individual recommendation level.

2 official reviewers nominated by SCAI; 1 official reviewer from the ACC/AHA Task Force on Practice Guidelines; and 8 content reviewers, including members from the AHA Committee on Diagnostic and Interventional Cardiac Catheterization and the ACCF Cardiac Catheterization and Intervention Committee.

2. GENERAL CONSIDERATIONS AND BACKGROUND

Coronary angioplasty was first introduced by Andreas Gruentzig in 1977 (2) as a nonsurgical method for coronary arterial revascularization. Fundamentally, the technique involved advancing a balloon-tipped catheter to an area of coronary narrowing, inflating the balloon, and then removing the catheter after deflation. Early reports demonstrated that balloon angioplasty could reduce the severity of coronary stenosis and diminish or eliminate objective and subjective manifestations of ischemia (3-5). Although angioplasty was clearly feasible and effective, the scope of coronary disease to be treated was quite narrow. Also, because angioplasty could result in sudden arterial occlusion and subsequent myocardial infarction (MI), immediate access to coronary bypass surgery was essential (6). With experience and time, however, the cognitive and technical aspects as much as the equipment used to perform angioplasty became more refined. Observational reports of large numbers of patients confirmed that coronary angioplasty could be applied to broad groups of coronary patients with higher rates of success and lower rates of complications than seen in initial experiences (7,8). More than 1 000 000 PCI procedures are performed yearly in the United States (9), and it has been estimated that nearly 2 000 000 procedures are performed annually worldwide.

The value of coronary angioplasty was further defined by comparing its results to those of alternative methods of treatment. Randomized clinical trials have assessed the outcomes of patients treated by a strategy of initial angioplasty to one of medical therapy alone or to coronary artery bypass surgery (10-14). The results of these trials have clarified the utility of angioplasty in terms of effectiveness, complications, and patient selection. The technique of coronary angioplasty has also been expanded by the development of devices that replace or serve as adjuncts to the balloon catheter. These "new devices" have been evaluated and have had a variable impact in enhancing the immediate- and long-term efficacy and safety of coronary angioplasty. The following section of this report expands on this background and describes the practice of PCI as it is applied today.

Advances in coronary-based interventions, especially the use of bare-metal stents (BMS) and drug-eluting stents (DES), have improved the efficacy and safety profile of percutaneous revascularization observed for patients undergoing PTCA. For example, stents reduce both the acute risk of major complications and late-term restenosis. The success of new coronary devices in meeting these goals is reflected in part by the rapid transition from the use of PTCA alone (less than 30%) to the high use of PCI with stenting, which was greater than 70% by the late 1990s (Figure 1) (15). Atherectomy devices and stenting, associated with improved acute angiographic and clinical outcomes compared with PTCA alone in specific subsets, continue to be applied to a wider patient domain that includes multivessel disease and complex coronary anatomy. However, strong evidence (level A data from multiple randomized clinical trials) is primarily available for stenting over PTCA in selected patients undergoing single-vessel PCI.

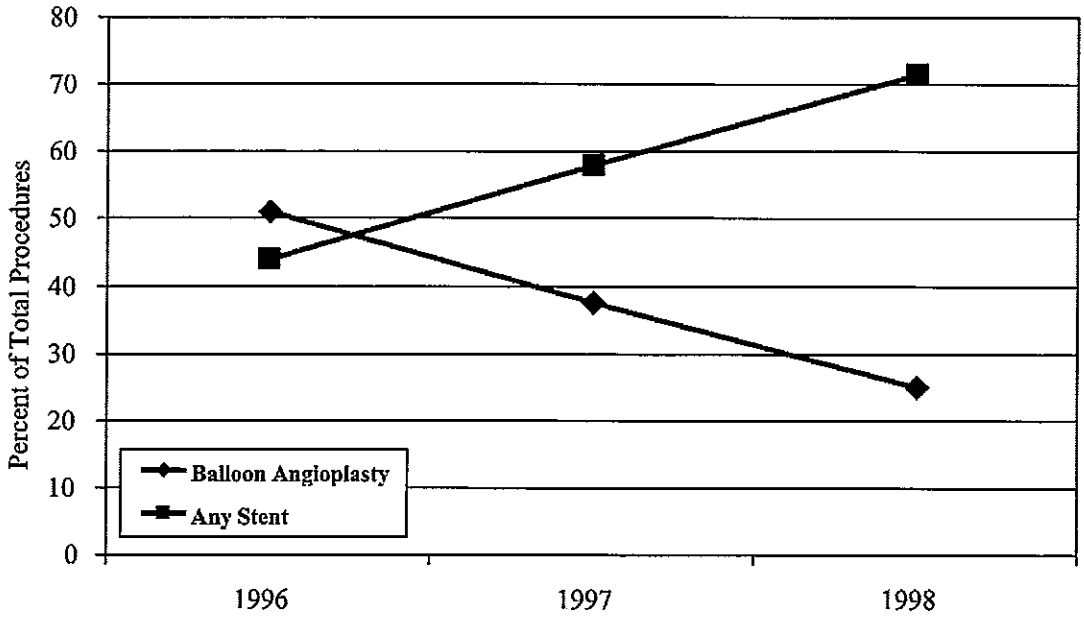

Figure 1. Frequency of device use in the SCAI registry. Source data from Laskey et al. Catheter Cardiovasc Interv 2000;49:19-22 (15).

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The range of non-balloon revascularization technology approved by the Food and Drug Administration (FDA) for use in native and/or graft coronary arteries includes balloon expandable stents, DES, extraction atherectomy, directional coronary atherectomy, rotational atherectomy, rheolytic thrombectomy catheter, proximal and distal embolic protection devices, excimer laser coronary atherectomy, and local radiation devices to reduce in-stent restenosis (ISR) (16,17). A variety of devices are under investigation, including new designs of balloon or self-expanding stents and mechanical thrombectomy devices. This guideline update will focus on the FDA-approved balloon-related and non-balloon coronary revascularization devices.

3. OUTCOMES

The outcomes of PCI are measured in terms of success and complications and are related to the mechanisms of the employed devices, as well as the clinical and anatomic patient-related factors. Complications can be divided into 2 categories: (a) those common to all arterial catheterization procedures and (b) those related to the specific technology used for the coronary procedure. Specific definitions of success and complications exist, and where appropriate, the definitions used herein are consistent with the ACC-National Cardiovascular Data Registry (NCDR®) Catheterization Laboratory Module version 3.0 (18). The committee recommends such standards whenever feasible in order to accommodate the common database for the assessment of outcomes. With increased operator experience, new technology, and adjunctive pharmacotherapy, the overall success and complication rates of angioplasty have improved.

3.1. Definitions of PCI Success

The success of a PCI procedure may be defined by angiographic, procedural, and clinical criteria.

3.1.1. Angiographic Success

A successful PCI produces substantial enlargement of the lumen at the target site. The consensus definition before the widespread use of stents was the achievement of a minimum stenosis diameter reduction to less than 50% in the presence of grade 3 Thrombolysis In Myocardial Infarction (TIMI) flow (assessed by angiography) (1). However, with the advent of advanced adjunct technology, including coronary stents, a minimum stenosis diameter reduction to less than 20% has been the clinical benchmark of an optimal angiographic result. Frequently, there is a disparity between the visual assessment and computer-aided quantitative stenosis measurement (19,20), and, thus, the determination of success may be problematic when success rates are self-reported.

3.1.2. Procedural Success

A successful PCI should achieve angiographic success without major clinical complications (e.g., death, MI, emergency coronary artery bypass surgery) during hospitalization (1,3). Although the occurrence of emergency coronary artery bypass surgery and death are easily identified end points, the definition of procedure-related MI has been debated. The development of Q waves in addition to a threshold value of creatine kinase (CK) elevation has been commonly used. Most agree that the definition of MI as put forth by the ACC/European Society of Cardiology document on the redefinition of MI (21) should be the accepted standard. However, the clinical significance and definition of cardiac biomarker elevations in the absence of Q waves remains the subject of investigation and debate (21a). Several reports have identified non–Q-wave MIs with CK-MB elevations 3 to 5 times the upper limit of normal as having clinical significance (22,23). One report suggests that a greater than 5 times increase in CK-MB is associated with worsened outcome (24). Thus, this degree of increase in CK-MB without Q waves is considered by most to qualify as an associated complication of PCI. Troponin T or I elevation occurs frequently after PCI. The timing of the peak elevation after PCI is unclear (25). Minor elevations do not appear to have prognostic value, whereas marked (greater than 5 times) elevations are associated with worsened 1-year outcome (Table 2) (26-40). Troponin T or I elevation occurs more frequently than CK-MB increase after PCI (34).

3.1.3. Clinical Success

In the short term, a clinically successful PCI includes anatomic and procedural success with relief of signs and/or symptoms of myocardial ischemia after the patient recovers from the procedure. The long-term clinical success requires that the short-term clinical success remain durable and that the patient have persistent relief of signs and symptoms of myocardial ischemia for more than 6 months after the procedure. Restenosis is the principal cause of lack of long-term clinical success when a short-term clinical success has been achieved. Restenosis is not considered a complication but rather an associated response to vascular injury. The incidence of clinically important restenosis may be judged by the frequency with which subsequent revascularization procedures are performed on target vessels after the index procedure.

3.2. Acute Outcome: Procedural Complications

Class I

All patients who have signs or symptoms suggestive of MI during or after PCI and those with complicated procedures should have CK-MB and troponin I or T measured after the procedure. ***(Level of Evidence: B)***

Class IIa

Routine measurement of cardiac biomarkers (CK-MB and/or troponin I or T) in all patients undergoing PCI is reasonable 8 to 12 hours after the procedure. ***(Level of Evidence: C)***

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Table 2. Incidence of Troponin Elevations After Percutaneous Coronary Intervention in the Published Literature

First Author of Study (Reference)	n	Marker	% Positive	Positive Definition	Prognostic Information
Hunt (29)	22	Troponin I	0	Greater than 6 ng per mL	N/A
Ravkilde (30)	23	Troponin T	13	Greater than 0.12 ng per mL	N/A
Karim (31)	25	Troponin T	44	Greater than 0.2 ng per mL	N/A
La Vecchia (32)	19 (Stent) 25 (balloon PCI)	Troponin T and troponin I	37 cTnI; 21 cTnT 14 cTnI; 0 cTnT	N/A	N/A
Johansen (33)	75	Troponin T	28	Greater than 0.1 ng per mL	N/A
Shyu (34)	59 (Stent) 61 (balloon PCI)	Troponin T	29 13	Greater than 0.1 ng per mL	Significantly higher incidence of elevated cTnT in patients undergoing stenting than angioplasty alone.
Bertinchant (35)	105	Troponin I	22	Greater than 0.1 ng per mL	No difference in incidence of recurrent angina, MI, cardiac death, or RR after 12 months between patients positive or negative for cTnI. Stenting not associated with more minor myocardial damage than angioplasty.
Garbarz (36)	109	Troponin I	27	Greater than 0.3 ng per mL	No association between post-PCI cTnI and adverse ischemic events.
Fuchs (37)	1129	Troponin I	31	Greater than 0.15 ng per mL	cTnT levels greater than 3× normal limit associated with increased risk of major in-hospital complications, but no association with adverse intermediate-term (8 months) clinical outcomes.
Cantor (26)	481	Troponin I	48 overall; 26 after excluding positive or unknown pre-PCI cTnI	Greater than 1.5 ng per mL	Significantly higher 90-day rates of MI and the composite of MI or death in patients with positive cTnI.
Wu (38)	98	Troponin T	26	Greater than 0.1 ng per mL	At a mean of 77 months follow-up, no increase in risk of major adverse events detected in relation to post-PCI cTnT elevation.
Kizer (27)	212	Troponin T	40 positive prior to PCI; 18 of baseline negative were positive post-PCI	Greater than or equal to 0.1 ng per mL	Pre-PCI cTnT elevation was significantly related to event-free survival during 6-year follow-up; in baseline negative patients, positive cTnT was the only independent predictor of major adverse events at 1 year; post-PCI elevations of cTnT greater than or equal to 5× normal was the strongest long-term predictor of major adverse events at 6 years.
Ricciardi (39)	286	Troponin I	13.6	Greater than 2.3 ng per mL	cTnI elevations greater than 3-fold care predictive of future major adverse cardiac events (MACE). Increased incidence of MACE is accounted for by higher rate of early RR and not late cardiac events.
Kini (40)	2873	Troponin I	38.9	Greater than 2 ng per mL	Neither cTnI peak elevations nor any subgroup predicted mid-term mortality in low- to medium-risk patients.

cTnI indicates cardiac troponin I; cTnT, cardiac troponin T; N/A, not applicable; PCI, percutaneous coronary intervention; and RR, repeat revascularization.

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Complications associated with PCI are similar to those resulting from diagnostic cardiac catheterization, but their prevalence is more frequent. Complications have been categorized as major (death, MI, and stroke) or minor (transient ischemic attack, access site complications, renal insufficiency, or adverse reactions to radiographic contrast). Additional specific complications include intracoronary thrombosis, coronary perforation, tamponade, and arrhythmias.

Reported rates for death after diagnostic catheterization range from 0.08% to 0.14%, whereas analyses of large registries indicate overall unadjusted in-hospital rates for PCI of 0.4% to 1.9% (Table 3) (41-52). This range is greatly influenced by the clinical indication for which PCI is performed, with the highest mortality rates occurring among patients with STEMI and cardiogenic shock. Death in such patients may not be a direct result of the PCI procedure but rather a consequence of the patient's underlying illness. For example, in a combined analysis of PCI as primary reperfusion therapy for STEMI, the short-term mortality rate was 7% (53). Even after exclusion of patients with cardiogenic shock, in-hospital mortality was 5%.

Myocardial infarction can be a direct result of PCI, most commonly due to abrupt coronary occlusion or intracoronary embolization of obstructive debris. Determining and comparing the incidence of MI after PCI is difficult because the definition of MI as a result of PCI is controversial. The conventional definition requires 2 of the following: a) prolonged chest discomfort or its equivalent; b) development of pathologic Q waves; and c) rise in serum cardiac biomarkers above a critical level. Rates of periprocedural MI using this definition have ranged from 0.4% to 4.9%. Using a consistent definition for MI, the incidence of this complication has declined approximately 50% with the routine use of intracoronary stents (21,21a,50).

More recently, an isolated rise and fall in either CK-MB or troponin is considered to be a marker of myocardial necrosis (21). The relationship between cardiac biomarker elevation and myocardial cell death and evidence of subendocardial infarction on magnetic resonance imaging (MRI) support this position (54,55). Furthermore, large rises in cardiac biomarkers are associated with an increased risk for late death (26,56,57). Whether death in such patients is a consequence of the myonecrosis or a marker of patients who are at increased risk for death because of more advanced coronary disease is unclear. Complicating our understanding of the implications of this definition is the very frequently observed mild to modest elevation of serum CK-MB among patients with apparently uncomplicated PCI. When troponin is measured after PCI, more than 70% of patients exhibit elevated values after an otherwise successful intervention (58). Such patients may have no symptoms or electrocardiographic (ECG) abnormalities to suggest ischemia yet are "enzyme positive." One study has suggested a postprocedural increase in troponin T of 5 times normal is predictive for adverse events at 6 years. The long-term prognostic significance of smaller postprocedural troponin T elevations awaits further investigation (27) (Table 2) (26-40).

Another study indicated that more extensive stent expansion resulted in CK release but did not increase adverse cardiac events (59). Accordingly, it is important to acknowledge that the significance of mild biomarker rises after clinically successful PCI should be distinguished from situations wherein patients experience an unequivocal "clinical" infarction manifested by chest pain and diagnostic ECG findings (60).

Routine measurement of CK-MB is advocated by some (21) and actually mandated by certain healthcare systems. In this regard, the current Committee supports the recommendations of the 2001 Guidelines and recommends that all patients who have signs or symptoms suggestive of MI during or after PCI and those with complicated procedures should have CK-MB and troponin I or T measured after the procedure. In addition, the Committee recommends that routine measurement of cardiac biomarkers (CK-MB and/or troponin I or T) in every patient undergoing PCI is reasonable 8 to 12 h after the procedure. In such patients, a new CK-MB or troponin I or T rise greater than 5 times the upper limit of normal would constitute a clinically significant periprocedural MI.

The need to perform emergency coronary artery bypass surgery (CABG) has been considered as a potential complication of PCI. Typically, CABG is performed as a rescue revascularization procedure to treat acute ischemia or infarction resulting from PCI-induced acute coronary occlusion. In the era of balloon angioplasty, the rate of emergency CABG was 3.7% (49). In a more contemporary time period, with the availability of stents, the reported rate was 0.4% among a similar cohort of patients.

Various definitions have been proposed for stroke. A common feature to definitions has been a loss of neurologic function of vascular cause that lasts more than 24 h. More recently, attention has been directed to refining the definition of transient ischemic attack (TIA), which indirectly broadens that of stroke (61). The time-based definition of a TIA is a sudden, focal neurologic deficit that lasts less than 24 h that is of presumed vascular origin and confined to an area of the brain or eye perfused by a specific artery. The new definition of TIA is a brief episode of neurologic dysfunction caused by brain or retinal ischemia, with clinical symptoms typically lasting less than 1 hour and without evidence of infarction. Presence of cerebral infarction by imaging techniques constitutes evidence of stroke regardless of the duration of symptoms.

Bleeding is a complication of increasing concern with the more frequent use of potent antithrombin and antiplatelet agents. A frequently used definition for bleeding developed by the TIMI group includes classification as major, moderate, or minor. Major bleeding is defined as intracranial, intraocular, or retroperitoneal hemorrhage or any hemorrhage requiring a transfusion or surgical intervention or that results in a hematocrit decrease of greater than 15% or hemoglobin decrease of greater than 5 g per dL (62). Episodes of hemorrhage of lesser magnitude would fall into the moder-

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Table 3. Unadjusted In-Hospital Outcome Trends After Percutaneous Coronary Interventions

Registry	Years	Reference	n	Clinical Success, %	In-Hospital Mortality, %	Q-Wave MI, %	Emergency CABG, %
NHLBI (I)‡	1977-1981	(41)	3079*	61	1.2	NR	5.8
NHLBI (II)§	1985-1986	(41)	2311*	78	1.0	4.8	5.8
BARI Registry‖	1988-1991	(42)	1189*	NR	0.7	2.8	4.1
Northern New England¶	1990-1993	(43)	13 014†	88.8	1.0	2.4	2.2
SCAI#	1990-1994	(44)	4366†	91.5	2.5	NR	3.4
NACI**	1990-1994	(45)	4079*	NR	1.6	1.6	1.9
NY State Database	1991-1994	(46,47)	62 670*	NR	0.9	NR	3.4
Northern New England¶	1994-1995	(43)	7248†	89.2	1.1	2.1	2.3
NCN	1994-1997	(48)	76 904†	NR	1.3	NR	1.7
Northern New England¶	1995-1997	(43)	14 490†	91.5	1.2	2.0	1.3
NHLBI Dynamic Registry‡‡	1997-1998	(49)	1559*	92	1.9	2.8	0.4
NHLBI Dynamic	1997-1999	(50)	857	91	0.9	0.8	1.9
ACC-NCDR	1998-2000	(51)	100 292	96.5	1.4	0.4	1.9
NY State Database	1997-2000	(52)	22 102	NR	0.68	NR	NR

CABG indicates coronary artery bypass graft surgery; MI, myocardial infarction; NACI, New Approaches in Coronary Interventions; NCN, National Cardiovascular Network; and NR, not reported.

*N indicates number of patients.

†N indicates number of procedures.

‡In NHLBI (I), emergency CABG was defined as in-hospital CABG.

§In NHLBI (II), MI was defined as the presence of at least 2 of the 3 criteria: clinical symptoms, Q waves on ECG (Minnesota code), or elevated cardiac enzyme level (double the normal levels for CK or its MB fraction without Q waves). Emergency CABG was defined as in-hospital CABG.

‖In BARI, MI was defined as the appearance of ECG changes (new pathologic Q waves) supported by abnormal CK-MB elevations.

¶In Northern New England, a new MI was defined as a clinical event, ECG changes, and a creatinine phosphokinase rise at least 2 times normal levels with positive isozymes. Emergency CABG was defined as surgery performed to treat acute closure, unstable angina, or congestive heart failure requiring intravenous nitroglycerin or ABP, or tamponade resulting from the intervention.

#In SCAI, a new MI was defined as any significant infarction (greater than 3 times normal rise in MB fraction).

**In NACI, MI was defined as a Q-wave MI.

††MI was defined as 2 or more of the following: 1) typical chest pain greater than 20 min not relieved by nitroglycerin; 2) serial ECG recordings showing changes from baseline or serially in ST-T and/or Q waves in at least 2 contiguous leads; or 3) serum enzyme elevation of CK-MB greater than 5% of total CK (total CK more than 2 times normal; lactate dehydrogenase subtype 1 greater than lactate dehydrogenase subtype 2).

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ate/minor categories. A listing of other bleeding classifications has been developed for use by the ACC-NCDR® (18).

3.3. Acute Outcome: Success Rates

Success has been described on both a lesion and patient basis. In early studies of PTCA, lesion success is defined as an absolute 20% reduction in lesion severity with final stenosis less than 50%. When describing the results of multiple attempted lesions, success is classified as either partial (some but not all attempted lesions successfully treated) or total (each attempted lesion successfully treated). Procedural success is defined as the achievement of either partial or total angiographic success without death, MI, or emergency CABG (49).

Reported rates of angiographic success now range between 82% and 98% depending on the device used and the types of lesions attempted. Formal comparisons demonstrate that success rates are now higher (91% to 92%) in the era of new technology, which includes stents and contemporary drug therapies, than in the era of conventional balloon angioplasty (72% to 74%) (49). The types of lesions attempted strongly influence success rates. The chance of dilating a chronic total occlusion averages 65%, and specific clinical and anatomic factors have been identified that affect this rate (63). Quite different are the success rates for total occlusions associated with STEMI. Success rates over 90% can be expected in this subgroup (64).

With an increase in angiographic success rates and a decline in periprocedural MI and the need for emergency CABG, procedural success rates have risen from a range of 80% to 85% to a range of 90% to 95% (Table 3) (41-52).

3.4. Long-Term Outcome and Restenosis

Although improvements in technology, such as stents, have resulted in an improved acute outcome of the procedure, the impact of these changes on long-term (5 to 10 years) outcome may be less dramatic because factors such as advanced age, reduced left ventricular (LV) function, and progression of complex multivessel disease in patients currently undergoing PCI may have a more important influence. In addition, available data on long-term outcome are mostly limited to patients undergoing PTCA. Ten-year follow-up of the initial cohort of patients treated with PTCA revealed an 89.5% survival rate (95% in patients with single-vessel disease, 81% in patients with multivessel disease) (65). In patients undergoing PTCA within the 1985-1986 National Heart, Lung, and Blood Institute (NHLBI) PTCA Registry (66), 5-year survival was 92.9% for patients with single-vessel disease, 88.5% for those with 2-vessel disease, and 86.5% for those with 3-vessel disease. In patients with multivessel disease undergoing PTCA in the Bypass Angioplasty Revascularization Investigation (BARI) (10), 5-year survival was 86.3%, and infarct-free survival was 78.7%. Specifically, 5-year survival was 84.7% in patients with 3-vessel disease and 87.6% in patients with 2-vessel disease.

In addition to multivessel disease, other clinical factors adversely impact late mortality. In randomized patients with treated diabetes undergoing PTCA in BARI, the 5-year survival was 65.5%, and the cardiac mortality rate was 20.6% compared with 5.8% in patients without treated diabetes (67), although among eligible but not randomized diabetic patients treated with PTCA, the 5-year cardiac mortality rate was 7.5% (68). In the 1985-1986 NHLBI PTCA Registry, 4-year survival was significantly lower in women (89.2%) than in men (93.4%) (69). In addition, although LV dysfunction was not associated with an increase in in-hospital mortality or nonfatal MI in patients undergoing PTCA in the same registry, it was an independent predictor of a higher long-term mortality (70).

A major determinant of event-free survival after coronary intervention is the incidence of restenosis, which had, until the development of stents, remained fairly constant despite multiple pharmacologic and mechanical approaches to limit this process (Table 4) (71-95). The incidence of restenosis after coronary intervention varies depending on the definition, i.e., whether clinical or angiographic restenosis or target-vessel revascularization is measured (96). Data from multiple randomized clinical trials and prospective registries suggest that DES incorporating either rapamycin or paclitaxel with a timed-release polymer are associated with a reduction in restenosis rates to less than 10% across a wide spectrum of clinical and angiographic subsets.

The pathogenesis of the response to mechanical coronary injury is thought to relate to a combination of growth factor stimulation, smooth muscle cell migration and proliferation, organization of thrombus, platelet deposition, and elastic recoil (97,98). In addition, change in vessel size (or lack of compensatory enlargement) has been implicated (99). It has been suggested that attempts to reduce restenosis have failed in part because of lack of recognition of the importance of this factor (100). Although numerous definitions of restenosis have been proposed, greater than 50% diameter stenosis at follow-up angiography has been most frequently used because it was thought to correlate best with maximal flow and therefore ischemia. However, it is now recognized that the response to arterial injury is a continuous rather than a dichotomous process, occurring to some degree in all patients (101). Therefore, cumulative frequency distributions of the continuous variables of minimal lumen diameter or percent diameter stenosis are frequently used to evaluate restenosis in large patient populations (102) (Figure 2) (80).

Although multiple clinical factors (diabetes, unstable angina [UA]/NSTEMI, STEMI, and prior restenosis) (103,104), angiographic factors (proximal left anterior descending artery [LAD], small vessel diameters, total occlusion, long lesion length, and saphenous vein grafts [SVGs]) (105), and procedural factors (higher postprocedure percent diameter stenosis, smaller minimal lumen diameter, and smaller acute gain) (102) have been associated with an increased incidence of restenosis, the ability to integrate these factors and predict the risk of restenosis in individual patients after the procedure remains difficult. The most promising potential

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Table 4. Selected Trials of Pharmacological and Mechanical Approaches to Limit Restenosis

Study	Year	Reference	n	Agent	Restenosis Rate, %	
					Placebo or Control	Agent
Schwartz	1988	(71)	376	Aspirin and dipyridamole	39	38
Ellis	1989	(72)	416	Heparin	37	41
Pepine	1990	(73)	915	Methylprednisolone	39	40
CARPORT	1991	(74)	649	Vapiprost	19	21
O'Keefe	1992	(75)	197	Colchicine	22	22
MERCATOR	1992	(76)	735	Cilazapril	28	28
CAVEAT*	1993	(77)	500	DCA versus PTCA	57	50
CCAT	1993	(78)	136	DCA versus PTCA	43	46
Serruys	1993	(79)	658	Ketanserin	32	32
BENESTENT*	1994	(80)	520	Stent versus PTCA	32	22
ERA	1994	(81)	458	Enoxaparin	51	52
Leaf	1994	(82)	551	Fish oil	46	52
STRESS*	1994	(83)	410	Stent versus PTCA	42	32
Weintraub	1994	(84)	404	Lovastatin	42	39
BOAT*	1998	(85)	492	DCA versus PTCA	40	31
Wantanabe*	1996	(86)	118	Probucol	40	20
Tardif*	1997	(87)	317	Probucol	39	21
BENESTENT II*	1998	(88)	823	Stent versus PTCA	31	17
TREAT*	1999	(89)	255	Tranilast	39	18
PRESTO*	2000	(90)	192	DCA and Tranilast	26	11
ARTIST*	2002	(91)	298	Rotablation (in-stent) versus PTCA	51	65
START*	2002	(92)	476	Radiation (in-stent)	45	29
SIRIUS*	2003	(93)	1058	Sirolimus-coated stent versus bare stent	36	9
TAXUS-IV*	2004	(94)	1314	Paclitaxel-coated stent versus bare stent	27	8
RESCUT	2004	(95)	428	Cutting balloon (in-stent) versus PTCA	31	30

DCA indicates directional coronary atherectomy; n, number of patients; and PTCA, percutaneous transluminal coronary angioplasty.
*P less than 0.05.

approaches to favorably impact the restenosis process are stents and, more recently, DES and catheter-based radiation. More than 6300 patients have been studied in 12 randomized clinical trials to assess the efficacy of PTCA versus stents to reduce restenosis (Table 5) (80,83,88,106-114).

The pivotal BENESTENT (BElgian NEtherlands STENT study) (80) and STRESS (STent REStenosis Study) trials (83) documented that stents significantly reduce angiographic restenosis compared with balloon angioplasty (BENESTENT: 22% vs 32%; STRESS: 32% vs 42%, respectively). These results were further corroborated in the BENESTENT II trial, in which the angiographic restenosis rate was reduced by almost half (from 31% to 16% in patients treated with balloon angioplasty versus heparin-coated stents, respectively) (88).

In addition, randomized studies in patients with ISR have shown that both intracoronary gamma and beta radiation significantly reduced the rate of subsequent angiographic and clinical restenosis by 30% to 50% (92,115-117). Late subacute thrombosis was observed in some of these series (117), but this syndrome has resolved with judicious use of stents and extended adjunct antiplatelet therapy with ticlopidine or clopidogrel. The development of DES has significantly reduced the rate of ISR (see Section 7.3.6 for full discussion).

3.5. Predictors of Success/Complications

3.5.1. Lesion Morphology and Classification

Target lesion anatomic factors related to adverse outcomes have been widely examined. Lesion morphology and absolute stenosis severity were identified as the prominent predictors of immediate outcome during PTCA in the prestent era (118,119). Abrupt vessel closure, due primarily to thrombus or dissection, was reported in 3% to 8% of patients and was associated with certain lesion characteristics (120-122). The risk of PTCA in the prestent era relative to anatomic subsets has been identified in previous NHLBI PTCA Registry data (7) and by the ACC/AHA Task Force on Practice Guidelines (1,123). The lesion classification based on severity of characteristics proposed in the past (123-125) has been principally altered using the present PCI techniques, which capitalize on the ability of stents to manage initial and subsequent complications of coronary interven-

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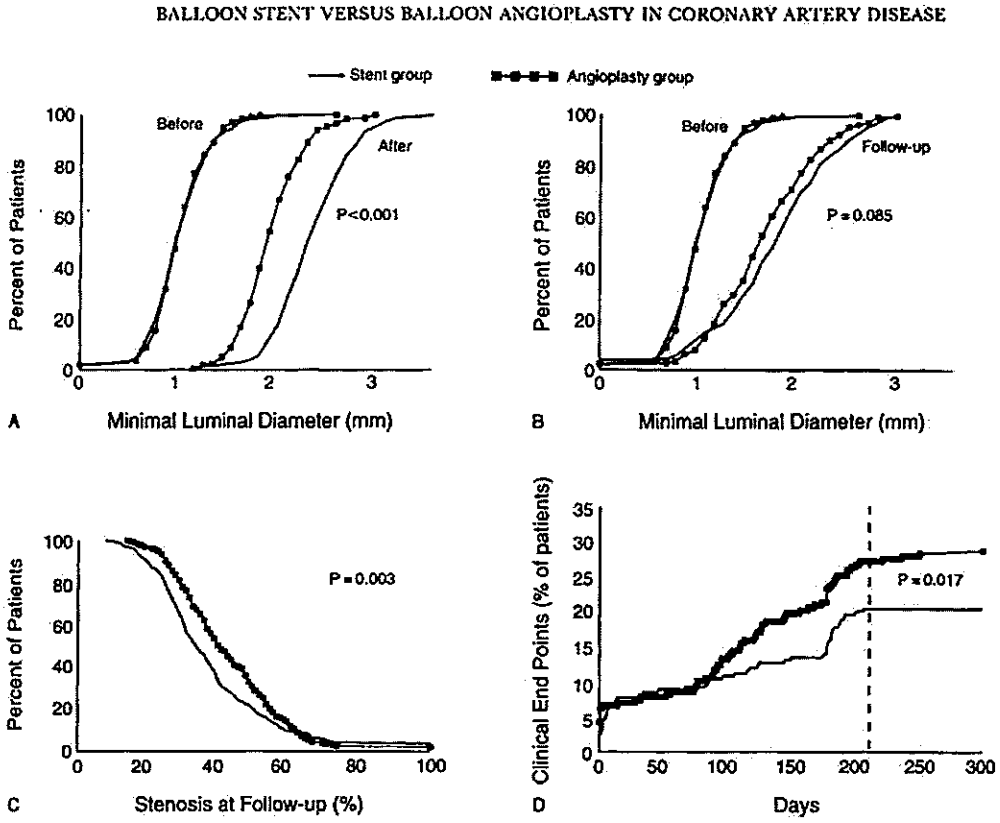

Figure 2. Balloon stent vs balloon angioplasty in coronary artery disease. Cumulative frequency distribution curves for the 2 study groups, showing minimum lumen diameters measured before and after intervention and follow-up (B), the percentage of stenosis at follow-up, and the percentage of patients with clinical end points. Significant differences were apparent that consistently favored the stent group over the angioplasty group with respect to the increased minimal lumen diameter at intervention (A) and follow-up (B), the percentage of stenosis at follow-up (C), and the incidence of major clinical events (D). The vertical dashed line in D indicated the end of the study. Reprinted with permission from Serruys et al. N Engl J Med 1994;331:489-95 (80). Copyright 2004 Massachusetts Medical Society. All rights reserved.

tions (126). As a result, the Committee has revised the previous ACC/AHA lesion classification system to reflect high-risk (at least 1 type C lesion characteristic) and non–high-risk (no type C lesion characteristic) lesions (Table 6) in accordance with the PCI Clinical Data Standards from the ACC-NCDR® (18). Studies (127-130) have confirmed that complex coronary lesions remain predictive of adverse events after PCI. However, although the risk of restenosis and technical failure remains high for chronic total occlusions, the risk of acute complications is not increased.

The SCAI proposed a new lesion classification using 7 lesion characteristics (131). This system dichotomizes lesions by the presence or absence of a type C characteristic and vessel patency versus total occlusion, yielding 4 lesion classes (Table 7) (132). Utilizing data from the voluntary ACC-NCDR®, the SCAI group presented analyses that showed that the more simplified SCAI lesion classification provided better discrimination for success and complications than the ACC/AHA lesion classification system (132,133).

The SCAI lesion classification system was validated from a voluntary registry, which imposes a potential bias because the operator classified the lesion after finishing the case and knowing whether the case was successful or had complications. No prospective studies using core laboratory analysis have validated this system. Nonetheless, the SCAI classification system utilizing vessel patency in addition to C and non-C class appears promising to categorize the risk of success and complications with PCI.

3.5.1.1. Clinical Factors

Coexistent clinical conditions can increase the complication rates for any given anatomic risk factor. For example, complications occurred in 15.4% of patients with diabetes versus 5.8% of patients without diabetes undergoing balloon angioplasty in a multicenter experience (119,122). Several studies have reported specific factors associated with increased risk of adverse outcome after PTCA. These factors include advanced age, female gender, UA, congestive heart failure (HF), diabetes, and multivessel CAD (10,118,119,127-130,134,135). Elevated baseline C-reactive protein (CRP) has recently also been shown to be predictive of 30-day death and MI (128,136). Other markers of inflammation, such as

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Table 5. Studies Comparing Balloon Angioplasty with Stents for Native Coronary Artery Lesions

Study (Ref)	Year	Follow-Up, mo	n, Stent/ Angioplasty	Angiographic Restenosis, %			TVR, %			Death, %		
				Stent	Angioplasty	*P* value	Stent	Angioplasty	*P* value	Stent	Angioplasty	*P* value
STRESS (83)	1994	6	205/202	31.6	42.1	0.046	10.2	15.4	0.06	1.5	1.5	NS
BENESTENT (80,107)	1996	7/12*	259/257	22	32	0.02	10	21	0.001	1.2	0.8	NS
Versaci et al. (108)	1997	12	60/60	19	40	0.02	6.6	22	NA	NA	NA	NA
STRESS II (109)	1998	12	100/89	NA	NA	NA	10	20	NA	17‖	34‖	NA
BENESTENT II (88)	1998	6	413/410	16	31	Less than 0.001	8†	13.7	0.02	0.2%	0.5%	NS
OCBAS (110)	1998	7	57/59	18.8	16.6	NA	17.5	9.2	NA	0	1.6	NS
EPISTENT (111,112)‡	1998	6	794/796	NA	NA	NA	8.7	15.4	Less than 0.001	0.5	1.8	0.02
START (113)	1999	6/48§	229/223	22	37	Less than 0.002	12	24.6	Less than 0.002	2.7	2.4	NS
OPUS (114)	2000	6	479 (Overall)	NA	NA	NA	3.0	10.1	0.003	0.4	1.2	NS

mo indicates months; NA, data not reported for that category, NS, not significant; and TVR, target vessel revascularization. Data are for lesions in coronary arteries with vessel diameter greater than or equal to 3.0 mm.

*6-7 months angiographic follow-up and 12 months clinical follow-up.

†Any repeat procedure.

‡Stent plus abciximab versus percutaneous transluminal angioplasty plus abciximab.

§6 months angiographic follow-up and 48 months clinical follow-up.

‖End point of death/any MI/CABG/target lesion percutaneous transluminal angioplasty.

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Table 6. Lesion Classification System

Descriptions of a High-Risk Lesion (Type C Lesion)
Diffuse (length greater than 2 cm)
Excessive tortuosity of proximal segment
Extremely angulated segments, greater than 90°
Total occlusions more than 3 months old and/or bridging collaterals*
Inability to protect major side branches
Degenerated vein grafts with friable lesions*

*The high risk with these criteria is for technical failure and increased restenosis, not for acute complications.

interleukin-6 and other cytokines, have also been shown to be predictive of outcome (137). The BARI trial found that patients with diabetes and multivessel CAD had an increased periprocedural risk of ischemic complications and increased 5-year mortality compared with patients without diabetes or patients with diabetes undergoing bypass surgery using internal mammary artery (IMA) grafts (10,42). Patients with impaired renal function, especially those with diabetes, are at increased risk for contrast nephropathy (138) and increased 30-day and 1-year mortality (139,140). Renal insufficiency is a strong predictor of outcome in both primary and elective PCI (141-143). Increased risk for death or severe compromise in LV function may occur in association with a complication involving a vessel that also supplies collateral flow to viable myocardium. Certain variables were used to prospectively identify patients at risk for significant cardiovascular compromise during PTCA (144,145). These resulted in a composite 4-variable scoring system, prospectively validated to be both sensitive and specific in predicting cardiovascular collapse for failed PTCA, which includes: 1) percentage of myocardium at risk (e.g., greater than 50% viable myocardium at risk and LV ejection fraction of less than 25%), 2) preangioplasty percent diameter stenosis, 3) multivessel CAD, and 4) diffuse disease in the dilated segment (124) or a high myocardial jeopardy score (125). Patients with higher preprocedural jeopardy scores were shown to have a greater likelihood of cardiovascular collapse when abrupt vessel closure occurred during PTCA (144).

Table 7. SCAI Lesion Classification System: Characteristics of Class I-IV Lesions

Type I lesions (highest success expected, lowest risk)
- (1) Does not meet criteria for C lesion
- (2) Patent

Type II lesions
- (1) Meets any of these criteria for ACC/AHA C lesion
  - Diffuse (greater than 2 cm length)
  - Excessive tortuosity of proximal segment
  - Extremely angulated segments, greater than 90°
  - Inability to protect major side branches
  - Degenerated vein grafts with friable lesions
- (2) Patent

Type III lesions
- (1) Does not meet criteria for C lesion
- (2) Occluded

Type IV lesions
- (1) Meets any of the criteria for ACC/AHA C lesion
  - Diffuse (greater than 2 cm length)
  - Excessive tortuosity of proximal segment
  - Extremely angulated segments, greater than 90°
  - Inability to protect major side branches
  - Degenerated vein grafts with friable lesions
  - Occluded for more than 3 months
- (2) Occluded

Reprinted from Krone et al. Evaluation of the American College of Cardiology/American Heart Association and the Society for Coronary Angiography and Interventions lesion classification system in the current "stent era" of coronary interventions (from the ACC-National Cardiovascular Data Registry®). Am J Cardiol 2003;92:394 (Appendix B) (132).

3.5.1.2. Left Main CAD

CABG has long been considered the "gold standard" for revascularization of lesions in the unprotected left main (ULM) coronary artery (146). With the advent of newer technology utilizing BMS and DES, experience has been gained in performing PCI in ULM coronary artery lesions. Some studies have demonstrated that stenting of the ULM is feasible and appears to be a promising strategy in selected patients (147-152). Patients treated for ULM disease have varied from those presenting with stable angina to those with MI and shock. However, despite the feasibility and high procedural success rate of ULM PCI in the pre-DES era, there are reports of an unacceptably high incidence of long-term adverse events (153-155). This may be attributed to the inclusion of high-risk patients, such as those not considered good surgical candidates. The experience with BMS for ULM PCI in the multicenter ULTIMA (Unprotected Left Main Trunk Intervention Multicenter Assessment) registry suggested a high early mortality (2% per month among hospital survivors over the first 6 months after hospital discharge), and careful surveillance with coronary angiography was recommended (153) (see Section 6.3.4). Patients presenting with MI, ULM occlusion, and cardiogenic shock have lower successful PCI rates (69.7% vs 100%, P equals 0.040), higher in-hospital mortality (71.4% vs 10%, P equals 0.0008), and higher 1-year mortality rates (P equals 0.0064) than stable MI patients regardless of performance of primary PCI with stents (155).

More recently, published studies of left main PCI using DES have reported 6-month or 1-year death rates ranging from 0% to 14% (Table 8) (147-150,152-161). Furthermore, ISR appears to be improved with the use of DES versus BMS. One of the larger studies performed to date showed that the 6-month angiographic restenosis rate was signifi-

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Table 8. Published Trials and Selected Registry Experiences of PCI for Unprotected Left Main Coronary Artery Stenosis

First Author, Year (Reference)	Device Used	n	In-Hospital Mortality, %	Mortality, % (Follow-Up Period)	Restenosis, %	TVR, %	Comments
Ellis 1994-1996 (147)	50% BMS	107	20.6	66.0 plus or minus 4.7 (9 mo)	20.8	N/A	Survival to hospital discharge 31% in acute MI patients; in elective patients, in-hospital mortality 5.9% in good candidates for CABG, 30.4% in poor CABG candidates; in-hospital survival strongly correlated with LVEF
Silvestri 1993-1998 (148)	100% BMS	140	9% high CABG risk; 0% low CABG risk	2% high CABG risk; 2.6% low CABG risk (6 mo)	23	17.4	Good immediate results of PCI in ULM stenosis, especially in good CABG candidates
Black 1994-1998 (149)	100% BMS	92	4.3	10.8 (7.3 plus or minus 5.8 mo)	N/A	7.3	PCI to ULM appears better in candidates for CABG than in patients in whom CABG is contraindicated; trend toward cardiac mortality with 3-vessel disease and low LVEF; low final stent lumen diameter only significant predictor of cardiac mortality
ULTIMA 1993-1998 (153)	68.8% BMS	279	13.7	24.2 (1 y)	N/A	33.6*	46% of patients were deemed inoperable or at high risk for CABG; in patients less than 65 y old with LVEF greater than 30% and no shock, 0% periprocedural deaths and 1-year mortality 3.4%; 2% per month death rate among hospital survivors over 6 months after discharge; careful surveillance with coronary angiography recommended
Park 1995-2000 (150)	100% BMS	127	0	3.1 (25.5 plus or minus 16.7 mo)	19	11.8	Elective stenting in patients with normal LVEF; IVUS may optimize immediate results; significantly lower restenosis rate with debulking before stenting
Takagi 1993-2001 (154)	96% BMS	67	0	16.4 (31 plus or minus 23 mo)	31.4	23.9	High rate of restenosis and RR; 11.9% cardiac mortality; significantly higher cardiac mortality in patients with Parsonnet score greater than 15 at 3 years
Park 1995-2000 (152)	100% BMS	270	0	7.4 (32.3 plus or minus 18.5 mo)	21.1	16.7†	Good overall long-term (3-year) survival in selected patients with normal LVEF; combined CAD and post-procedural lumen diameter significant predictors of MACE
Sakai 1992-2000 (155)	65% to 74% BMS	38	71.4% with shock; 10% without shock	71.4% with shock; 20% without shock (1 y)	N/A	N/A	Patients with acute MI due to ULM stenosis and shock have poor survival regardless of performance of PCI with stents

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Table 8. *Continued*

First Author, Year (Reference)	Device Used	n	In-Hospital Mortality, %	Mortality, % (Follow-Up Period)	Restenosis, %	TVR, %	Comments
de Lezo 2002-2004 (156)	100% SES	52	0	0 (12 plus or minus 4 mo)	3.8	1.9	Treatment with SES appears feasible and safe; promising midterm results
Agostoni 2002-2003 (158)	100% DES	58	2	5 (1 y)	N/A	7	Rate of events did not differ significantly between IVUS and angiographically guided procedures; Anatomic location of atherosclerotic disease in ULM artery only independent predictor of events at follow-up
Chieffo 2002-2004 (159)	100% DES	85	0	3.5 (6 mo)	19	19	Despite higher risk profile, patients receiving DES had significant advantage in the incidence of MACE compared with historical control group receiving BMS
Park 2003-2004 (160)	100% SES	102	0	0 (1 y)	7	2	SES implantation in ULM and normal LVEF associated with low in-hospital and 1-year mortality; SES more effective in preventing in-stent restenosis than historical BMS control
RESEARCH/ 2003 T-SEARCH 2002- (161)	100% DES	95 (15 protected LM)	11	14 (1 y)	N/A	6	More than 50% of study population at high surgical risk by Parsonnet classification; 47% relative risk reduction in MACE in DES group compared with BMS control, driven by significantly lower incidence of MI and TVR

*1-Year estimate; †32.3 plus or minus 18.5 mo.
n indicates number of patients; LVEF, LV ejection fraction; MACE, major adverse cardiac events; RR, repeat revascularization; SES, sirolimus-eluting stent; TVR, target-vessel revascularization; and ULM, unprotected left main.

cantly lower in the ULM group receiving DES than in those who received BMS (7.0% vs 30.3%, *P* less than 0.001) (160). The lower rate of restenosis of DES compared with BMS has been confirmed in other studies of ULM PCI (159).

There have been some attempts to predict success of ULM PCI using customary risk factors such as age, renal failure, coronary calcification, and location of the lesion in the left main coronary artery. In general, younger patients with preserved LV function, noncalcified coronary arteries, and complete delivery of stent, fare better. Maintenance of antiplatelet therapy after the procedure is critical, as is the implementation of secondary prevention therapies. Careful postprocedure surveillance with coronary angiography is needed to prevent fatal MI or sudden death that may be associated with ISR with a large area of myocardium in jeopardy; however, the frequency and best method of follow-up are unknown (162). One study's authors from the BMS era suggested routine surveillance angiography at 2 and 4 months after PCI (153). Others advocate routine stress testing or cardiac catheterization at 3 and 6 months even in asymptomatic patients (148,150). Studies from the DES era have reported performing routine angiography 4 to 8 months after PCI or earlier if clinically indicated by symptoms or documented myocardial ischemia (159,160). Other issues that remain to be resolved are technical issues (e.g., optimal bifurcation stenting technique, stent size), degree of revascularization necessary, cost-effectiveness, and the selection of patients best suited for DES.

In conclusion, CABG using IMA grafting is the "gold standard" for treatment of ULM disease and has proven benefit on long-term outcomes. The use of DES has shown encouraging short-term outcomes, but long-term follow-up is needed. Nevertheless, the use of PCI for patients with significant ULM stenosis who are candidates for revascularization but not suitable for CABG can improve cardiovascular outcomes and is a reasonable revascularization strategy in carefully selected patients. Recommendations for ULM PCI in specific angina subsets can be found in Sections 5.1, 5.2, 5.3, and 5.4 and in Section 6.3.4 for post-PCI follow-up.

3.5.2. Risk of Death

In the majority of patients undergoing elective PCI, death as a result of PCI is directly related to the occurrence of coronary artery occlusion and is most frequently associated with pronounced LV failure (144,145). The clinical and angiographic variables associated with increased mortality include advanced age, female gender, diabetes, prior MI, multivessel disease, left main or equivalent coronary disease, a large area of myocardium at risk, pre-existing impairment of LV or renal function, post-PCI worsening of renal function, and collateral vessels supplying significant areas of myocardium that originate distal to the segment to be dilated (10,118,120,122,134,135,138,139,140,144,163-167). Periprocedural stroke also increases in-hospital and 1-year mortality (168). PCI in the setting of STEMI is associated with a significantly higher death rate than is seen in elective PCI.

3.5.3. Women

An estimated 33% of the more than 1 million PCIs performed in the United States annually are in women. The need for more data concerning outcomes from PCI in women has led the AHA to issue a scientific statement summarizing available studies (169). Compared with men, women undergoing PCI are older and have a higher incidence of hypertension, diabetes mellitus, hypercholesterolemia, and comorbid disease (69,170-174). Women also have more UA and a higher functional class of stable angina (Canadian Cardiovascular Society [CCS] class III and IV) for a given extent of disease (175). Yet, despite the higher-risk profile in women, the extent of epicardial coronary disease is similar to (or less than) that in men. In addition, although women presenting for revascularization have less multivessel disease and better LV systolic function, the incidence of HF is higher in women than in men. The reason for this gender paradox is unclear, but it has been postulated that women have more diastolic dysfunction than men (176).

Early reports of patients undergoing PTCA revealed a lower procedural success rate in women (172); however, subsequent studies have noted similar angiographic outcome and incidence of MI and emergency CABG in women and men (69). Although reports have been inconsistent, in several large-scale registries, in-hospital mortality is significantly higher in women (177), and an independent effect of gender on acute mortality after PTCA persists after adjustments for the baseline higher-risk profile in women (69,178). The reason for the increase in mortality is unknown, but small vessel size (179) and hypertensive heart disease in women have been thought to play a role. Although a few studies have noted that gender is not an independent predictor of mortality when body surface area (a surrogate for vessel size) is accounted for (171), the impact of body size on outcome has not been thoroughly evaluated. The higher incidence of vascular complications, coronary dissection, and perforation in women undergoing coronary intervention has been attributed to the smaller vasculature in women than in men. In addition, diagnostic IVUS studies have not detected any gender-specific differences in plaque morphology or luminal dimensions once differences in body surface area were corrected, which suggests that differences in vessel size account for some of the apparent early and late outcome differences previously noted in women (180). It has also been postulated that the volume shifts and periods of transient ischemia during PTCA are less well tolerated by the hypertrophied ventricle in women, and HF has shown to be an independent predictor of mortality in both women and men undergoing PTCA (181).

Women continue to have increased bleeding and vascular complications compared with men, but these rates have decreased with the use of smaller sheath sizes and early sheath removal, weight-adjusted heparin dosing, and less aggressive anticoagulation regimens (169). Use of IIb/IIIa platelet receptor antagonists during PCI is not associated with an increased risk of major bleeding in women

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(182,183), and the direct thrombin inhibitor bivalirudin during elective PCI appears to reduce the risk of bleeding (combined major and moderate bleeding) in both women and men compared with unfractionated heparin (184).

Improved outcomes have been reported in more recently treated women undergoing both PTCA and PCI, despite the fact that the women are older and have more complex disease than women treated previously (Table 9) (69,170,185-189). In fact, in the 1993-1994 NHLBI PTCA Registry (open to women only), procedural success was higher and major complications lower than in women treated in the 1985-1986 registry (190). Additionally, in patients undergoing PTCA in BARI, in-hospital mortality, MI, emergency coronary artery bypass surgery rates, and 5-year mortality were similar in women and men, although women had a higher incidence of periprocedural HF and pulmonary edema (188).

The widespread use of stents and adjunctive pharmacologic therapy has improved outcomes in patients undergoing contemporary PCI (80,83,112,191-202). Early studies of drug-eluting stents in small vessels (less than or equal to 2.75 mm), of particular importance in women, report favorable long-term results in both women and men (203). The hope that stents would eliminate the difference in outcomes between women and men has not been realized. Gender differences in mortality have persisted for patients treated with stents both in the setting of acute and nonacute MI (204). In a meta-analysis of invasive versus conservative therapy of patients with UA/NSTEMI, men demonstrated a clear survival advantage using routine invasive therapy with GP IIb/IIIa inhibitors and intracoronary stents; however, using similar therapy, the results for women were not significantly improved (205), although it has been shown that the benefits of an invasive strategy have been limited to high-risk women (206).

In women with STEMI, the relative benefit of primary PCI compared with fibrinolytic therapy is similar to that in men, but there is a larger absolute benefit in women owing to their higher event rate (207). In patients with shock complicating acute MI, the benefit of revascularization is similar in women and men (208).

In general, the risks and benefits of adjunctive pharmacotherapy in women are similar to those in men, although an increased rate of minor bleeding has been reported in women treated with abciximab (183). When IIb/IIIa platelet receptor antagonists are used with unfractionated heparin, a lower dose of the latter should be considered to decrease the risk of bleeding in women (Table 9) (69,170,185-189).

Few gender-specific data are available on the outcomes of other percutaneous coronary devices. Although directional coronary atherectomy has been associated with lower procedural success and higher bleeding complications in women (209), similar benefit to that in men has been reported from embolic protection devices used in saphenous vein PCI (210) and from vascular brachytherapy (169).

Table 9. Gender-Specific Mortality Risk

Study	Years	Reference	Women Versus Men (n)	Follow-Up (years)	Device	Mortality, Men Versus Women (%)	*P*	Adjusted OR (95% CI)
Mayo Clinic	1979-1990	(186)	3027 (824 vs 2203)	5.5	PTCA	27 versus 22	0.06	0.94 (0.76 to 1.15)
Emory University	1980-1991	(187)	10 785 (2845 vs 7940)	5	PTCA	8 versus 5	0.0002	1.08 (0.84 to 1.39)
NHLBI PTCA Registry	1985-1986	(69)	2136 (546 vs 1590)	4	PTCA	6.6 versus 10.8	0.001	1.20 (0.84 to 1.73)
BARI	1988-1994	(188)	1829 (489 vs 1340)	5	PTCA	12.8 versus 12.0	NS	0.60 (0.43 to 0.84)
NACI	1990-1994	(189)	2855 (975 vs 1880)	1	PCI	5.7 versus 5.9	NS	NS
Northern New England	1994-1999	(170)	33 666 (10 997 vs 22 689)	In-hospital	PCI	1.21 versus 1.06	0.096	1.24 (0.96 to 1.60)
NHLBI Dynamic Registry	1997-1998	(185)	2524 (895 vs 1629)	1	PCI	4.3 versus 6.5	0.022	1.26* (0.85 to 1.87)

CI indicates confidence interval; NS, not significant; n, number of patients; OR, odds ratio; PCI, percutaneous coronary intervention; and PCTA, percutaneous transluminal coronary angioplasty. For expansion of study names, see corresponding reference.
*Expressed as relative risk (RR).

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3.5.4. The Elderly Patient

Age greater than 75 years is one of the major clinical variables associated with increased risk of complications (211-214). In the elderly population, the morphologic and clinical variables are compounded by advanced years, with the very elderly having the highest risk of adverse outcomes (215). In octogenarians, although feasibility has been established for most interventional procedures, the risks associated with both percutaneous and nonpercutaneous revascularization are increased (216-218). Octogenarians undergoing PCI have a higher incidence of prior MI, lower LV ejection fraction, and more frequent HF (219,220). In the stent era, procedural success and restenosis rates are comparable to those for nonoctogenarians, albeit with higher incidences being reported for in-hospital and long-term mortality and for vascular and bleeding complications (221). A multicenter study compared an early invasive strategy versus an early conservative strategy in 2220 patients hospitalized for UA/NSTE-MI. Among patients 65 years or older, the early invasive strategy conferred a 4.8% absolute risk reduction (39% Relative Risk Reduction [RRR]) in death or MI at 6 months. In a post hoc analysis, patients aged 75 years or older experienced a 10.8% reduction (56% RRR) in 6-month death or MI with an early invasive strategy. However, there was a significant major bleeding rate in patients aged 75 years or older assigned to an invasive versus a conservative strategy (16.6% vs 6.5%, *P* equals 0.009) (222). For patients enrolled in the Controlled Abciximab and Device Investigation to Lower Late Angioplasty Complications (CADILLAC) trial of PCI for STEMI using routine stenting versus balloon angioplasty, with or without abciximab administration in both revascularization strategies, 1-year mortality increased exponentially for each decile of age after 65 years (1.6% for patients less than 55 years, 2.1% for 55 to 65 years, 7.1% for 65 to 75 years, 11% for greater than 75 years; *P* less than 0.0001). The incidence of stroke and major bleeding was also increased in the elderly at 1 year. Abciximab administration did not confer a benefit in elderly patients but was deemed safe. In contrast, routine stent implantation in elderly patients reduced 1-year rates of ischemic target-vessel revascularization (7.0% vs 17.6%, *P* less than 0.0001) and subacute or late thrombosis (0% vs 2.2%, *P* equals 0.005) compared with balloon angioplasty. The authors acknowledged that additional risks/benefits of stent or IIb/IIIa inhibitor use in elderly patients with STEMI might have become evident had more patients been enrolled in this study (223). Thus, with rare exception (primary PCI for cardiogenic shock in patients greater than 75 years of age), a separate category has not been created in these guidelines for the elderly (224). However, their higher incidence of comorbidities and risk for bleeding complications should be taken into account when considering the need for PCI (218,225).

3.5.5. Diabetes Mellitus

In the TIMI-IIB study of MI, patients with diabetes mellitus had significantly higher 6-week (11.6% vs 4.7%), 1-year (18.0% vs 6.7%), and 3-year (21.6% vs 9.6%) mortality rates than nondiabetic patients (226). Patients with diabetes with a first MI who were randomly assigned to the early invasive strategy faired worse than those managed conservatively (42-day mortality: death or MI, or death alone, 14.8% vs 4.2%; *P* less than 0.001) (227). An early catheterization and intervention strategy after fibrinolysis was of little benefit in these patients with diabetes. Although adjusted in-hospital mortality was not different in diabetic and nondiabetic patients, data from the NHLBI registry showed that at 1 year, adjusted mortality and repeat revascularization were significantly higher in diabetics (228). Thus, routine catheterization and PCI in this patient subgroup should be based on clinical need and ischemic risk stratification.

Stenting decreases the need for target-vessel revascularization procedures in diabetic patients compared with PTCA (229). The efficacy of stenting with GP IIb/IIIa inhibitors was assessed in the diabetic population compared with those without diabetes in a substudy of the EPISTENT (Evaluation of IIb/IIIa Platelet Inhibitor for Stenting) trial (230). One hundred seventy-three diabetic patients were randomized to stent/placebo combination, 162 patients to stent/abciximab combination, and 156 patients to PTCA/abciximab combination. For the composite end point of death, MI, or target-vessel revascularization, the rates were as follows: 25%, 23%, and 13% for the stent/placebo, PTCA/abciximab, and stent/abciximab groups (*P* equals 0.005). Irrespective of revascularization strategy, abciximab significantly reduced 6-month death and MI rate in patients with diabetes for all strategies. Likewise, 6-month target-vessel revascularization was reduced in the stent/abciximab group approach. One-year mortality for diabetics was 4.1% for the stent/placebo group and 1.2% for the stent/abciximab group. Although this difference was not significant, the combination of stenting and abciximab among diabetics resulted in a significant reduction in 6-month rates of death and target-vessel revascularization compared with stent/placebo or PTCA/abciximab therapy (230). Similar results in 1-year target-vessel revascularization and mortality have been reported with abciximab and the small-molecule GP IIb/IIIa inhibitor tirofiban (231). (See Section 6.2.2 Glycoprotein IIb/IIIa Inhibitors.) The BARI trial, in which stents and abciximab were not used, showed that survival was better for patients with treated diabetes undergoing CABG with an arterial conduit than for those undergoing PTCA (232). The benefit of CABG in patients with diabetes may be related to lessened mortality after subsequent Q-wave MI among patients with diabetes. In the BARI trial, the benefit of bypass surgery in diabetic patients was greater in those patients with more extensive disease (e.g., more than 4 lesions). This advantage was largely due to a lower mortality for subsequent MI (233).

Since the BARI trial was completed, several studies have assessed the use of PCI with stenting versus CABG in patients with multivessel disease. Patients with diabetes were assessed specifically in studies from the ARTS (Arterial Revascularization Therapies Study) and AWESOME (Angina

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With Extremely Serious Operative Mortality Evaluation) groups. Glycoprotein IIb/IIIa inhibitors were used in approximately 11% of AWESOME PCI patients and were not incorporated into the ARTS protocol. At 3 years of follow-up, the survival rates of the diabetic subsets treated with CABG and PCI were not significantly different in either ARTS or AWESOME. Repeat revascularization was higher with PCI in the subsets of patients with diabetes in both trials.

Randomized trials, meta-analysis of trials, and epidemiological studies have shown the superiority of DES over BMS in terms of reducing late repeat revascularization (234-236). There are, as yet, inadequate data from which to infer impact on long-term survival after PCI for patients with diabetes. The sum effect of DES and GP IIb/IIIa inhibitors will be assessed against contemporary CABG in multivessel-disease patients with diabetes in the upcoming National Institutes of Health (NIH)–sponsored Future Revascularization Evaluation in Patients With Diabetes Mellitus: Optimal Management of Multivessel Disease (FREEDOM trial) (237). A discussion about the selection of patients with diabetes for surgical revascularization or PCI may be found in Section 3.6, Comparison With Bypass Surgery. Preliminary data suggest late outcomes in diabetic patients after PCI are similar to nondiabetics if the hemoglobin A1C can be maintained less than 7.0% (238). Management of other risk factors, particularly lipid abnormalities, in patients with diabetes has also been shown to have a very significant effect on long-term outcome (239-242). These observations emphasize the importance of diabetes management and secondary prevention therapies after PCI.

3.5.6. PCI After Coronary Artery Bypass Surgery

Although speculated to be at higher risk, patients having PCI of native vessels after prior coronary bypass surgery have, in recent years, nearly equivalent interventional outcomes and complication rates compared with patients having similar interventions without prior surgery. For PCI of SVG, studies indicate that the rate of successful angioplasty exceeds 90%, the death rate is less than 1.2%, and the rate of Q-wave MI is less than 2.5% (Table 10) (243-248). The incidence of non–Q-wave MI may be higher than that associated with native coronary arteries (249-251).

In consideration of PCI for SVG, the age of the SVG and duration and severity of myocardial ischemia should be taken into consideration. Use of GP IIb/IIIa blockers has not been shown to improve results of angioplasty in vein grafts (252). However, preliminary studies of 2 different distal embolic protection devices (Percusurge and GuideWire) (253-255) are associated with promising results (254,255) (see Section 5.5.2, Late Ischemia After CABG). The native vessels should be treated with PCI if feasible. Patients with older and/or severely diseased SVGs may benefit from elective repeat CABG surgery rather than PCI (256,257).

In some circumstances, PCI of a protected left main coronary artery stenosis with a patent and functional LAD or left circumflex coronary conduit can be considered. PCI should be recognized as a palliative procedure with the potential to delay the ultimate application of repeat CABG surgery.

3.5.7. Specific Technical Considerations

Certain outcomes of PCI may be specifically related to the technology utilized for coronary recanalization. Periprocedural CK-MB elevation appears to occur more frequently after use of ablative technology such as rotational or directional atherectomy (23,77,85,243,258). Antecedent UA appears to be a clinical predictor of slow flow and periprocedural infarction after ablative technologies (259), and direct platelet activation has been demonstrated to occur with both directional and rotational atherectomy (260). In support of the premise that platelets play a pathophysiologic role in periprocedural MI are observations that the presence and magnitude of CK-MB elevation after ablative technologies can be reduced to levels observed after PTCA by the administration of prophylactic platelet GP IIb/IIIa receptor blockade (261,262).

Coronary perforation may occur more commonly after the use of atheroablative devices, including rotational, directional, or extraction atherectomy, and excimer laser coronary angioplasty. However, the incidence of perforation has been reported variably to be 0.10% to 1.14% with balloon angioplasty, 0.25% to 0.70% with directional coronary atherectomy, 0.0% to 1.3% with rotational atherectomy, 1.3% to 2.1% with extraction atherectomy, and 1.9% to 2.0% after excimer laser coronary angioplasty (263,264). Coronary perforation complicates PCI more frequently in the elderly and in women. Although 20% of perforations may be secondary to the coronary guidewire, most are related to the specific technology used. Perforation is usually (80% to 90%) evident at the time of the interventional procedure and should be a primary consideration in the differential diagnosis for cardiac tamponade manifest within 24 h of the procedure. Perforations may be classified on the basis of angiographic appearance as type I (extraluminal crater without extravasation), type II (pericardial and myocardial blush without contrast jet

Table 10. Probability of Success, Complications, and Restenosis After Balloon Angioplasty or Stenting in Patients After Coronary Bypass Surgery

Conduit Site	Reference	Success Rate	Death Rate	MI Rate*	Restenosis Rate†
Saphenous vein graft	(243-246)	Greater than 92%	Less than 2%	15%	20% to 35%
Internal mammary artery	(247)	97%	Less than 1%	12.5%	7% anastomotic, 25% ostial site
Left main	(248)	95%	Less than 2%	10%	25%

MI indicates myocardial infarction.
*Greater than 3 times normal CK-MB on serial determinations after intervention.
†Restenosis measured as target-vessel revascularization.

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extravasation), and type III (extravasation through a frank [1 mm] perforation) (263). In the absence of extravasation (type III), the majority of perforations may be effectively managed without urgent surgical intervention. Type III perforations have been successfully managed nonoperatively with pericardiocentesis, reversal of anticoagulation, and either prolonged perfusion balloon inflation at the site of perforation or deployment of a covered stent. Perforations caused by atheroablative devices usually require surgical repair.

3.5.8. Issues of Hemodynamic Support in High-Risk PCI

Controversy exists about the ability to predict hemodynamic compromise during PCI. Hemodynamic compromise, defined as a decrease in systolic blood pressure to an absolute level less than 90 mm Hg during balloon inflation, was often associated with LV ejection fraction less than 35%, greater than 50% of myocardium at risk, and PTCA performed on the last remaining vessel (120,163).

Early feasibility studies of high-risk PTCA using percutaneous cardiopulmonary support (CPS) indicated that although initial likelihood of success was high, vascular morbidity was also high, with an incidence of 43% (265,266). However, no study has published data to validate commonly used high-risk categorizations.

Elective high-risk PCI can be performed safely without intra-aortic balloon pump (IABP) or CPS in most circumstances. Emergency high-risk PCI such as primary PCI for STEMI can usually be performed without IABP or CPS. CPS for high-risk PCI should be reserved only for patients at the extreme end of the spectrum of hemodynamic compromise, such as those patients with extremely depressed LV function and patients in cardiogenic shock. However, in patients with borderline hemodynamics, ongoing ischemia, or cardiogenic shock, insertion of an intra-aortic balloon just before coronary instrumentation has been associated with improved outcomes (267,268). Furthermore, it is reasonable to obtain vascular access in the contralateral femoral artery before the procedure in patients in whom the risk of hemodynamic compromise is high, thereby facilitating intra-aortic balloon insertion, if necessary.

For high-risk patients, clinical and anatomic variables influencing complications and outcome should be assessed before the performance of PCI to determine procedural risk, the risk of abrupt vessel closure, and potential for cardiovascular collapse. In patients having a higher-risk profile (such as those with LV dysfunction, single patent vessel or ULM, degenerated SVG, or high thrombus burden in the obstructed vessel), consideration of alternative therapies, particularly coronary bypass surgery, formalized surgical standby, or periprocedural hemodynamic support should be addressed before proceeding with PCI. Several small retrospective studies have evaluated the use of elective balloon pump support before high-risk PCI. These studies generally reveal successful reperfusion by PCI, with improved procedural or in-hospital morbidity and mortality (267,269,270). An alternative approach is to use standby IABP, which results in slightly greater complications for patients undergoing standby IABP than for those in whom the IABP was in place before the procedure (271). Available data for the use of IABP in high-risk patients involve retrospective analyses of relatively small numbers of patients; therefore, no formal recommendations are suggested. The decision to proceed with IABP before PCI remains a clinical judgment made by the physician based on the high-risk characteristics of coronary anatomy and overall status of the patient.

3.6. Comparison With Bypass Surgery

The major advantage of PCI is its relative ease of use and avoidance of general anesthesia, thoracotomy, extracorporeal circulation, central nervous system complications, and prolonged convalescence. Repeat PCI can be performed more easily than repeat bypass surgery, and revascularization can be achieved more quickly in emergency situations. The disadvantages of PCI are early restenosis and the inability to relieve many totally occluded arteries and/or those vessels with extensive atherosclerotic disease.

Coronary artery bypass surgery has the advantages of greater durability (graft patency rates exceeding 90% at 10 years with arterial conduits) (272) and more complete revascularization regardless of the morphology of the obstructing atherosclerotic lesion. Generally speaking, the greater the extent of coronary atherosclerosis and its diffuseness, the more compelling the choice of coronary artery bypass surgery, particularly if LV function is depressed. Patients with a lesser extent of disease and localized lesions are good candidates for endovascular approaches.

PTCA and coronary artery bypass surgery have been compared in many nonrandomized and randomized studies. Whereas randomized controlled trials are the only way to completely eliminate bias between comparative therapies, large prospective registries can best extend observations to broad segments of the population who might be excluded from randomized trials. Through risk-adjustment methodologies, large groups of patients can be evaluated between therapies to attempt to eliminate the impact of baseline differences. A number of registries have compared coronary bypass graft surgery with PCI (52). New York State mandates a registry of all patients undergoing PCI and CABG that is monitored by audit and provides survival data on all New York State residents. Patients with multivessel disease treated between January 1, 1997, and December 31, 2000, were followed up for 3 years (52). During this period when stent utilization was common, the adjusted hazard ratio favored surgery for all subsets of multivessel disease patients. The surgical advantage was greatest for patients with 3-vessel disease with involvement of the proximal LAD and least for patients with 2-vessel disease without anterior descending involvement. One important factor differentiating the techniques was significantly more complete revascularization in the surgery group. By identifying trends such as

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these, registries can provide important insight for clinical improvement.

The most accurate comparisons of outcomes are best made from prospective randomized trials of patients suitable for either treatment. Although results of these trials provide useful information for selection of therapy in several patient subgroups, prior studies of PTCA may not reflect outcome of current PCI practice, which includes frequent use of stents and antiplatelet drugs. Similarly, many previous studies of CABG may not reflect outcome of current surgical practice, in which arterial conduits are used whenever practicable. Beating heart bypass operations are also employed for selected patients with single-vessel disease with reduced morbidity (273). In addition, patients are selected for PCI (with or without stenting) because of certain lesion characteristics, and these anatomic criteria are not required for CABG.

Randomized trials also must be interpreted carefully. It is unethical to withhold subsequent PCI or CABG from patients solely because they fail an earlier treatment; thus, comparative prospective studies can only compare initial strategies of revascularization. This critically important point is frequently overlooked by those who claim that a randomized study proves equally good outcome of one method of revascularization over the other.

Despite these limitations, some generalizations can be made from comparative trials of PTCA and CABG. First, for most patients with single-vessel disease, late survival is similar with either revascularization strategy, and this might be expected given the generally good prognosis of most patients with single-vessel disease managed medically (274-276).

Two prospective clinical trials have evaluated PTCA and CABG for revascularization of isolated disease of the LAD. Investigators in the Medicine, Angioplasty or Surgery Study (MASS) used a combined end point of cardiac death, MI, or refractory angina requiring repeat revascularization by surgery; at 3 years of follow-up, this combined end point occurred in 24% of PTCA patients, 17% of medical patients, and 3% of surgical patients (277). Importantly, there was no difference in overall survival in the 3 groups. In the Lausanne trial of 134 patients with isolated LAD disease treated by either PTCA (68 patients) or bypass with an IMA, survival was similar in the 2 groups, and 94% of PTCA patients and 95% of CABG patients were free of limiting symptoms (278). However, patients in the PTCA group took more antianginal drugs than surgical patients, and at median follow-up of 2.5 years, 86% of CABG-treated versus 43% of PTCA-treated patients were free from late events (*P* less than 0.01); this difference was primarily due to restenosis (32%) requiring subsequent CABG (16%) or PTCA (15%). Neither of the 2 aforementioned trials included stenting, a technique that would be expected to reduce rates of early restenosis by as much as 50% in appropriately selected lesions (108,279,280).

In a similar manner, the 3-year follow-up of the Argentine randomized trial of PTCA versus CABG multivessel disease (ERACI study) (279) demonstrated that in patients randomized to PTCA or bypass surgery, the 1-, 3-, and 5-year follow-up results indicated that freedom from combined cardiac events was significantly greater for bypass surgery than for the PTCA group (77% vs 47%; *P* less than 0.001). However, there were no differences in overall and cardiac mortality or in the frequency of MI between the 2 groups. Patients who had bypass surgery were more frequently free of angina (79% vs 57%) and had fewer additional reinterventions (6.3% vs 37%) than patients who had PTCA. This study indicated that freedom from combined cardiac events at 3-year follow-up was greater in bypass patients than in those who had PTCA and that the PTCA group had a higher incidence of recurrence of angina and need for repeat procedures. Cumulative cost at 3 years was greater for surgery than for the PTCA group.

In the ARTS trial, the first trial to compare stenting with surgery, there was no significant difference in mortality between PCI and surgical groups at 1 and 3 years (281,282). The main difference compared with previous PTCA and CABG trials was an approximate 50% reduction in the need for repeat revascularization in a group randomized to PCI with stent placement (281).

Similar results were reported by the Stent or Surgery (SoS) trial. In this trial, 988 patients with multivessel disease were randomized to PCI (78% received stents) or CABG. At a median follow-up of 2 years, 21% of the PCI group required repeat revascularization compared with 6% of the CABG group (hazard ratio 3.85, 95% confidence interval [CI] 2.56-5.79, *P* less than 0.0001). The incidence of death or Q-wave MI was similar in both groups (hazard ratio 0.95, 95% CI 0.63-1.42, *P* equals 0.80). Mortality was higher in the PCI group, but this was influenced by a particularly low surgical mortality and a high rate of noncardiovascular deaths in the PCI group (283).

The ERACI II study randomized 450 patients with multivessel disease (91% UA) to PCI or CABG. At a mean follow-up of 18.5 months, survival was 96.9% in PCI group versus 92.5% in the CABG group (*P* less than 0.017). Freedom from MI was also better in the PCI group than in the CABG group (97.7% vs 93.4%, *P* less than 0.017). Similar to other studies, the need for repeat revascularization was higher in the PCI group (16.8% vs 4.8%, *P* less than 0.002) (284).

In the AWESOME study, 454 patients with medically refractory myocardial ischemia and high-risk features for adverse outcomes with surgery were randomized to either PCI (54% received stents) or CABG. High-risk features included: prior open heart surgery, age greater than 70 years, LV ejection fraction less than 0.35, MI within 7 days, or IABP required. Comparable survival was observed between the PCI and CABG groups at 3 years (80% vs 79%), with more frequent repeat revascularization in the PCI group. Additionally, survival free of UA in the PCI group was within 90% of that in the CABG group (285).

Direct comparison of initial strategies of PCI or CABG in patients with multivessel coronary disease is possible only by randomized trials because of selection criteria of patients for PCI. There have been 5 large (more than 300 patients) randomized trials of PTCA versus CABG and 2 smaller stud-

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ies and 5 large trials of PCI using stents versus CABG (10-12,279,281,283-289). Characteristics of the studies are summarized in Table 11 (11,12,279,282-290). These trials demonstrate that in appropriately selected patients with multivessel coronary disease, an initial strategy of standard PCI with BMS yields similar overall outcomes (e.g., death, MI) to initial revascularization with coronary artery bypass.

An important exception to the conclusion of the relative safety of PCI in multivessel disease is the subgroup of patients with treated diabetes mellitus. In BARI, the only trial with a sufficiently large patient enrollment to examine survival alone, the data showed that among treated diabetic patients assigned to PTCA, 7-year survival was 55.7% compared with 76.4% for patients having CABG (P equals 0.0011); the improved outcome with CABG was due to reduced cardiac mortality (5.8% vs 20.6%, P equals 0.0003), which was confined to those receiving at least 1 IMA graft (10,67,290). There was no mortality difference at 7 years in the remainder of the patients, those without diabetes and patients with diabetes not undergoing medical treatment (290). Better survival of diabetic patients with multivessel disease treated initially with CABG has also been observed in a large retrospective study from Emory (291) and in the 8-year results of Emory Angioplasty Surgery Trial (EAST) (292). In the BARI trial, the benefit of bypass surgery in diabetic patients was greater in those patients with more extensive disease (e.g., more than 4 lesions). This advantage was largely due to a lower mortality for subsequent MI (233,293). As compelling as these reports may be, it is of interest that treated diabetic patients enrolled in the BARI registry did not show a similar advantage for CABG over PCI, which suggests that physician judgment in the selection of diabetic patients for PCI may be an important factor (42,68).

Patients with diabetes have been evaluated specifically in studies from the ARTS and AWESOME groups, which included the use of stents (294,295). GP IIb/IIIa inhibitors were used in approximately 11% of AWESOME PCI patients and were not incorporated into the ARTS protocol. After 3 years of follow-up, the survival rates of the diabetic subsets treated with CABG and PCI were not significantly different in either ARTS or AWESOME. Repeat revascularization was higher with PCI in the subsets of patients with diabetes in both trials. The sum effect of DES and GP IIb/IIIa inhibitors will be assessed against contemporary CABG in multivessel disease patients with diabetes in the upcoming NIH-sponsored FREEDOM trial.

Overall, 6 trials have been published comparing PCI using stents with CABG in single-vessel or multivessel disease. Both revascularization techniques relieve angina. In aggregate, these trials have not shown a difference between CABG and PCI in terms of mortality or procedural MI among the populations studied, which have mostly included low-risk patients. Stents appear to have narrowed the late repeat revascularization difference that favored CABG in the balloon era. Randomized trials, meta-analysis of trials, and epidemiological studies have shown the superiority of DES over BMS in terms of reducing late repeat revascularization (234-236) (see also Section 7.3.5 on DES). At this writing, no published studies are available comparing PCI with DES to CABG; thus, the impact of contemporary therapy with DES compared with CABG requires further evaluation. The ARTS II study compared outcomes for 600 surgically treated patients in ARTS II with 600 similar patients prospectively treated with multistent, sirolimus-eluting stent (SES) implantation [P.W. Serruys, oral presentation, American College of Cardiology Scientific Session, Orlando, Fla, March 2005]. Preliminary data from that study showed a lower rate of perioperative MI for the stent group. The surgery group still had fewer repeat revascularization procedures; however, the difference was markedly attenuated compared with the ARTS I BMS group. Furthermore, medical management of atherosclerosis, both before and after revascularization, has continued to evolve with the increased use of beta-blockers, inhibitors of the renin-angiotensin-aldosterone system, and lipid-lowering agents. Other changes in patient management that may influence these conclusions are the use of GP IIb/IIIa inhibitors, as mentioned above, and the use of direct thrombin inhibitors during PCI, the more frequent use of IMA grafts, and the emergence of less invasive surgical approaches. It is likely that during the progress of their disease, many patients will benefit from a combined application of percutaneous and surgical techniques, taking advantage of the low morbidity of percutaneous methods and the established long-term benefit of surgical revascularization with arterial conduits. Recommendations for revascularization in various patient subsets are presented in Section 5.

3.7. Comparison With Medicine

There has been a considerable effort made to evaluate the relative effectiveness of bypass surgery compared with PCI for coronary artery revascularization. In contrast to this, very little effort has been directed toward comparing medical therapy with PCI for the management of stable and UA. Several randomized trials are currently available comparing PCI with the medical management of angina (Table 12) (289,296-302). Most trials comparing PCI with medical therapy have utilized PTCA, not stents, in comparison with medical therapy, and no major trials are available comparing DES with medical therapy. The ACME (Angioplasty Compared to Medicine) investigators randomized 212 patients with single-vessel disease, stable angina pectoris, and ischemia on treadmill testing to PTCA or medical therapy. This trial demonstrated superior control of symptoms and better exercise capacity in patients managed with PTCA than in those given medical therapy. Death and MI were infrequent occurrences, and their incidence was similar in both groups. The Veterans Administration ACME trial investigators provided long-term results in an additional 101 randomized patients with double-vessel disease not previously reported (300) that indicated that patients randomized to medical therapy or PTCA had similar improvement in exercise duration, freedom from angina, and improvement in quality of life at the

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Table 11. Summary of Randomized Trials of PTCA and Stents Versus CABG for Multivessel Disease

Trial	Years	Ref	Location	n	Follow-Up, y	End Point	Comments
PTCA Trials							
RITA	1989-1991	(11)	U.K. multicenter	1011	2.5	Death or MI	45% of patients had SVD
EAST	1987-1990	(286)	Emory University	392	3	Death, Q-wave MI, or large ischemic defect on thallium	Repeat revascularization in 5.4% of PTCA group compared with 13% of patients having CABG
GABI	1986-1991	(12)	Germany multicenter	359	1	Freedom from angina	IMA used in only 37% of CABG patients; more than 80% of patients had 2-vessel disease
CABRI	1988-1993	(287)	Europe multicenter	1054	1	Mortality, symptom status	Complete revascularization with PTCA was not required
ERACI	1988-1990	(279)	Argentina	127	3.8	Event-free survival (MI, angina, and RR)	Similar in-hospital and 1-year survival and freedom from MI; less angina and fewer repeat procedures after CABG
BARI	1988-1991	(290)	North American multicenter	1829	7	Death	Overall survival similar with PTCA and CABG, but late survival of treated diabetic patients better with CABG when IMA grafts were used
Toulouse	1989-1993	(288)	France	152	2.8	Freedom from angina 1 year after revascularization	Similar survival with PTCA and CABG at 5 years, but better event-free survival with CABG (fewer repeat procedures)
Stent Trials							
ARTS	1997-1998	(282)	Europe multicenter	1205	3	Freedom from major adverse cardiac and CV events	No significant difference between PCI and CABG in terms of death, stroke, or MI; PCI was associated with greater need for RR
AWESOME	1995-2000	(285)	Veterans Affairs multicenter	454	3	Death	Comparable survival between PCI and CABG in patients with medically refractory myocardial ischemia, with higher RR in PCI group
ERACI II	1996-98	(284)	Argentina	450	1.5	MACE (death, Q-wave MI, stroke, RR)	Better survival and freedom from MI with PCI than with CABG; RR higher in PCI group
SoS	1996-99	(283)	Europe, Canada multicenter	988	1	RR	Significantly higher number of RRs with PCI; no difference in composite measure of death and Q-wave MI; fewer deaths in the CABG group
MASS II	1995-2000	(289)	Brazil single center	611	1	Cardiac death, nonfatal acute MI, and unstable angina	Included medical therapy arm; no difference in cardiac death or MI among patients in the CABG, PCI, or medical therapy groups; significantly greater need for RR procedures in patients who underwent PCI

CABG indicates coronary artery bypass graft surgery; CV, cerebrovascular; IMA, internal mammary artery; MACE, major adverse cardiac events; MI, myocardial infarction; n, number of patients; PCI, percutaneous coronary intervention; PTCA, percutaneous transluminal coronary angioplasty; Ref, reference; RR, repeat revascularization; SVD, single-vessel disease; and y, year.

Table 12. PCI Comparison With Medical Therapy

Study	Year	Ref	n	Patient Population	Treatment	Follow-Up	Results			Comments
							PCI	Medical Therapy	Significance (*P*)	
ACME	1992	(296)	212	Patients with single-vessel disease	Medical therapy vs balloon angioplasty	6 mo	64% less angina	46% less angina	Less than 0.01	The PTCA group had less angina, better exercise performance, and more improvement in quality-of-life scores but had more complications (emergency bypass 2 patients, MI in 5, and repeat PTCA in 16)
VA ACME	1997	(300)	328	Patients with documented chronic stable angina 227 single-vessel disease 101 double-vessel disease	Medical therapy vs balloon angioplasty	3 y	63% less angina	48% less angina	0.02	Among patients with single-vessel disease, the PTCA group had less angina, better exercise performance, and more improvement in quality-of-life scores
ACIP	1997	(301)	558	Patients with documented CAD and asymptomatic ischemia 183 angina-guided drug therapy 183 angina- plus ischemia-guided drug therapy 192 revascularization by PTCA or CABG	Angina-guided drug therapy vs angina- plus ischemia guided drug therapy vs revascularization	2 y	4.7% death or MI	8.8% death or MI for ischemia-guided drug therapy 12.1% death or MI for angina-guided drug therapy	Less than 0.01	40% of patients had previous MI, 23% had prior PTCA or CABG, and 38% had triple-vessel disease
AVERT	1999	(298)	341	Patients with stable CAD, normal LV function, and angina class I/II; patients required to complete 4 min on Bruce protocol	Medical therapy with atorvastatin vs PTCA	18 mo	21% ischemic events	13% ischemic events	0.048; 0.045 needed for significance due to interim analysis	Only 2 deaths among 341 patients in 18 months; significant improvement in angina in patients treated with PTCA compared with medical therapy

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Table 12. *Continued*

Study	Year	Ref	n	Patient Population	Treatment	Follow-Up	Results			Comments
							PCI	Medical Therapy	Significance (*P*)	
RITA-3	2003	(299)	1018	53% with Class II angina 47% with prior angina 7% with triple-vessel disease	Medical therapy vs balloon angioplasty	7 y	14.5% death or MI	12.3% death or MI	0.21	PTCA group had increased rates of death and MI but had 6.4% less class II angina or worse at 5 years and longer exercise treadmill time at 3 years
RITA-4	2002	(302)	1810	Suspected cardiac chest pain at rest with documented CAD (at least 1 of the following: ECG changes, pathological Q waves, previous arteriogram)	Medical therapy and either early invasive or conservative (selectively invasive) treatment strategy; both groups received enoxaparin in addition to standard medical therapy	1 y	7.6% death or MI	8.3% death or MI	NS	Similar results for death or MI between treatment groups; significant difference in primary end point (death, MI, refractory angina) due to halving of refractory angina in intervention group
MASS II	2004	(289)	611	Stable angina, multivessel disease, preserved LV function	Medical therapy, CABG, or PCI	1 y	4.5% death	1.5% death	NS	Aggressive medical management for multivessel disease has low incidence of early events, including death and Q-wave MI, but is inferior to PCI (and CABG) for control of angina

n indicates number of patients; CABG, coronary artery bypass graft; CAD, coronary artery disease; MI, myocardial infarction; PTCA, percutaneous transluminal coronary angioplasty; and PCI, percutaneous coronary intervention.

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time of 6-month follow-up. Thus, these patients with double-vessel PTCA did not demonstrate superior control of their symptoms as compared with medical therapy, as was experienced by the ACME patients with single-vessel disease. This small study suggests that PTCA is less effective in controlling symptoms in patients with double-vessel disease and stable angina than in those with single-vessel disease.

The Randomized Intervention Treatment of Angina (RITA)-2 investigators randomized 1018 patients with stable angina to PTCA or conservative (medical) therapy (297,299). Patients who had inadequate control of their symptoms with optimal medical therapy were allowed to cross over to myocardial revascularization. The combined end point of the trial was all-cause mortality and nonfatal MI. The 504 PTCA and 514 medically treated patients were followed up for a mean of 7 years. Death due to all causes occurred in 43 (8.5%) of the PTCA patients and 43 (8.4%) of the medical patients. Of the 86 deaths, only 8 were due to heart disease. Angina improved in both groups, but there was a 16.5% absolute excess of grade 2 or worse angina in the medical group at 3 months after randomization (*P* less than 0.001). These differences in angina narrowed over time, with the PTCA group always having less angina than the medically treated patients. Thus, RITA-2 demonstrated that PTCA results in better control of symptoms of ischemia and improves exercise capacity compared with medical therapy but is associated with a higher combined end point of death and periprocedural MI. It is important to remember that although the patients in this trial were asymptomatic or had only mild angina, 62% of them had multivessel CAD, and 34% had significant disease in the proximal segment of the LAD (301). Thus, most of these patients had severe anatomic CAD.

The Asymptomatic Cardiac Ischemia Pilot (ACIP) study provides additional information comparing medical therapy with PTCA or CABG revascularization in patients with documented CAD and asymptomatic ischemia by both stress testing and ambulatory ECG monitoring (301). This trial randomized 558 patients suitable for revascularization by PTCA or CABG to 3 treatment strategies: angina-guided drug therapy (n equals 183), angina- plus ischemia-guided drug therapy (n equals 183), and revascularization by PTCA or CABG surgery (n equals 192). Of the 192 patients who were randomized to revascularization, 102 were selected for PTCA and 90 for CABG. At 2 years of follow-up, death or MI had occurred in 4.7% of the revascularization patients compared with 8.8% of the ischemia-guided group and 12.1% of the angina-guided group (*P* less than 0.01). Because a large portion of the patients underwent CABG surgery instead of PTCA to achieve complete revascularization, it is not appropriate to directly compare these results with RITA-2. Nonetheless, the ACIP study suggests that outcomes of revascularization with CABG surgery and PTCA are very favorable compared with medical therapy in patients with asymptomatic ischemia with or without mild angina. It should be emphasized that aggressive lipid-lowering therapy was not widely employed in either treatment arm of ACIP.

The Atorvastatin Versus Revascularization Treatment (AVERT) trial (298) randomly assigned 341 patients with stable CAD, normal LV function, and class I and/or II angina to PTCA or medical therapy with 80 mg of atorvastatin daily (mean low-density lipoprotein cholesterol equals 77 mg per dL). At 18 months of follow-up, 13% of the medically treated group had ischemic events compared with 21% of the PTCA group (*P* equals 0.048). Angina relief was greater in those treated with PTCA. Although not statistically different when adjusted for interim analysis, these data suggest that in low-risk patients with stable CAD, aggressive lipid-lowering therapy can be as effective as PTCA in reducing ischemic events.

During the MASS-II trial (289), 611 patients with stable angina, multivessel disease, and preserved LV function were randomized to 3 treatment groups: medical therapy, CABG, or PCI (medical therapy n equals 203, CABG n equals 203, and PCI n equals 205). One-year survival was similar in the 3 groups at 98.5%, 96.0%, and 95.6%, respectively. At 1 year of follow-up, a Q-wave MI had occurred in 2% of CABG patients, 8% of the PCI patients, and 3% of the medical therapy patients. By 1 year, additional revascularization procedures were performed in 8.3% of medical therapy patients, 13.3% of PCI patients, and only 0.5% of CABG patients. More patients were free of angina at 1 year in the CABG and PCI groups (88% and 79%, respectively) than in the medical therapy groups, in which only 46% were free of angina. This small contemporary trial utilizing aggressive medical management demonstrated that medical therapy for multivessel disease has a low incidence of early events including death and Q-wave MI but is inferior to PCI and CABG for the control of angina.

Given the limited data available from randomized trials comparing medical therapy with PCI, it seems prudent to consider medical therapy for the initial management of most patients with CCS classification class I and II stable angina and to reserve PCI and CABG for those patients with more severe symptoms and ischemia. The symptomatic patient who wishes to remain physically active, regardless of age, will usually require PCI or CABG to accomplish this.

The Clinical Outcomes Utilization Revascularization and Aggressive Drug Evaluation (COURAGE) trial was designed to compare intensive medical therapy with PCI plus intensive medical therapy. Enrollment has been completed, and results are expected to be available in the next few years. This trial will provide further valuable information about the relative merits of medical treatment plus PCI versus medical treatment alone and will also give us a detailed assessment of outcomes relative to quality of life and economic cost (303). The Bypass Angioplasty Revascularization trial in patients with diabetes (BARI 2d) was designed to compare revascularization in addition to aggressive medical therapy in patients with diabetes compared with aggressive medical therapy alone. Enrollment was completed in the first quarter of 2005.

Patients with UA and NSTEMI have been randomized to medical therapy or PCI in the FRagmin and Fast

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Revascularisation during InStability in Coronary artery disease (FRISC) II and Treat Angina with Aggrastat and determine the Cost of Therapy with an Invasive or Conservative Strategy (TACTICS) TIMI 18 trials, as well as in RITA-3. These trials utilizing stenting as the primary therapy have favored the invasive approach (206,302,304). They are discussed in Section 5.3.

4. INSTITUTIONAL AND OPERATOR COMPETENCY

4.1. Quality Assurance

Class I

1. **An institution that performs PCI should establish an ongoing mechanism for valid peer review of its quality and outcomes. Review should be conducted both at the level of the entire program and at the level of the individual practitioner. Quality-assessment reviews should take risk adjustment, statistical power, and national benchmark statistics into consideration. Quality-assessment reviews should include both tabulation of adverse event rates for comparison with benchmark values and case review of complicated procedures and some uncomplicated procedures.** ***(Level of Evidence: C)***
2. **An institution that performs PCI should participate in a recognized PCI data registry for the purpose of benchmarking its outcomes against current national norms.** ***(Level of Evidence: C)***

Definition of Quality in PCI

Satisfactory quality in PCI may be defined as the appropriate selection of patients for the procedure and the achievement of risk-adjusted outcomes that are comparable to national benchmark standards in terms of procedure success and adverse event rates. To achieve optimal quality and outcomes in PCI, it is necessary that both the physician operator and the supporting institution be appropriately skilled and experienced.

Institutional Quality-Assurance Requirement

PCI is a demanding, technically complex procedure. The potential exists for substantial quality variation among both operators and institutions.

In the United States, responsibility for quality assurance is vested in the healthcare institution, which is responsible to the public to ensure that patient care conducted under its jurisdiction is of acceptable quality. Thus, the institution has the responsibility to monitor its PCI program's quality with respect to process, appropriateness, and outcomes in order to identify and correct any circumstances in which quality falls below accepted norms. Quality-assessment review should be conducted both at the level of the entire program and at the level of the individual practitioner.

Each institution that performs PCI must establish an ongoing mechanism for valid peer review of its quality and outcomes. The program should provide an opportunity for interventionalists, as well as for physicians who do not perform angioplasty but are knowledgeable about it, to review its overall results on a regular basis. The review process should tabulate the results achieved both by individual physician operators and by the overall program and compare them with national benchmark standards with appropriate risk adjustment. Valid quality assessment requires that the institution maintain meticulous records that include the patient demographic and clinical characteristics necessary to assess appropriateness and to conduct risk adjustment.

Role of Risk Adjustment in Assessing Quality

A raw adverse event rate that is not appropriately risk adjusted has little meaning. Data compiled from large registries of procedures performed in recent years have generated multivariate risk-adjustment models for adverse event rates for PCI in the current era. Six multivariate models of the risk of mortality after PCI have been published (43,47,305-308).

Although these models differ somewhat, they are consistent in identifying acute MI, shock, and age as important risk-stratification variables for mortality. The ACC-NCDR reported a univariate mortality rate of 0.5% for patients undergoing elective PCI, a mortality rate of 5.1% for patients undergoing primary PCI within 6 h of the onset of STEMI, and a mortality rate of 28% for patients undergoing PCI for cardiogenic shock (305). Thus, it is clear that to assess PCI mortality rates, patients should be stratified by whether they are undergoing elective PCI, primary PCI for acute STEMI without shock, or primary PCI for STEMI with shock.

Challenges in Determining Quality

As discussed above, given the complexity of case selection and procedure conduct, quality is difficult to measure in PCI and is not determined solely by adverse event rates even when properly adjusted for risk. Accurate assessment of quality becomes more problematic for low-volume operators and institutions, because absolute event rates are expected to be small. Thus, particularly in low-volume circumstances, quality may be better assessed by an intensive case review process conducted by recognized experts who can properly judge all of the facets of the conduct of a case. Case review also has merit in high-volume situations, because it can identify subtleties of case selection and procedure conduct that may not be reflected in pooled statistical data.

Requirement for Institutional Resources and Support

A high-quality PCI program requires appropriately trained and experienced skilled physician operators. However, the operator does not work in a vacuum. An operator needs a well-maintained, high-quality cardiac catheterization facility to practice effectively. In addition, the operator depends on a multidisciplinary institutional infrastructure for support and response to emergencies. Thus, to provide quality PCI services, the institution must ensure that its catheterization facility is properly equipped and managed and that all of its necessary support services are of high quality and are readily available.

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The Quality-Assessment Process

Quality assessment is a complex process that includes more than mere tabulation of success and complication rates. Components of quality in coronary interventional procedures include appropriateness of case selection, quality of procedure execution, proper response to intraprocedural problems, accurate assessment of procedure outcome, and appropriateness of postprocedure management. It is important to consider each of these parameters when conducting a quality-assessment review. A quality program performs appropriately selected procedures that achieve risk-adjusted outcomes, in terms of procedure success and complication rates, that are comparable to national benchmark standards. Patient characteristics that determine appropriateness are discussed elsewhere in this document. Multivariate models that predict risk have been published previously (43,47,305-308).

It is accepted that quality-assurance monitoring is best conducted through the peer review process despite the political challenges associated with colleagues evaluating each other. There has been a considerable controversy surrounding efforts to define standards, criteria, and methodologies for conducting quality assessment. There are many challenges to conducting this process in a fair and valid manner.

The cornerstone of quality-assurance monitoring is the assessment of procedural outcomes in terms of success and adverse event rates. Other components of quality-assurance monitoring include establishment of criteria for assessing procedure appropriateness and application of proper risk adjustment to interpret adverse event rates. Because adverse events should be rare, a valid estimate of a properly risk-adjusted adverse event rate generally requires tabulation of the results of a large number of procedures. This adds an additional challenge to the valid assessment of low-volume operators and institutions. The responsible supervising authority should monitor the issues outlined in Table 13 (309).

Initial Physician Operator Credentialing Criteria

The institutional credentialing committee should document that an interventionalist wishing to initiate practice meets the established training criteria, including those of the ACC Task Force on Training in Cardiac Catheterization and Interventional Cardiology (310-312). The ACC Training Statement (312) for coronary invasive training requires a 3-year comprehensive cardiac program with 12 months of training in diagnostic catheterization, during which the trainee performs 300 diagnostic catheterizations, with at least 200 of those as the primary operator. Interventional training requires a fourth year of fellowship, during which the trainee should perform more than 250 but not more than 600 interventional procedures (312). The physician's training program director should certify that the candidate has completed the program and has achieved the necessary competence to perform coronary interventional procedures independently. The certification should also include whether the candidate has achieved requisite competence in related interventional techniques such as rotational atherectomy, balloon valvuloplasty, and closure of patent foramen ovale and atrial septal defect.

It is recommended that an interventional cardiology operator be certified by the American Board of Internal Medicine in interventional cardiology. Ideally, board certification in interventional cardiology should be required for credentialing. The American Board of Internal Medicine certifying examination in interventional cardiology has been administered annually since 1999. As of the 2004 administration, a total of 4718 individuals have been certified.

Privilege Renewal

Criteria for practitioner privilege renewal should be based on both activity level and outcomes. The assessment process should ascertain whether a physician operator's activity level is sufficient to maintain competence. In addition, the assessment process should assess the appropriateness of the operator's case selection and compare the operator's risk-adjusted outcomes with established national benchmark standards (310). This is discussed in depth in Section 4.2. Current benchmark standards for mortality, complication rates, and risk adjustment will be subject to future revision as procedure technique is refined and newer data emerge. It is important that institutions assist with these efforts by participating in active database efforts to track clinical and procedural information for individual operators and their institutions.

Outcome Data Tabulation and Reporting

Institutions performing PCI should gather data needed to monitor their outcomes and should submit their data to a national registry for benchmarking purposes. Institutions should conduct meticulous record keeping that details the cases performed-patient demographics and comorbidities,

Table 13. Key Components of a Quality-Assurance Program

Clinical proficiency
General indications/contraindications
Institutional and individual operator complication rates, mortality and emergency CABG
Institutional and operator procedure volumes
Training and qualifications of support staff
Equipment maintenance and management
Quality of laboratory facility [See ACC/SCAI Expert Consensus Document on Catheterization Laboratory Standards (309)]
Quality improvement process
Establishment of an active concurrent database to track clinical and procedural information and patient outcomes for individual operators and the institution. The ACC-NCDR® or other databases are strongly recommended for this purpose
Radiation safety
Educational program in the diagnostic use of X-ray
Patient and operator exposure

ACC indicates American College of Cardiology; CABG, coronary artery bypass graft surgery; NCDR®, National Cardiovascular Data Registry; and SCAI, Society for Cardiovascular Angiography and Interventions.

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cardiovascular characteristics including type of presentation, coronary anatomy, ventricular function, procedures performed, and periprocedural complications. These data are necessary to permit appropriate risk adjustment. Institutions should carefully monitor their risk-adjusted outcomes at the level of the institution and of the individual operators and should ascertain that their outcomes fall within national norms. One example is the ACCF CathKit®, a tool that provides templates and guidance for the quality assessment process.

This Writing Committee agrees with the ACC Task Force recommendations for the Assessment and Maintenance of Proficiency in Coronary Interventional Procedures (310). Institutions and healthcare providers performing PCI should meet the standards outlined in Table 14 (309,310,312) and in Section 4.2.

4.2. Operator and Institutional Volume

Class I

1. **Elective PCI should be performed by operators with acceptable annual volume (at least 75 procedures) at high-volume centers (more than 400 procedures) with onsite cardiac surgery (310,312).** ***(Level of Evidence: B)***
2. **Elective PCI should be performed by operators and institutions whose historical and current risk-adjusted outcomes statistics are comparable to those reported in contemporary national data registries.** ***(Level of Evidence: C)***
3. **Primary PCI for STEMI should be performed by experienced operators who perform more than 75 elective PCI procedures per year and, ideally, at least 11 PCI procedures for STEMI per year. Ideally, these procedures should be performed in institutions that perform more than 400 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year.** ***(Level of Evidence B)***

Class IIa

1. **It is reasonable that operators with acceptable volume (at least 75 PCI procedures per year) perform PCI at low-volume centers (200 to 400 PCI procedures per year) with onsite cardiac surgery (310,312).** ***(Level of Evidence: B)***
2. **It is reasonable that low-volume operators (fewer than 75 PCI procedures per year) perform PCI at high-volume centers (more than 400 PCI procedures per year) with onsite cardiac surgery (310,312). Ideally, operators with an annual procedure volume less than 75 should only work at institutions with an activity level of more than 600 procedures per year. Operators who perform fewer than 75 procedures per year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume of at least 150 procedures per year.** ***(Level of Evidence: B)***

Table 14. Considerations for the Assessment and Maintenance of Proficiency in Coronary Interventional Procedures

Institutions
Quality-assessment monitoring of privileges and risk-stratified outcomes
Provide support for a quality-assurance staff person (e.g., nurse) to monitor complications
Minimal institutional performance activity of 200 interventions per year, with ideal minimum of 400 interventions per year
Interventional program director who has a career experience of more than 500 PCI procedures and who is board certified by the ABIM in interventional cardiology
Facility and equipment requirements to provide high-resolution fluoroscopy and digital video processing
Experienced support staff to respond to emergencies (see Section 4.3, Role of On-Site Cardiac Surgical Backup for discussion)
Establishment of a mentoring program for operators who perform fewer than 75 procedures per year by individuals who perform at least 150 procedures per year
Physicians
Procedural volume of 75 per year or more
Continuation of privileges based on outcome benchmark rates, with consideration of not granting privileges to operators who exceed adjusted case mix benchmark complication rates for a 2-year period
Ongoing quality assessment comparing results with current benchmarks, with risk stratification of complication rates
Board certification by ABIM in interventional cardiology

ABIM indicates American Board of Internal Medicine; and PCI, percutaneous coronary intervention.

Class IIb

The benefit of primary PCI for STEMI patients eligible for fibrinolysis when performed by an operator who performs fewer than 75 procedures per year (or fewer than 11 PCIs for STEMI per year) is not well established. ***(Level of Evidence: C)***

Class III

It is not recommended that elective PCI be performed by low-volume operators (fewer than 75 procedures per year) at low-volume centers (200 to 400) with or without onsite cardiac surgery (310,312). An institution with a volume of fewer than 200 procedures per year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer this service. ***(Level of Evidence: B)***

Operator and Institution Volume-Outcome Relationships

Threshold activity level standards for institutions and operators have been particularly controversial. Such standards are

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derived from the principle that proper skill maintenance requires a requisite activity level. It is logical that both a threshold experience and an ongoing activity level are necessary to achieve and maintain requisite proficiency in PCI.

Standards originally formulated for the earliest versions of these guidelines were based on opinion (Level of Evidence: C) drawing on the well-documented existence of volume-outcome relationships for other complex surgical procedures. Initially, a panel of experts identified a threshold activity level of 75 procedures per year as necessary for maintenance of competence in PCI (313). Subsequent studies of PCI continue to identify annual procedural volume both at the program level and at the operator level as strongly correlated with complication rates. Most studies' findings are consistent with the operator threshold of 75 procedures per year (47, 306,309,314-320).

Most studies of the PCI volume-outcome relationship focus on mortality and emergent bypass surgery as quality-determining outcome variables. These variables, while important, encompass only a portion of the overall quality determinants for PCI.

McGrath et al. examined volume outcome relationships using procedures performed on 167 208 Medicare recipients in 1997 (321). Procedures performed by low-volume physicians (fewer than 30 Medicare procedures per year) had a greater emergency CABG rate (2.25%) than procedures performed by high-volume physicians (more than 60 Medicare procedures per year; 1.55%, *P* less than 0.001). An increased 30-day mortality rate was found for low-volume programs (fewer than 80 Medicare procedures per year) versus high-volume programs (more than 160 Medicare procedures per year; 4.29% vs 3.15%, *P* less than 0.001).

Kimmel et al., using data from the SCAI, found that an inverse relationship existed between the number of angioplasty procedures performed at a hospital and the rate of major complications (315). These results were risk stratified and independent of the patient-risk profile. Significantly fewer complications occurred in laboratories that performed at least 400 angioplasty procedures per year.

Jollis et al. found that low-volume hospitals were associated with higher rates of emergency coronary artery bypass surgery and death (316). Improved outcomes were identified with a threshold volume of 75 Medicare angioplasties per physician and 200 Medicare angioplasty procedures per hospital. Using a 35% to 50% ratio of Medicare patients, the threshold value was 150 to 200 angioplasty procedures per cardiologist and 400 to 600 angioplasty procedures per institution (322).

Epstein et al., using an administrative data set, analyzed risk-adjusted mortality in 362 748 admissions to 1000 United States hospitals between 1997 and 2000 during which a PCI was performed (323). They found a consistent trend of decreasing risk-adjusted mortality with increasing hospital volume. The differences between groups were small, and there was considerable heterogeneity within groups, which indicates that hospital volume is not the sole determinant of outcome.

Other studies have also supported the relationship of complication rate to procedural volume (47,306,314). Although some investigators have suggested that low procedure volume does not contribute to poor outcomes (44,309), these studies are small in number and underpowered for analysis (318).

Progress in technique and instrumentation has reduced absolute complication rates, which makes the procedure safer and more effective. This has fueled the opinion that the volume-outcome relationship has weakened, justifying advocacy that PCI be diffused to smaller-volume institutions and lower-volume operators. Although it is possible to consider earlier studies anachronistic because of the lack of availability of coronary stents and other adjunctive therapies, studies based on data sets accumulated in the stent era continue to show a volume-outcome relationship (albeit with lower absolute event rates).

Brown evaluated the outcomes of PCI at all hospitals in California in 1997 (324). Mortality for PCI in which a stent was used was 1.5% in hospitals performing fewer than 400 procedures per year compared with 1.1% in hospitals performing more than 400 procedures per year. The rate of emergent CABG was 1.2% in hospitals performing fewer than 400 procedures per year compared with 0.8% in hospitals that performed more than 400 procedures per year.

Moscucci et al. studied the outcomes of 18 504 consecutive PCIs performed at 14 hospitals in Michigan in 2002 (325). Operator volume was divided in quintiles (1-33, 34-89, 90-139, 140-206, and 207-582 procedures per year). The primary end point was a composite of MACE including death, CABG, stroke or TIA, MI, and repeat PCI at the same site during the index hospitalization. The unadjusted MACE rate was significantly higher in quintiles 1 and 2 of operator volume than in quintile 5 (7.38% and 6.13% vs 4.15%, *P* equals 0.002 and *P* equals 0.0001, respectively). A similar trend was observed for in-hospital death. After adjustment for comorbidities, patients treated by low-volume operators had a 63% increased odds of MACE (adjusted odds ratio [OR] 1.63, 95% CI 1.29-2.06, *P* less than 0.0001 for quintile 1; adjusted OR 1.63, 95% CI 1.34-1.90, *P* less than 0.0001 for quintile 2 vs quintile 5) but not of in-hospital death. Overall, high-volume operators had better outcomes than low-volume operators in both low-risk and high-risk patients (325).

Distinction Between Elective PCI and Primary PCI for STEMI

Elective PCI and primary PCI for STEMI are different, although related, disciplines. Experience in elective PCI translates only partially to experience with primary PCI for STEMI. Throughout this guideline, a distinction is drawn between primary PCI, which is performed under emergency circumstances, and all other PCI procedures, which are included under the term "elective." The volume-outcome relationship exists for both elective procedures and primary angioplasty for STEMI (326-328) but has important differences. Available data indicate that the best results are

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obtained by operators who are highly experienced both in elective PCI and in primary PCI for STEMI who work in institutions that have established an active program for performing primary PCI for STEMI.

Operator experience in elective PCI is not sufficient to confer expertise in primary PCI for STEMI. This finding is not surprising, because there are aspects of procedure conduct that are unique to primary PCI for STEMI.

Vakili et al., analyzing primary PCI procedures for STEMI performed in New York State, found no relationship between physician total angioplasty procedure volume and mortality after primary PCI for STEMI but did find an association between an operator's primary PCI activity level and the outcome of primary PCI for STEMI that was independent of the operator's experience in elective PCI (328,329). Low-volume physicians, who performed 1 to 10 primary PCI procedures per year, had an unadjusted mortality rate of 7.1% compared with 3.8% for physicians who performed 11 or more primary PCI procedures per year.

Magid et al. analyzed the National Registry of Myocardial Infarction (NRMI) database and grouped acute-care hospitals by volume tertiles of primary PCI for STEMI procedures (327). They found a reduction in risk-adjusted mortality with increasing hospital volume of PCI: low volume (fewer than 16 procedures), 6.2%; intermediate volume (17 to 48 procedures), 4.5%; and high volume (more than 49 procedures), 3.4% (327). Canon et al. analyzed or reviewed 20 080 consecutive patients with STEMI in the NRMI-2 database (330). A multivariate model was used to show that overall adjusted mortality was lower as volume increased, with the greatest reduction in mortality occurring at hospitals performing more than 3 angioplasties per month (330). Different studies identified different cutpoints. The relationship between the studies is graded, and the individual cutpoints are artifacts of analysis methodology.

Vakili et al. found a doubling of mortality in STEMI patients who underwent PCI in hospitals that performed fewer than 400 total PCI procedures per year compared with hospitals that performed more than 400 (8.1% vs 4.3%) (329). Furthermore, they found that high-volume hospitals that performed more than 56 primary PCI procedures per year had a nonsignificant trend toward a lower crude mortality rate (4.0% vs 5.8%), with a multivariate OR for mortality of 0.53 (0.29 to 1.1). The best outcomes were achieved by high-volume physicians working in high-volume hospitals (crude mortality rate 3.7% compared with 7.1% for low-volume physicians in low-volume hospitals; adjusted relative risk 0.51, 95% CI 0.26 to 0.99).

Canto et al. (331) also found a graded relationship between hospital volume and mortality after PCI for STEMI. The highest quartile of hospital volume performed more than 33 primary PCIs for STEMI per year and achieved a 28% reduction in mortality compared with the lowest-volume hospitals.

Appropriateness of Activity Levels as a Surrogate for Quality

The documented relationships between activity level and outcome are statistical associations, and activity level is not a surrogate for quality. The heterogeneity within hospital volume groups found by Epstein et al. (323) validates that activity level is an incomplete surrogate for quality. An activity level above a threshold value does not guarantee good quality, and an activity level below a threshold value may not necessarily indicate lower quality. Thus, high-volume operators and institutions are not necessarily of uniformly high quality, and low-volume operators and institutions are not, by definition, poor.

However, an activity level below a threshold necessarily raises the question of whether an operator or institution has sufficient ongoing experience to maintain expertise and skills. In particular, it is plausible that an operator or institution that is below a threshold activity level cannot accrue the necessary ongoing experience to perform complex procedures skillfully, to acquire experience with new techniques and devices, and to respond effectively to adverse and emergency situations. The emergency response consideration is particularly relevant, because the likelihood of a serious complication cannot be predicted from patient baseline characteristics.

Quality Assessed by Outcomes: Statistical Power Considerations and the Importance of Case Reviews

The quality of both institutions and operators should ultimately be judged through the quality-assessment process as outlined in Section 4.1. Because expected adverse event rates are low, a large number of procedures are required to achieve the requisite statistical power to assign an interpretable confidence interval to an operator's or a program's adverse event rate estimate. Furthermore, adverse event rates cannot be interpreted without appropriate risk adjustment.

The first approximation in assessing an operator's or a program's quality is to compare the actual adverse event rate to an expected rate as predicted by an accepted risk-prediction model (ACC-NCDR® model or Dynamic Registry model). Calculation of an expected adverse event rate can be conducted by entering the characteristics of the group of patients treated into the model. The model yields an expected adverse event rate with confidence intervals that can then be compared with the actual event rate. Interpretation of the expected adverse event rate is complex because of the precision of the estimate. An arbitrary criterion will need to be applied to determine whether a particular actual adverse event rate is an outlier when compared with the expected event rate. For example, 50% of operators may be expected to have an adverse event rate above the expected value purely by chance. Thus, merely being above the predicted mean value does not automatically identify an operator or a program as an outlier.

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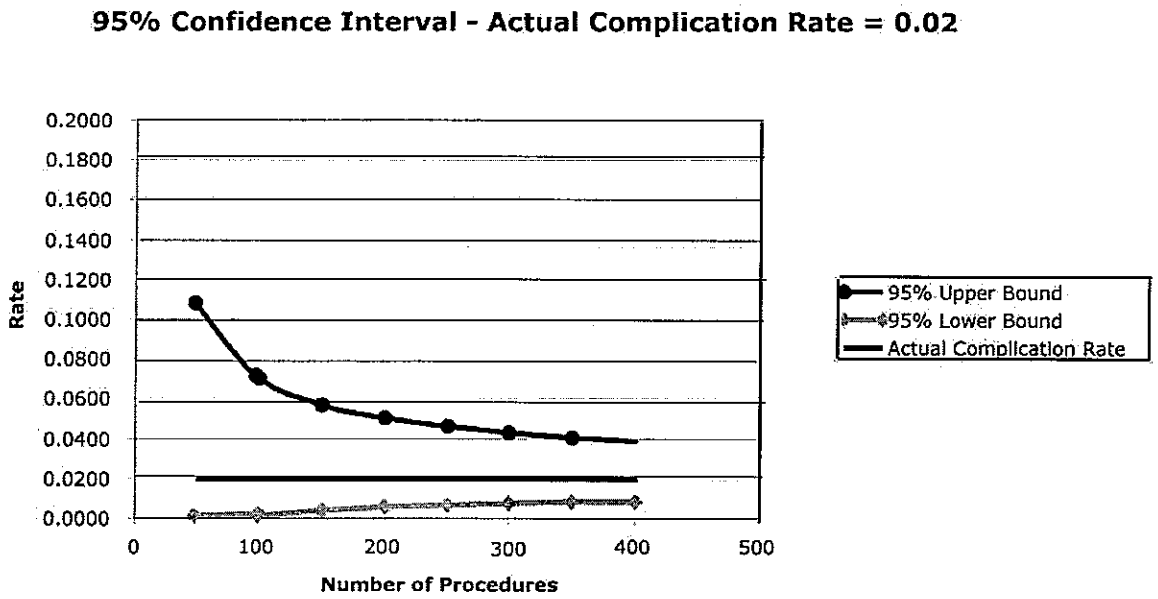

Figure 3. Plot of an actual adverse event rate of 2% over a procedure number range from 25 to 400. The horizontal line at 0.02 represents the actual adverse event rate. The curved lines above and below the horizontal line represent the upper and lower bounds of the 95% confidence interval of the estimate of the adverse event rate. Note that as the number of procedures decreases, the range between the upper and lower bounds increases, which indicates lack of stability of any adverse event rate estimate at procedure numbers below 200.

Furthermore, valid assessment of an operator's or an institution's actual adverse event rate becomes problematic if the number of procedures available for analysis is small. The statistical basis for this issue is illustrated in Figures 3 and 4.

Figure 3 plots the upper and lower 95% CI bounds of an observed adverse event rate of 2% (1 adverse event per 50 procedures) as a function of the number of procedures available for analysis. It demonstrates that if only 50 cases are available, the upper bound of the confidence interval is 10.6%. Thus, if 50 cases are performed with 1 adverse event, it is possible that the true adverse event rate is as high as 10.6%. However, it is also possible that it is as low as 0.05%. The upper-bound value decreases as the number of cases increases such that if 400 cases are available, it is only 3.9%.

If only a small number of cases are available, even if no adverse events occur, it may be difficult to exclude that an increased risk of adverse events exists. Figure 4 plots the upper bound of the 95% CI for very low numbers of cases

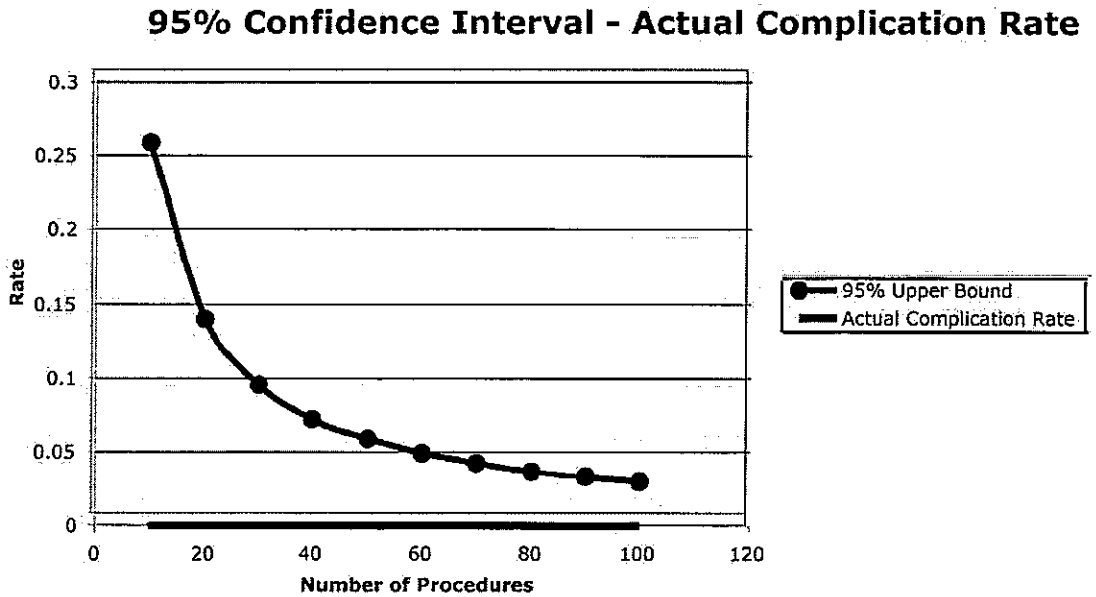

Figure 4. Plot of an actual complication rate of 0% over a procedure number range from 10 to 100. The format is similar to Figure 3. The horizontal line at 0 represents the actual complication rate. The curved line above the horizontal line represents the upper bound of the 95% confidence interval of the estimate of the complication rate. Note that if 50 procedures are performed without a complication, the upper bound of the 95% confidence interval of the estimated rate is 6%.

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performed with a zero adverse event rate. It demonstrates that if 10 consecutive cases are performed without a complication, the upper bound of the 95% CI is 25%. If 50 cases are performed without an adverse event, the upper bound is 5.8%.

Thus, although it is likely that certain low-volume operators and institutions perform procedures with acceptable quality, satisfactory quality is difficult to prove unless a sufficient number of procedures are compiled for analysis. The quality-assessment process must take the above issues into consideration. This means that it is essential that institution and operator outcomes be tracked over sufficiently long periods of time to assemble a sufficient number of procedures to permit a satisfactory analysis.

In addition, mere tabulation of adverse event rates, even with appropriate risk adjustment, is inadequate to judge operator or program quality. Such tabulations do not address numerous other quality issues, in particular, appropriateness. Thus, the quality-assessment process should also conduct detailed reviews both of cases that have adverse outcomes (to determine the cause(s) of the adverse event) and of uncomplicated cases (to judge case selection appropriateness and procedure execution quality). These reviews should be conducted by recognized experienced interventionalists drawn either from within the institution or externally if a requisite number of appropriately qualified, unconflicted individuals are not available.

Role of Low-Volume PCI Programs

There is an ongoing debate as to whether PCI services should be diffused widely to be available in most healthcare institutions or whether the service should be regionalized and concentrated in specialized high-volume centers. Given the widespread availability of sophisticated interventional/surgical programs in the United States, it is difficult to demonstrate a need for additional low-volume programs to perform elective angioplasty except in underserved areas that are geographically distant from major centers. At this writing, outcome data that link activity level to outcomes indicate that the development of small cardiovascular surgical programs to support angioplasty is a poor use of resources that will likely lead to suboptimal results (320). In general, the proliferation of small angioplasty or small surgical programs to support such angioplasty programs is not needed to improve patient access to PCI services and would appear not to be in the interest of fostering optimal quality; thus, it should be discouraged. An exception to this principle should be when geographic considerations become important determinants of patient access.

These data support the conclusion that not every cardiologist desiring to perform PCI should perform these procedures, and not every hospital that would like to have an interventional program should start one (322). This caveat is particularly true where high-volume programs and operators are already nearby.

The Writing Committee, therefore, recommends that elective PCI be performed by higher-volume operators (75 cases per year) with advanced technical skills (e.g., subspecialty certification) at institutions with fully equipped interventional laboratories and an experienced support staff. This setting is optimally a high-volume center (more than 400 cases per year) with an onsite cardiovascular surgical program (332).

It is recommended that primary PCI for STEMI be performed by higher-volume operators experienced in both elective PCI and primary PCI for STEMI with ongoing activity levels of more than 75 elective PCI procedures per year and, ideally, annual PCI for STEMI activity levels of at least 11 per year. It is clear that an effective PCI for STEMI program, irrespective of whether cardiac surgery is available onsite, requires appropriate physician operator expertise, appropriate institutional commitment, and the achievement of the requisite utilization levels. The nursing and technical catheterization laboratory staff must be experienced in handling acutely ill patients, must be skilled in all aspects of interventional equipment, and must participate in a 24-hours-per-day, 365-days-per-year call schedule. Ideally, these procedures should be performed in institutions that perform more than 400 elective PCIs per year and more than 36 primary PCIs for STEMI per year and that achieve risk-adjusted outcomes that are comparable to national benchmark standards.

The Writing Committee cannot recommend angioplasty by low-volume operators (fewer than 75 cases per year) working in low-volume institutions (200 to 400 cases per year) with or without onsite surgical coverage. As noted earlier, ongoing investigational experience and clinical data are mandatory if these recommendations are to be modified. Any change in this recommendation awaits further data assessing the safety and outcomes for patients treated in various settings.

4.3. Role of Onsite Cardiac Surgical Back-Up

Class I

1. **Elective PCI should be performed by operators with acceptable annual volume (at least 75 procedures per year) at high-volume centers (more than 400 procedures annually) that provide immediately available onsite emergency cardiac surgical services.** ***(Level of Evidence: B)***
2. **Primary PCI for patients with STEMI should be performed in facilities with onsite cardiac surgery.** ***(Level of Evidence: B)***

Class III

Elective PCI should not be performed at institutions that do not provide onsite cardiac surgery. ***(Level of Evidence: C)****

*Several centers have reported satisfactory results based on careful case selection with well-defined arrangements for immediate trans-

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fer to a surgical program (333-337,348-353). A small, but real fraction of patients undergoing elective PCI will experience a life-threatening complication that could be managed with the immediate onsite availability of cardiac surgical support but cannot be managed effectively by urgent transfer. Wennberg, et al., found higher mortality in the Medicare database for patients undergoing elective PCI in institutions without onsite cardiac surgery (356). This recommendation may be subject to revision as clinical data and experience increase.

The purpose of cardiac surgical backup for PCI is to provide emergent hemodynamic support and revascularization to salvage complications that cannot be addressed by catheter-based techniques. PCI can be complicated by life-threatening hemodynamic and ischemic emergencies that can be addressed only by the availability of emergency cardiac surgery. The role of onsite cardiac surgical backup is 2-fold: onsite cardiac surgical backup provides prompt availability of cardiac surgical support in the event of a hemodynamic or ischemic emergency, and onsite cardiac surgical backup is a surrogate for an institution's overall capability to provide a highly experienced and promptly available team to respond to a catheterization laboratory emergency.

Cardiac surgical backup for PCI has evolved from a formal surgical standby in the 1980s to an informal arrangement of first-available operating room and, in some cases, off-site surgical backup (44,333-337). With the advent of intracoronary stenting, there has been a decrease in the need for emergency CABG ranging between 0.4% and 2% (49,305,338-342). Not surprisingly, emergency CABG surgery for a patient with an occluded or dissected coronary artery is associated with a higher mortality than elective surgery (146,343-347). Emergency procedures are also associated with high rates of perioperative infarction and less frequent use of arterial conduits. Complex CAD intervention, hemodynamic instability, and prolonged time to reperfusion are contributing factors to the increased risk of emergency bypass surgery.

Technical improvements in PCI instruments and technique have led to the concept that the requirement for emergency cardiac surgery is sufficiently rare that PCI can be performed safely without onsite surgery. This has led to the development of elective angioplasty programs without onsite surgical coverage. Several centers have reported satisfactory results based on careful case selection with well-defined arrangements for immediate transfer to a surgical program (333-337,348-352). These studies of angioplasty without onsite surgical coverage have not identified significant differences in the outcomes, which recalls the infrequent rate of complications (353). Despite many reported successful angioplasty series without onsite surgical backup and a very low percentage of need for off-site surgery in failed angioplasty, some clinicians have expressed concern (354,355) about the appropriateness of elective angioplasty in centers without onsite surgical coverage.

Even with current interventional techniques, life-threatening complications requiring surgical intervention still occur. Such complications include left main coronary dissection, spiral coronary trunk dissection, and coronary perforation. Many emergency surgery patients did not receive a coronary stent, which indicates that either a stent delivery was not feasible or a stent would not solve the problem that required surgical intervention. Data from the ACC-NCDR® indicate that PCI programs staffed by highly experienced practitioners still experience a 0.4% likelihood of a patient requiring emergency cardiac surgery for a complication that developed during a procedure. Roughly half of patients who require emergency surgery are severely hemodynamically unstable at the time of transfer to the operating room. Furthermore, analyses of series of patients requiring emergency cardiac surgery indicate that patient baseline characteristics do not predict the risk of the need for emergency surgery (305,342).

It has been argued that a well-planned strategy to provide rapid transfer to a surgical center in the event of a complication is tantamount to providing onsite surgical backup support. Such strategies are unrealistic because they are logistically difficult to achieve and require that a critically ill patient be transported outside of a hospital environment, possibly without a physician in attendance. Furthermore, if an institution without cardiac surgery is sufficiently close to one that provides surgery to permit sufficiently timely transfer, there is little justification for not transferring the patient electively in the first place.

Although individual programs have reported successful results, the national experience with PCI programs at institutions that do not offer onsite cardiac surgery has been less satisfactory. Wennberg et al. (356) analyzed the Medicare database for a 2-year period from 1999 to 2001 (when stents and IIb/IIIa inhibitors were in widespread use). They identified 178 hospitals without onsite cardiac surgical facilities and 943 hospitals with onsite cardiac surgery that performed PCI during that period. After adjusting for baseline differences, they found similar mortality rates in patients who underwent primary PCI for STEMI. However, for the larger nonprimary/rescue PCI population, mortality was higher in hospitals without onsite cardiac surgery (adjusted OR 1.38; 95% CI 1.14 to 1.67; *P* equals 0.001). This increase in mortality was primarily confined to hospitals that performed 50 or fewer Medicare PCIs per year. This experience is consistent with the concept that expansion of PCI services outside of large, full-service centers creates small, low-volume programs with inadequate infrastructure that are not able to perform PCI at the same level of sophistication and quality that a larger institution can.

This Writing Committee concludes that performance of elective PCI in a setting without immediately available onsite cardiac surgery potentially compromises patient safety and is not recommended. Although the frequency of PCI complications for which the outcome is favorably affected by prompt surgery is small, it is nonetheless finite. Consequently, performance of PCI in such a setting exposes the patient to a small but very real additional and medically unnecessary risk. In addition, an institution without an established cardiac surgery program is likely to be a low-volume institution less able to offer as high quality PCI service as a larger, full-service institution. Therefore, at this time, the

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Writing Committee continues to support the recommendation that elective PCI should not be performed in facilities without onsite cardiac surgery. Mere convenience should not replace safety and efficacy in establishing an elective PCI program without onsite surgery. As with many dynamic areas in interventional cardiology, these recommendations may be subject to revision as clinical data and experience increase.

4.4. Primary PCI for STEMI Without Onsite Cardiac Surgery

Class IIb

Primary PCI for patients with STEMI might be considered in hospitals without onsite cardiac surgery, provided that appropriate planning for program development has been accomplished, including appropriately experienced physician operators (more than 75 total PCIs and, ideally, at least 11 primary PCIs per year for STEMI), an experienced catheterization team on a 24 hours per day, 7 days per week call schedule, and a well-equipped catheterization laboratory with digital imaging equipment, a full array of interventional equipment, and intra-aortic balloon pump capability, and provided that there is a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital with appropriate hemodynamic support capability for transfer. The procedure should be limited to patients with STEMI or MI with new or presumably new left bundle-branch block on ECG and should be performed in a timely fashion (goal of balloon inflation within 90 minutes of presentation) by persons skilled in the procedure (at least 75 PCIs per year) and at hospitals performing a minimum of 36 primary PCI procedures per year. ***(Level of Evidence: B)***

Class III

Primary PCI should not be performed in hospitals without onsite cardiac surgery and without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without appropriate hemodynamic support capability for transfer. ***(Level of Evidence: C)***

Fibrinolytic trials in STEMI have demonstrated that early reperfusion saves myocardium and reduces mortality (357-360). Randomized trials comparing primary PCI for STEMI have shown that primary PCI performed by a highly experienced team achieves superior results. Primary PCI, compared with fibrinolytic therapy, has achieved modest reductions in overall mortality, but its overall benefit is chiefly leveraged by a reduction in early recurrent ischemic events (361-364).

In patients who have a contraindication to fibrinolytic therapy, or when there are complications such as cardiogenic shock, catheter-based therapy may limit infarct size (365,366). Thus, the potential overall superiority and greater applicability of primary PCI for the treatment of STEMI has raised the question of whether primary PCI should be performed at institutions with diagnostic cardiac catheterization laboratories that do not perform elective PCI or have onsite cardiac surgery. For this reason, the establishment of PCI programs at institutions without onsite cardiovascular surgery has been promoted as necessary to maintain quality of care (333-335,367-376).

PCI in the early phase of a STEMI requires a cognitive knowledge base and technical skill set that is somewhat different from that required to perform elective PCI. Primary PCI for STEMI can be technically difficult and requires even more skill and experience than routine PCI in the stable patient. The linkage between experience in performing elective PCI and primary PCI is incomplete (328). A successful primary PCI program requires an experienced operator and an experienced laboratory technical staff accustomed to managing critically ill patients (377). In addition, it is necessary to have available a broad range of catheters, guidewires, stents, and other devices (e.g., IABP) that are required to achieve results in an acutely ill patient (Table 15) (368).

Observational data from large, multi-institutional data sets have demonstrated that patients with STEMI who are treated with primary PCI performed by interventionalists with limited experience at institutions with low volume experience outcomes comparable to those achieved by fibrinolytic therapy (331). Thus, the benefits of primary PCI for STEMI require the infrastructure of a well-organized program with requisite experience and capabilities. In the absence of such capabilities, either onsite fibrinolytic therapy or transfer to a center that routinely performs complex PCI will often be a more effective and efficient course of action (123). The Danish Myocardial Infarction Study (DANAMI-2) demonstrated superior results in patients with STEMI who were urgently transferred to an experienced PCI center compared with those for whom fibrinolytic therapy was administered locally. In addition, the results in patients emergently transferred for primary PCI were comparable to those achieved in patients receiving primary PCI who initially presented to the PCI center institution (378). Nonetheless, fibrinolysis remains an acceptable form of therapy (379) and is likely preferable to acute PCI by an inexperienced team (62,379).

There are important institutional considerations in creating an effective program of primary PCI for STEMI. An institution must commit its catheterization facility to be capable of a 24-hours-per-day, 7-days-per-week rapid response to a patient presenting with STEMI. In addition, the institution's catheterization facility staff must be sufficiently trained and experienced in the management of the seriously ill patient with STEMI. In general, this means that the institution best positioned to provide effective PCI for STEMI is the institution with an active high-quality elective PCI program.

It has been demonstrated that institutions without an elective PCI program that care for a large number of patients with STEMI can create high-quality programs of PCI for STEMI. These programs require the 24-hours-per-day, 7-days-per-week availability of experienced interventionalists and an institutional commitment to invest in the physical and

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Table 15. Criteria for the Performance of Primary PCI at Hospitals Without On-Site Cardiac Surgery

The operators must be experienced interventionalists who regularly perform elective PCI at a surgical center (greater than or equal to 75 cases per year). The catheterization laboratory must perform a minimum of 36 primary PCI procedures per year.
The nursing and technical catheterization laboratory staff must be experienced in handling acutely ill patients and must be comfortable with interventional equipment. They must have acquired experience in dedicated interventional laboratories at a surgical center. They participate in a 24-hours-per-day, 365-days-per-year call schedule.
The catheterization laboratory itself must be well-equipped, with optimal imaging systems, resuscitative equipment, and IABP support, and must be well-stocked with a broad array of interventional equipment.
The cardiac care unit nurses must be adept in hemodynamic monitoring and IABP management.
The hospital administration must fully support the program and enable the fulfillment of the above institutional requirements.
There must be formalized written protocols in place for immediate and efficient transfer of patients to the nearest cardiac surgical facility that are reviewed/tested on a regular (quarterly) basis.
Primary PCI must be performed routinely as the treatment of choice around the clock for a large proportion of patients with AMI, to ensure streamlined care paths and increased case volumes.
Case selection for the performance of primary PCI must be rigorous. Criteria for the types of lesions appropriate for primary PCI and for the selection for transfer for emergency aortocoronary bypass surgery are shown in Table 14.
There must be an ongoing program of outcomes analysis and formalized periodic case review.
Institutions should participate in a 3- to 6-month period of implementation, during which time development of a formalized primary PCI program is instituted that includes establishment of standards, training of staff, detailed logistic development, and creation of a quality-assessment and error-management system.

AMI indicates acute myocardial infarction; IABP, intra-aortic balloon pump; and PCI, percutaneous coronary intervention.
Adapted with permission from Wharton et al. J Am Coll Cardiol 1999;33:1257-65 (368).

cognitive resources needed to support a high-quality program. The feasibility of such an undertaking was first demonstrated by Wharton et al. in a 2-center study (368) and subsequently confirmed in multicenter studies by Aversano et al. (380) and Wharton et al. (375).

Before the use of stenting and GP receptor blockers, primary angioplasty in certain hospitals had been associated with acute mortality rates greater than those reported from centers with established primary angioplasty programs. Overall, in-hospital mortality rates have ranged from 1.4% to 13% (334,335,370).

Criteria have been suggested for the performance of primary PCI at hospitals without onsite cardiac surgery (Tables 15 and 16) (319,368,381). Of note, large-scale registries have shown an inverse relationship between the number of primary angioplasty procedures performed and in-hospital mortality (321,327,331). These data suggest that both door-to-balloon time and in-hospital mortality are significantly lower in institutions that perform more than 36 primary angioplasty procedures per year (330). It is important to point out that these data were achieved in hospitals with established elective PCI programs, and the numerical data may not extrapolate directly to hospitals that perform only primary PCI.

As an alternative to establishing numerous freestanding, modest-sized, primary PCI-only programs, a community may choose to concentrate PCI in a subset of its healthcare institutions, identifying well-qualified and experienced centers to perform this procedure. Suboptimal results may relate to operator/staff inexperience and capabilities and delays in performing angioplasty for logistical reasons (382).

From clinical data and expert consensus, the Writing Committee recommends that primary PCI for STEMI performed at hospitals without established elective PCI programs be restricted to those institutions capable of performing a requisite minimum number of primary angioplasty procedures (36 per year) by highly experienced operators after careful program development according to the procedures used by the C-PORT (Cardiovascular Patient Outcomes Research Team trial) and PAMI-No SOS (PAMI with No Surgery On Site) studies, including a proven plan for rapid and effective PCI and rapid access to cardiac surgery in a nearby facility (383). Although some experience suggests that an institution can develop an effective stand-alone primary PCI program, currently available data also indicate that concentration rather than diffusion of this capability will provide the most effective patient care. Thus, a strategy of emergency transfer to an established center with a well-developed primary PCI program is preferred to the development of new freestanding primary PCI programs.

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Table 16. Patient Selection for Primary PCI and Emergency Aortocoronary Bypass at Hospitals Without On-Site Cardiac Surgery

Avoid intervention in hemodynamically stable patients with:
Significant (greater than or equal to 60%) stenosis of an unprotected left main coronary artery upstream from an acute occlusion in the left coronary system that might be disrupted by the angioplasty catheter
Extremely long or angulated infarct-related lesions with TIMI grade 3 flow
Infarct-related lesions with TIMI grade 3 flow in stable patients with 3-vessel disease (319, 381)
Infarct-related lesions of small or secondary vessels
Hemodynamically significant lesions in other than the infarct artery
Transfer for emergency aortocoronary bypass surgery patients with:
High-grade residual left main or multivessel coronary disease and clinical or hemodynamic instability present after primary PCI of occluded vessels, preferably with IABP support.

IABP indicates intra-aortic balloon pump; PCI, percutaneous coronary intervention; and TIMI, Thrombolysis In Myocardial Infarction.

Adapted with permission from Wharton et al. J Am Coll Cardiol 1999;33:1257-65 (368).

4.5. Elective PCI Without Onsite Surgery

Class III

Elective PCI should not be performed at institutions that do not provide onsite cardiac surgery. ***(Level of Evidence: C)****

*Several centers have reported satisfactory results based on careful case selection with well-defined arrangements for immediate transfer to a surgical program (333-337,348-353). A small, but real fraction of patients undergoing elective PCI will experience a life-threatening complication that could be managed with the immediate onsite availability of cardiac surgical support but cannot be managed effectively by urgent transfer. Wennberg et al., found higher mortality in the Medicare database for patients undergoing elective PCI in institutions without onsite cardiac surgery (356). This recommendation may be subject to revision as clinical data and experience increase.

Technical improvements in interventional cardiology have led to the development of elective angioplasty programs without onsite surgical coverage. Several centers have reported satisfactory results based on careful case selection with well-defined arrangements for immediate transfer to a surgical program (333-337,348-353). The studies of angioplasty without onsite surgical coverage have not identified significant differences in outcomes, which recalls the infrequent rate of complications (353). Despite many reported successful angioplasty series without onsite surgical backup and a very low percentage need for off-site surgery in failed angioplasty, some clinicians have expressed concern (354,355) about the appropriateness of elective angioplasty in centers without onsite surgical coverage. Life-threatening complications of elective PCI are, fortunately, rare but have not been reduced to negligible levels. A small but valid fraction of patients undergoing elective PCI will experience a life-threatening complication that could be managed with the immediate onsite availability of cardiac surgical support but cannot be managed effectively by urgent transfer. Lotfi et al. reported the experience of a large, high-quality coronary interventional center (384). Of 6582 PCI procedures performed between 1996 and 2000, 45 (0.7%) required emergency cardiac surgery. Of the 45 patients, 11 (0.2%) required truly emergent surgery because they were too unstable to tolerate an interhospital transfer. Thus, under the best of circumstances 1 in 500 patients undergoing elective PCI will experience a life-threatening complication that can be salvaged by immediate access to onsite cardiac surgery. As previously noted, Section 4.4, Wennberg, et al., found higher mortality in the Medicare database for patients undergoing elective PCI in institutions without onsite cardiac surgery (356). Furthermore, the availability of onsite cardiac surgery is a surrogate for overall program size and capability, as well as for the availability of many other experienced support services.

Caution is warranted before an unrestricted policy for PCI in hospitals without appropriate facilities is endorsed. Several outstanding and critically important clinical issues, such as timely management of ischemic complications, adequacy of specialized postinterventional care, logistics for managing cardiac surgical or vascular complications and operator/laboratory volumes, and accreditation, must be addressed. Mere convenience should not replace safety and efficacy in the establishment of an elective PCI program without onsite surgery.

At this time, the Writing Committee, therefore, continues to support the recommendation that elective PCI should not be performed in facilities without onsite cardiac surgery. As with many dynamic areas in interventional cardiology, these recommendations may be subject to revision as clinical data and experience increase.

5. CLINICAL PRESENTATIONS

A broad spectrum of clinical presentations exists wherein patients may be considered candidates for PCI, ranging from asymptomatic to severely symptomatic or unstable, with variable degrees of jeopardized myocardium. In this guideline, the CCS classification system for grading angina pectoris is used to summarize the severity of angina, as shown below (Table 17) (385).

Each time a patient is considered for revascularization, the potential risk and benefits of the particular procedure under consideration must be weighed against alternative therapies (Table 18). When PCI is considered, the benefits and risks of surgical revascularization and medical therapy always deserve thoughtful discussion with the patient and family. The initial simplicity and associated low morbidity of PCI compared with surgical therapy is always attractive, but the patient and family must understand the limitations inherent in current PCI procedures, including a realistic presentation

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Table 17. Grading of Angina Pectoris According to CCS Classification

Class	Description of Stage
I	"Ordinary physical activity does not cause...angina," such as walking or climbing stairs. Angina occurs with strenuous, rapid, or prolonged exertion at work or recreation.
II	"Slight limitation of ordinary activity." Angina occurs on walking or climbing stairs rapidly; walking uphill; walking or stair climbing after meals; in cold, in wind, or under emotional stress; or only during the few hours after awaking. Angina occurs on walking more than 2 blocks on the level and climbing more than 1 flight of ordinary stairs at a normal pace and under normal conditions.
III	"Marked limitations of ordinary physical activity." Angina occurs on walking 1 to 2 blocks on the level and climbing1 flight of stairs under normal conditions and at a normal pace.
IV	"Inability to carry on any physical activity without discomfort—anginal symptoms may be present at rest."

CCS indicates Canadian Cardiovascular Society.
Adapted with permission from Campeau. Circulation 1976;54:522-3 (385).

Table 18. Provider Checklist: Key Areas for Consideration

Patients at High Risk
Assess key clinical and anatomic variables
Consider alternative therapies such as CABG in consultation with the patient
Ensure that formalized surgical standby is available
Ensure periprocedural hemodynamic support is available
Patients at Low Risk
Assess key clinical and anatomic variables
Consider alternative therapies such as medical therapy in consultation with the patient

CABG indicates coronary artery bypass graft surgery.

of the likelihood of restenosis and the potential for incomplete revascularization compared with CABG surgery. In patients with CAD who are asymptomatic or have only mild symptoms, the potential benefit of antianginal drug therapy along with an aggressive program of risk reduction must also be understood by the patient before a revascularization procedure is performed. In those clinical settings in which PCI is recommended without evidence that it will reduce cardiovascular mortality but in which it does hold a promise to reduce symptoms, a class IIa or IIb classification has been chosen, which indicates a role for patient preference.

5.1. Patients With Asymptomatic Ischemia or CCS Class I or II Angina

Class IIa

1. **PCI is reasonable in patients with asymptomatic ischemia or CCS class I or II angina and with 1 or more significant lesions in 1 or 2 coronary arteries suitable for PCI with a high likelihood of success and a low risk of morbidity and mortality. The vessels to be dilated must subtend a moderate to large area of viable myocardium or be associated with a moderate to severe degree of ischemia on noninvasive testing.** ***(Level of Evidence: B)***
2. **PCI is reasonable for patients with asymptomatic ischemia or CCS class I or II angina, and recurrent stenosis after PCI with a large area of viable myocardium or high-risk criteria on noninvasive testing.** ***(Level of Evidence: C)***
3. **Use of PCI is reasonable in patients with asymptomatic ischemia or CCS class I or II angina with significant left main CAD (greater than 50% diameter stenosis) who are candidates for revascularization but are not eligible for CABG.** ***(Level of Evidence: B)***

Class IIb

1. **The effectiveness of PCI for patients with asymptomatic ischemia or CCS class I or II angina who have 2- or 3-vessel disease with significant proximal LAD CAD who are otherwise eligible for CABG with 1 arterial conduit and who have treated diabetes or abnormal LV function is not well established.** ***(Level of Evidence: B)***
2. **PCI might be considered for patients with asymptomatic ischemia or CCS class I or II angina with nonproximal LAD CAD that subtends a moderate area of viable myocardium and demonstrates ischemia on noninvasive testing.** ***(Level of Evidence: C)***

Class III

PCI is not recommended in patients with asymptomatic ischemia or CCS class I or II angina who do not meet the criteria as listed under the class II recommendations or who have 1 or more of the following:

a. **Only a small area of viable myocardium at risk** ***(Level of Evidence: C)***
b. **No objective evidence of ischemia.** ***(Level of Evidence: C)***
c. **Lesions that have a low likelihood of successful dilatation.** ***(Level of Evidence: C)***
d. **Mild symptoms that are unlikely to be due to myocardial ischemia.** ***(Level of Evidence: C)***
e. **Factors associated with increased risk of morbidity or mortality.** ***(Level of Evidence: C)***
f. **Left main disease and eligibility for CABG.** ***(Level of Evidence: C)***
g. **Insignificant disease (less than 50% coronary stenosis).** ***(Level of Evidence: C)***

In the previous ACC/AHA guidelines for PCI, specific recommendations were made separately for patients with single-vessel or multivessel disease (1,123). The current techniques of PCI have matured to the point at which, in patients with favorable anatomy, the competent practitioner can perform either single-vessel or multivessel PCI with low risk and with a high likelihood of initial success. For this reason, in this update of the guidelines, recommendations have been made largely based on the patient's clinical condition, spe-

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cific coronary lesion morphology and anatomy, LV function, and associated medical conditions, and less emphasis has been placed on the number of lesions or vessels requiring PCI. The CCS classification of angina (I to IV) is used to define the severity of symptoms. The categories described in this section refer to an initial PCI procedure in a patient without prior CABG surgery. The randomized trials comparing PCI and medical therapy have been discussed (Table 12) (11,12,279,282-290).

The Writing Committee recognizes that the majority of patients with CCS class I or II angina should be treated medically. The published ACIP study (301) casts some doubt on the wisdom of medical management for those higher-risk patients who are asymptomatic or have mild angina but have objective evidence by both treadmill testing and ambulatory monitoring of significant myocardial ischemia and CAD. In addition, a substantial portion of the middle-aged and older-age populations in the United States remain physically active, participating in sports, such as tennis and skiing, or performing regular and vigorous physical exercise, such as jogging, have CAD. For such individuals with moderate or severe ischemia and few symptoms, revascularization with PCI or CABG surgery may reduce their risk of serious or fatal cardiac events (301). For this reason, patients in this category of higher-risk asymptomatic ischemia or mild symptoms and severe anatomic CAD are placed in class IIa or IIb recommendations. PCI may be considered if there is a high likelihood of success and a low risk of morbidity or mortality. The judgment of the experienced physician is deemed valuable in assessing the extent of ischemia.

5.2. Patients With CCS Class III Angina

Class IIa

1. **It is reasonable that PCI be performed in patients with CCS class III angina and single-vessel or multivessel CAD who are undergoing medical therapy and who have 1 or more significant lesions in 1 or more coronary arteries suitable for PCI with a high likelihood of success and low risk of morbidity or mortality.** ***(Level of Evidence: B)***
2. **It is reasonable that PCI be performed in patients with CCS class III angina with single-vessel or multivessel CAD who are undergoing medical therapy with focal saphenous vein graft lesions or multiple stenoses who are poor candidates for reoperative surgery.** ***(Level of Evidence: C)***
3. **Use of PCI is reasonable in patients with CCS class III angina with significant left main CAD (greater than 50% diameter stenosis) who are candidates for revascularization but are not eligible for CABG.** ***(Level of Evidence: B)***

Class IIb

1. **PCI may be considered in patients with CCS class III angina with single-vessel or multivessel CAD who are undergoing medical therapy and who have 1 or more lesions to be dilated with a reduced likelihood of success.** ***(Level of Evidence: B)***
2. **PCI may be considered in patients with CCS class III angina and no evidence of ischemia on noninvasive testing or who are undergoing medical therapy and have 2- or 3-vessel CAD with significant proximal LAD CAD and treated diabetes or abnormal LV function.** ***(Level of Evidence: B)***

Class III

PCI is not recommended for patients with CCS class III angina with single-vessel or multivessel CAD, no evidence of myocardial injury or ischemia on objective testing, and no trial of medical therapy, or who have 1 of the following:

a. **Only a small area of myocardium at risk.** ***(Level of Evidence: C)***
b. **All lesions or the culprit lesion to be dilated with morphology that conveys a low likelihood of success.** ***(Level of Evidence: C)***
c. **A high risk of procedure-related morbidity or mortality.** ***(Level of Evidence: C)***
d. **Insignificant disease (less than 50% coronary stenosis).** ***(Level of Evidence: C)***
e. **Significant left main CAD and candidacy for CABG.** ***(Level of Evidence: C)***

The primary benefit of PCI among patients with CCS class III angina and single-vessel or multivessel CAD resides in the relief of symptoms, which may be accomplished with medical therapy. However, many patients with moderate or severe stable angina do not respond adequately to medical therapy and often have significant coronary artery stenoses that are suitable for revascularization with CABG surgery or PCI. In addition, a proportion of these patients have reduced LV systolic function, which places them in a group that is known to have improved survival with CABG surgery and possibly with revascularization by PCI (386-389). In patients without diabetes with 1- or 2-vessel disease in whom angioplasty of 1 or more lesions has a high likelihood of initial success, PCI is the preferred approach. In a minority of such patients, CABG surgery may be preferred, particularly for those in whom the LAD can be revascularized with the IMA or in those with left main coronary disease. (See Section 3.5.1.2 on left main CAD.)

5.3. Patients With UA/NSTEMI

Class I

An early invasive PCI strategy is indicated for patients with UA/NSTEMI who have no serious comorbidity and coronary lesions amenable to PCI. Patients must have any of the following high-risk features:

a. **Recurrent ischemia despite intensive anti-ischemic therapy.** ***(Level of Evidence: A)***
b. **Elevated troponin level.** ***(Level of Evidence: A)***
c. **New ST-segment depression.** ***(Level of Evidence: A)***
d. **HF symptoms or new or worsening MR.** ***(Level of***

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Evidence: A)

e. **Depressed LV systolic function.** *(Level of Evidence: A)*
f. **Hemodynamic instability. (Level of Evidence: A)**
g. **Sustained ventricular tachycardia.** *(Level of Evidence: A)*
h. **PCI within 6 months.** *(Level of Evidence: A)*
i. **Prior CABG.** *(Level of Evidence: A)*

Class IIa

1. **It is reasonable that PCI be performed in patients with UA/NSTEMI and single-vessel or multivessel CAD who are undergoing medical therapy with focal saphenous vein graft lesions or multiple stenoses who are poor candidates for reoperative surgery.** *(Level of Evidence: C)*
2. **In the absence of high-risk features associated with UA/NSTEMI, it is reasonable to perform PCI in patients with amenable lesions and no contraindication for PCI with either an early invasive or early conservative strategy.** *(Level of Evidence: B)*
3. **Use of PCI is reasonable in patients with UA/NSTEMI with significant left main CAD (greater than 50% diameter stenosis) who are candidates for revascularization but are not eligible for CABG.** *(Level of Evidence: B)*

Class IIb

1. **In the absence of high-risk features associated with UA/NSTEMI, PCI may be considered in patients with single-vessel or multivessel CAD who are undergoing medical therapy and who have 1 or more lesions to be dilated with reduced likelihood of success.** *(Level of Evidence: B)*
2. **PCI may be considered in patients with UA/NSTEMI who are undergoing medical therapy who have 2- or 3-vessel disease, significant proximal LAD CAD, and treated diabetes or abnormal LV function.** *(Level of Evidence: B)*

Class III

In the absence of high-risk features associated with UA/NSTEMI, PCI is not recommended for patients with UA/NSTEMI who have single-vessel or multivessel CAD and no trial of medical therapy, or who have 1 or more of the following:

a. **Only a small area of myocardium at risk.** *(Level of Evidence: C)*
b. **All lesions or the culprit lesion to be dilated with morphology that conveys a low likelihood of success.** *(Level of Evidence: C)*
c. **A high risk of procedure-related morbidity or mortality.** *(Level of Evidence: C)*
d. **Insignificant disease (less than 50% coronary stenosis).** *(Level of Evidence: C)*
e. **Significant left main CAD and candidacy for CABG.** *(Level of Evidence: B)*

Clinical investigations have evaluated the use of routine catheterization and PCI for patients with UA or NSTEMI and have yielded inconsistent results. TIMI-IIIB was the first trial to compare strategies of routine catheterization and revascularization in addition to medical therapy and selective use of aggressive treatment. In TIMI-IIIB, there was no difference in the incidence of death or recurrent MI at 1 year between the 2 strategies, but patients treated by the aggressive strategy experienced less angina and repeat hospitalizations for ischemia and required fewer medications (390). In the VANQWISH trial (Veterans Affairs Non–Q-Wave Infarction Strategies in Hospital) performed by the US Veterans Administration, no difference in death or death and MI was observed between the 2 strategies at late follow-up, but the minority of patients in the aggressive strategy received revascularization, and the mortality rate for those having CABG was high (391). The FRISC II trial compared medical and revascularization approaches among patients after 6 days of low-molecular-weight heparin therapy before a decision regarding PCI (304). Those randomized to the conservative therapy only underwent PCI if they had at least 3 mm of ST-segment depression on stress testing. Compared with prior studies, patients assigned to the aggressive strategy in FRISC II experienced a 22% reduction (*P* equals 0.031) in the incidence of death or MI at 6 months (9.4%) compared with conservatively treated patients (12.1%). In addition, there was a significant decrease in the MI rate alone and a nonsignificantly lower mortality rate in the treated group (1.9% vs 2.9%; *P* equals 0.10). Symptoms of angina and hospital readmission were decreased 50% by the invasive strategy. These findings were supported by long-term follow-up from the FRISC II study that indicated that low-molecular-weight heparin and early intervention lowered the risk of death, MI, and revascularization in unstable coronary syndromes, at least during the first month of therapy. Early protective therapy could be used to reduce the risk of late events in patients waiting for definitive PCI (392). This treatment benefit was most pronounced for high-risk patients. The FRISC II trial (304) results support the use of catheterization and revascularization for selected patients with an acute coronary syndrome. The TACTICS trial randomized 2220 patients to an early invasive strategy in which cardiac catheterization and revascularization were performed 4 to 48 h after randomization or to a conservative strategy in which revascularization was reserved for those patients who developed recurrent ischemia after medical stabilization (393). All patients were treated with aspirin, heparin, beta-blockers, cholesterol-lowering therapy, and tirofiban. The primary end point, a composite of death, MI, and rehospitalization for worsening chest pain by 6 months, was lower in patients assigned to the invasive strategy (15.9% vs 19.4% in patients assigned to conservative therapy; *P* equals 0.0025). The rate of death or MI was also significantly reduced at 6 months in the invasive strategy arm (7.3% vs 9.5% in patients assigned

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to conservative therapy; *P* less than 0.05) (393). The TIMI-TACTICS group (394) has proposed a new risk stratification. The early invasive strategy was particularly effective for patients at moderate to high risk. The greater benefits derived from PCI in the TACTICS and FRISC trials compared with the TIMI III and VANQWISH trials can be explained in part by the use of stents and GP-receptor blockers and lower periprocedural complications in the TACTICS and FRISC II trials. In several studies published to date, the use of routine invasive therapy in patients with UA/NSTEMI, accompanied by IIb/IIIa receptor antagonists, has been shown to improve survival (205,302,393,395-397). New trials such as RITA-3 (302) further demonstrate the safety and effectiveness of an early invasive strategy.

It is recognized by the Committee that the assessment of risk of unsuccessful PCI or serious morbidity or mortality must always be made with consideration of the alternative therapies available for the patient, including more intensive or prolonged medical therapy or surgical revascularization (Table 19) (302,304,390,391,393), especially in patients with UA/NSTEMI.

When CABG surgery is a poor option because of high risk due to special considerations or other organ system disease, patients otherwise in class IIb may be appropriately managed with PCI. Under these special circumstances, formal surgical consultation is recommended.

5.4. Patients With STEMI

5.4.1. General and Specific Considerations

Class I

General considerations:

1. **If immediately available, primary PCI should be performed in patients with STEMI (including true posterior MI) or MI with new or presumably new left bundle-branch block who can undergo PCI of the infarct artery within 12 hours of symptom onset, if performed in a timely fashion (balloon inflation goal within 90 minutes of presentation) by persons skilled in the procedure (individuals who perform more than 75 PCI procedures per year, ideally at least 11 PCIs per year for STEMI). The procedure should be supported by experienced personnel in an appropriate laboratory environment (one that performs more than 200 PCI procedures per year, of which at least 36 are primary PCI for STEMI, and that has cardiac surgery capability). *(Level of Evidence: A)* Primary PCI should be performed as quickly as possible, with a goal of a medical contact-to-balloon or door-to-balloon time within 90 minutes. *(Level of Evidence: B)***

Specific Considerations:

2. **Primary PCI should be performed for patients less than 75 years old with ST elevation or presumably new left bundle-branch block who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock, unless further support is futile because of the patient's wishes or contraindications/unsuitability for further invasive care. *(Level of Evidence: A)***
3. **Primary PCI should be performed in patients with severe congestive heart failure and/or pulmonary edema (Killip class 3) and onset of symptoms within 12 hours. The medical contact-to-balloon or door-to-balloon time should be as short as possible (i.e., goal within 90 minutes). *(Level of Evidence: B)***

Class IIa

1. **Primary PCI is reasonable for selected patients 75 years or older with ST elevation or left bundle-branch block or who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock. Patients with good prior functional status who are suitable for revascularization and agree to invasive care may be selected for such an invasive strategy. *(Level of Evidence: B)***
2. **It is reasonable to perform primary PCI for patients with onset of symptoms within the prior 12 to 24 hours and 1 or more of the following:**
   a. **Severe congestive heart failure *(Level of Evidence: C)***
   b. **Hemodynamic or electrical instability *(Level of Evidence: C)***
   c. **Evidence of persistent ischemia *(Level of Evidence: C)***

Class IIb

The benefit of primary PCI for STEMI patients eligible for fibrinolysis when performed by an operator who performs fewer than 75 PCI procedures per year (or fewer than 11 PCIs for STEMI per year) is not well established. *(Level of Evidence: C)*

Class III

1. **Elective PCI should not be performed in a non-infarct-related artery at the time of primary PCI of the infarct related artery in patients without hemodynamic compromise. *(Level of Evidence: C)***
2. **Primary PCI should not be performed in asymptomatic patients more than 12 hours after onset of STEMI who are hemodynamically and electrically stable. *(Level of Evidence: C)***

Acute STEMI results from a severe and sudden cessation of myocardial blood flow, most commonly due to atherosclerotic-thrombotic occlusion of a major epicardial coronary artery. PCI is a very effective method for re-establishing coronary perfusion and is suitable for 90% of patients. Considerable data support the use of PCI for patients with STEMI (53,364,398). Reported rates of achieving TIMI 3 flow, the goal of reperfusion therapy, range from 70% to 90% (399). Late follow-up angiography demonstrates that 87% of infarct arteries remain patent (400). Although most studies of primary PCI have been in patients who are eligible to receive fibrinolytic therapy, considerable experience supports the

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Table 19. Invasive Versus Conservative Strategies in Unstable Angina Patients

Study	Years	Ref	n	Patient Population	Treatment	Follow-Up	Results			Comments
							PCI	Medical Therapy	P	
TIMI-IIIB	1989-1992	(390)	1473	Patients 21 to 76 years of age presenting within 24 h of ischemic discomfort at rest consistent with unstable angina or non–Q-wave MI	Medical therapy (tPA vs placebo) and early invasive or conservative strategy	6 wk	16.2% combined primary end points	18.1% combined primary end points	NS	Although no difference was found in combined primary end points (death, MI, positive ETT), the early invasive strategy was associated with shorter hospital stay and lower incidence of rehospitalization
						1 y	12.4 %	10.6%		
VANQWISH	1993-1996	(391)	920	Patients with an evolving MI	Invasive vs conservative	Average 23 mo	32.9% death and MI	30.3% death and MI	0.35	Fewer patients treated conservatively had death plus MI or death at hospital discharge at 1 month and at 1 year; the invasive group had a higher CABG mortality rate (11.6% vs 3.4%)
FRISC II	1996-1998	(304)	2457	Patient's ischemic symptoms in previous 48 hours accompanied by ECG changes or elevated markers	Early invasive therapy or noninvasive treatment strategy. Patients also received dalteparin or placebo for 3 months	6 mo	9.4% death or MI	12.1% death or MI	0.031	Invasive strategy was associated with 50% lower recurrent angina and hospital readmission rates
TACTICS-TIMI 18	1997-1999	(393)	2220	UA and NSTEMI with ECG changes, elevated levels of cardiac biomarkers, a history of CAD, or all 3 findings	Medical therapy (aspirin, heparin, tirofiban) and either early invasive or conservative (selectively invasive) treatment strategy	6 mo	7.3% death or MI	9.5% death or MI	Less than 0.05	Significant 22% relative risk reduction in composite end point of death, nonfatal MI, and rehospitalization
RITA-3	1997-2001	(302)	1810	Suspected cardiac chest pain at rest with documented evidence of CAD (at least 1 of the following: ECG changes, pathological Q waves, previous arteriogram)	Medical therapy and either early invasive or conservative (selectively invasive) treatment strategy; both groups received enoxaparin in addition to standard medical therapy	1 y	7.6% death or MI	8.3% death or MI	NS	Similar results for death or MI between treatment groups; significant difference in primary end point (death, MI, refractory angina) due to halving of refractory angina in the intervention group

CABG indicates coronary artery bypass graft surgery; CAD, coronary artery disease; ECG, electrocardiography; ETT, exercise treadmill test; MI, myocardial infarction; mo, month; n, number; NS, not significant; NSTEMI, non–ST-elevation myocardial infarction; PCI, percutaneous coronary intervention; Ref, reference; tPA, alteplase; UA, unstable angina; wk, week; and y, year.

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value of PCI for patients who may not be suitable for fibrinolytic therapy owing to an increased risk of bleeding (401).

Primary PCI has been compared with fibrinolytic therapy in 23 randomized clinical trials (361-363,378,380,381,402-415), including the SHOCK (SHould we emergently revascularize Occluded Coronaries in cardiogenic shocK?) trial (366). The recommendations for primary PCI in patients with cardiogenic shock are discussed and summarized separately in Section 5.4.6. These investigations consistently demonstrate that PCI-treated patients experience lower short-term mortality rates (7.0% vs 9.0%, relative risk 0.73, 96% CI 0.62 to 0.86, *P* equals 0.0002, and 5.0% vs 7.0%, relative risk 0.70, 95% CI 0.58 to 0.85, *P* equals 0.003 excluding the SHOCK trial), fewer nonfatal reinfarctions (3.0% vs 7.0%, relative risk 0.35, 95% CI 0.27 to 0.45, *P* equals 0.0003), and fewer hemorrhagic strokes (0.05% vs 1.0%, relative risk 0.05, 95% CI 0.006 to 0.35, *P* equals 0.0001) than those treated by fibrinolysis (53), albeit with an increased risk of bleeding (7.0% vs 5.0%, RR 1.3, 95% CI 1.02 to 1.65, *P* equals 0.032). These results have been achieved in medical centers and by providers experienced in the performance of primary PCI and under circumstances in which angioplasty can be performed promptly after patient presentation. The magnitude of the treatment differences for death, nonfatal reinfarction, and stroke vary depending on whether PCI is compared with streptokinase or a fibrin-specific lytic. The short- and long-term outcomes of patients with STEMI treated by fibrinolysis versus PCI and the numbers of patients who need to be treated to prevent 1 event or to cause a harmful complication when PCI is selected instead of fibrinolysis as the reperfusion strategy are shown in Figure 5 (53,416,417).

Time from symptom onset to reperfusion is an important predictor of patient outcome. Two studies (330,418) have reported increasing mortality rates with increasing door-to-balloon times. Other studies have shown better LV function and fewer complications when reperfusion occurs before PCI (419,420). An analysis of the randomized controlled trials comparing fibrinolysis with primary PCI suggests that the mortality benefit with PCI exists when treatment is delayed by no more than 60 min (Figure 6) (421). Mortality increases significantly with each 15-minute delay in the time between arrival and restoration of TIMI-3 flow (door-to–TIMI-3 flow time), which further underscores the importance of timely reperfusion in patients who undergo primary PCI (422). Given that the door-to-needle time goal is 30 min, this Writing Committee joins the Task Force on the Management of Acute Myocardial Infarction of the European Society of Cardiology (423) and the ACC/AHA STEMI Guidelines Writing Committee (332) in lowering the door-to-balloon time goal from 120 to 90 min in an attempt to maximize the benefits for reperfusion by PCI (Figure 7) (418). Importantly, after adjustment for baseline characteristics, time from symptom onset to balloon inflation is significantly correlated with 1-year mortality in patients undergoing primary PCI for STEMI (relative risk equals 1.08 for each 30-minute delay from symptom onset to balloon inflation, *P* equals 0.04) (424).

The enthusiasm for primary PCI has led to the concept of emergency interhospital transfer for catheter-based reperfusion rather than fibrinolytic therapy in the initial hospital (425-427). Five randomized trials have enrolled 2466 patients with favorable results for PCI versus fibrinolytic therapy (378,381,407,412). Mortality was reduced with PCI (6.8% vs 9.6%, relative risk 0.69, 95% CI 0.51 to 0.0.92, *P* equals 0.01), as was the combined end point of death, nonfatal reinfarction, and stroke (8.5% vs 15.5%, relative risk 0.51, 95% CI 0.39 to 0.65, *P* less than 0.0001). Importantly, mean time to treatment was delayed only 44 min in these studies (Figure 8) (378,415). In contrast, first hospital door-to-balloon time, as recorded in 1346 patients undergoing hospital transfer before PCI in NRMI-4, was 185 min in the United States in 2002 (Figure 9) (428). Emergency transport in Europe is centrally organized and more efficient than in the United States (Table 20) (378,381,407,412,415). Delays in door-to-balloon time versus door-to-needle time of more than 60 min because of interhospital transfer might negate the potential mortality benefit of transfer for primary PCI over immediate intravenous fibrinolysis demonstrated in these trials (421). However, transfer of patients to PCI-capable centers should be accomplished when fibrinolytic therapy is contraindicated or unsuccessful, when cardiogenic shock ensues, when the anticipated delay is less than 60 min, or when symptoms have been present for more than 2 to 3 h (410,415). To achieve optimal results, a systems approach for rapid triage and transfer must be established. Time from first hospital door to balloon inflation in the second hospital should be as short as possible, with a goal within 90 min. Significant reductions in door-to-balloon times might be achieved by transporting patients directly to PCI centers, rather than transporting them to the nearest hospital, if interhospital transfer will subsequently be required to obtain primary PCI. Central to the success of all of the acute reperfusion strategies is a well-developed process of triage, as discussed in the STEMI guidelines (332,429).

Primary PCI with stenting has been compared with fibrinolytic therapy in 12 randomized clinical trials (366,378,380,381,407-412,415,430). These investigations demonstrate that PCI-treated patients experience lower mortality rates (5.9% vs 7.7%, OR 0.75, 95% CI 0.60 to 0.94, *P* equals 0.013), fewer reinfarctions (1.6% vs 5.1%, OR 0.31, 95% CI 0.21 to 0.44, *P* equals 0.0001), and fewer hemorrhagic strokes than those treated by fibrinolysis (53). Compared with PTCA, intracoronary stents achieve a better immediate angiographic result with a larger arterial lumen, less reclosure of the infarct-related artery, and fewer subsequent ischemic events (431-433). Primary stenting has been compared with primary angioplasty in 9 studies (64,106,433-440) (Table 21). There were no differences in mortality (3.0% vs 2.8%) or reinfarction (1.8% vs 2.1%) rates. However, subsequent target-vessel revascularization rates were lower with stenting (440).

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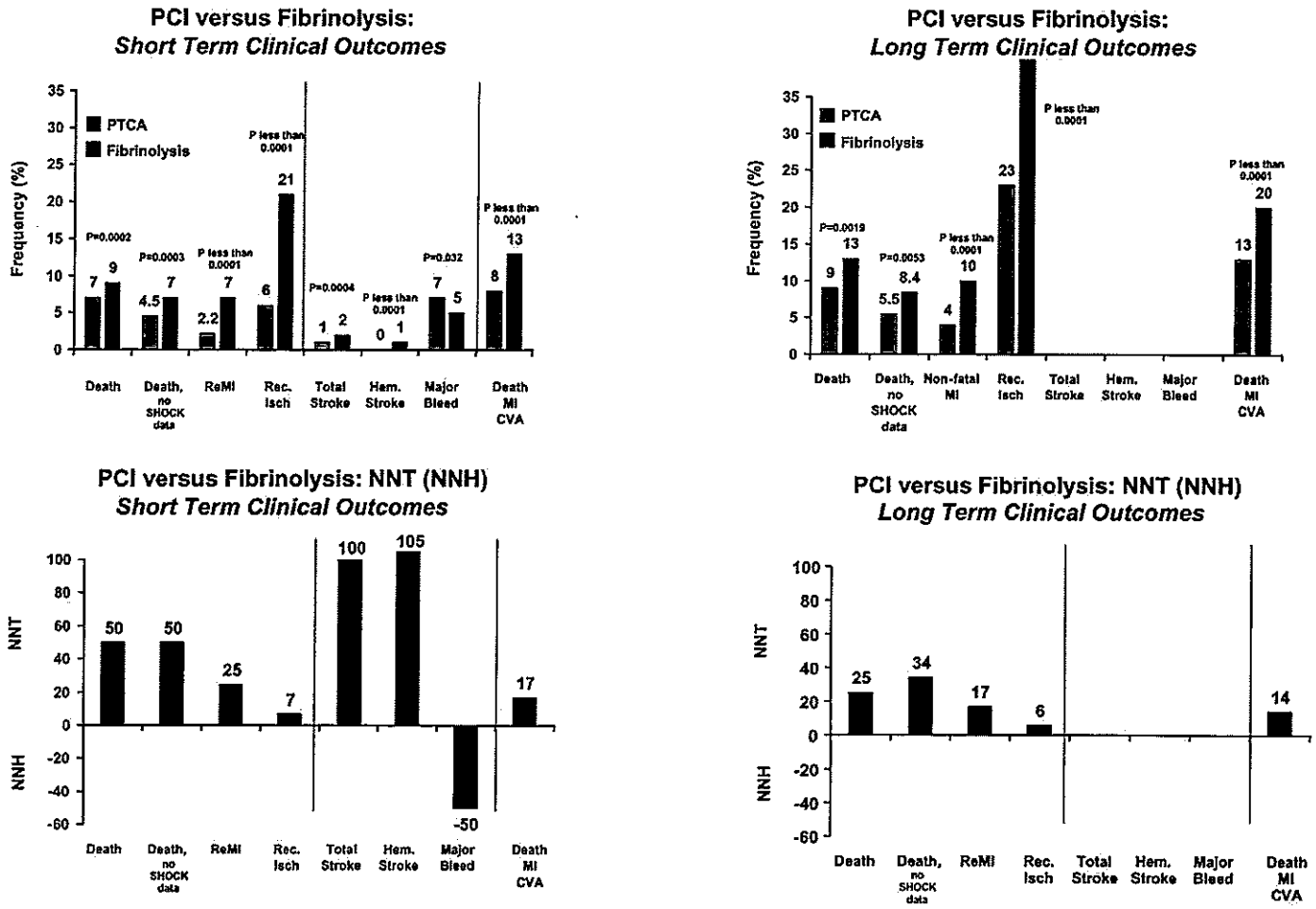

Figure 5. Percutaneous coronary intervention vs fibrinolysis for STEMI. The short-term (4 to 6 weeks; top left) and long-term (top right) outcomes for the various end points shown are plotted for STEMI patients randomized to PCI or fibrinolysis for reperfusion in 23 trials (n=7739). Based on the frequency of events for each end point in the 2 treatment groups, the number needed to treat (NNT) or number needed to harm (NNH) is shown for the short-term (bottom left) and long-term (bottom right) outcomes. Modified with permission from Elsevier (Keeley et al. The Lancet, 2003, 361, 13-20). Note: The magnitude of the treatment differences for death, nonfatal reinfarction, and stroke vary depending on whether PCI is compared with streptokinase or a fibrin-specific lytic. For example, when primary PCI is compared with alteplase (tPA) and the SHOCK trial is excluded, the mortality rate is 5.5% vs 6.7% (OR 0.81, 95% CI 0.64 to 1.03, *P* equals 0.081). Source: Melandri. Circulation 2003;108:e162. CVA indicates cerebrovascular accident; Hem. Stroke, hemorrhagic stroke; MI, myocardial infarction; PCI, percutaneous coronary intervention; PTCA, percutaneous transluminal coronary angioplasty; Rec. Isch, recurrent ischemia; ReMI, recurrent MI; and STEMI, ST-elevation myocardial infarction.

Preliminary reports suggest that compared with conventional BMS, DES are not associated with increased risk when used for primary PCI in patients with STEMI. Postprocedure vessel patency, biomarker release, and the incidence of short-term adverse events were similar in patients receiving SES or BMS. Thirty-day event rates of death, reinfarction, or revascularization were 7.5% versus 10.4%, respectively (*P* equals 0.4) (441).

Furthermore, the impact of IIb/IIIa platelet receptor antagonists in the setting of primary PCI has undergone considerable evaluation. In a randomized trial of stents plus abciximab compared with fibrinolysis plus abciximab in patients with STEMI, myocardial salvage and salvage index measured by technetium-99m sestamibi scintigraphy was significantly greater in the stent group (430). In a similar study comparing primary PCI with stent plus abciximab to fibrinolysis with alteplase, infarct size was smaller and the cumulative incidence of death, reinfarction, or stroke at 6 months significantly lower in the primary PCI group (411).

However, results of studies comparing primary PCI with stents with or without IIb/IIIa platelet receptor antagonists have been less consistent. In the CADILLAC trial, a composite of death, reinfarction, disabling stroke, and ischemia-driven target-vessel revascularization was similar in patients treated with stents with or without abciximab (64). Yet, in a similar randomized comparison of stent plus abciximab versus stent alone in patients with STEMI (ADMIRAL trial; Abciximab before Direct angioplasty and stenting in Myocardial Infarction Regarding Acute and Long-term follow-up), a composite of death, reinfarction, or urgent target-

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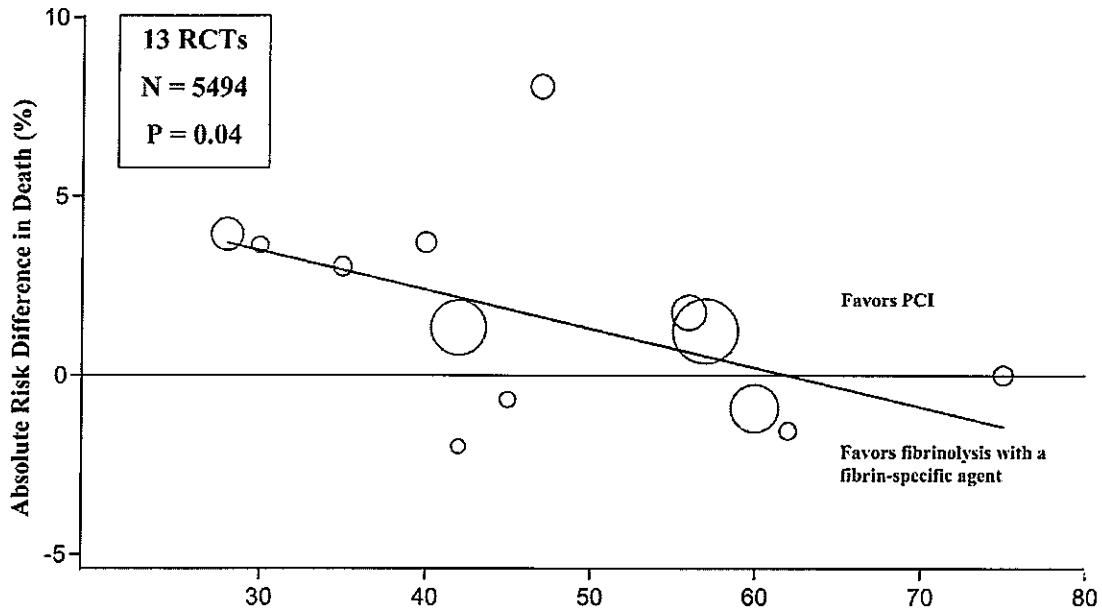

Figure 6. PCI versus fibrinolysis with fibrin-specific agents: is timing (almost) everything? PCI indicates percutaneous coronary intervention. Modified with permission from Nallamothu and Bates. Am J Cardiol 2003;92:824-6 (421).

vessel revascularization at 30 days occurred significantly less often in the abciximab group than in the control group (6.0% vs 14.6%, *P* equals 0.01), a difference that was sustained at 6 months of follow-up (442). The less favorable comparable clinical outcomes in patients treated with abciximab in the CADILLAC trial compared with those in the ADMIRAL trial have been attributed to the earlier administration of abciximab in the latter trial. The results of a pooled analysis of these 2 trials plus 3 similar trials (RAPPORT, ISAR-2, and ACE) (443-445) suggest that early (before coronary angiography) administration of abciximab will be associated with the most favorable clinical outcomes (446).

PCI appears to have its greatest mortality benefit in high-risk patients. In patients with cardiogenic shock, an absolute 9% reduction in 30-day mortality with mechanical revascularization instead of immediate medical stabilization was reported in the SHOCK trial (366) (see Section 5.4.6, PCI for Cardiogenic Shock). In NRMI-II, patients with HF had a

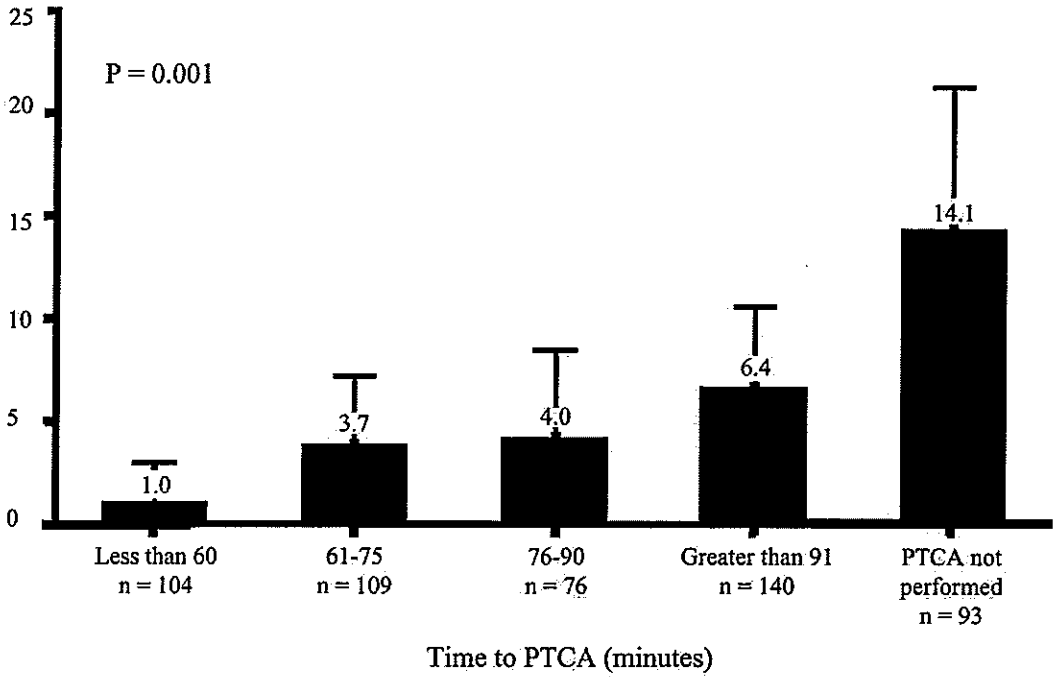

Figure 7. Relationship between 30-day mortality and time from study enrollment to first balloon inflation. Patients assigned to angioplasty in whom angioplasty was not performed are also shown. n indicates number of patients; and PTCA, percutaneous transluminal coronary angioplasty. Reprinted with permission from Berger et al. Circulation 1999;100:14-20 (418).

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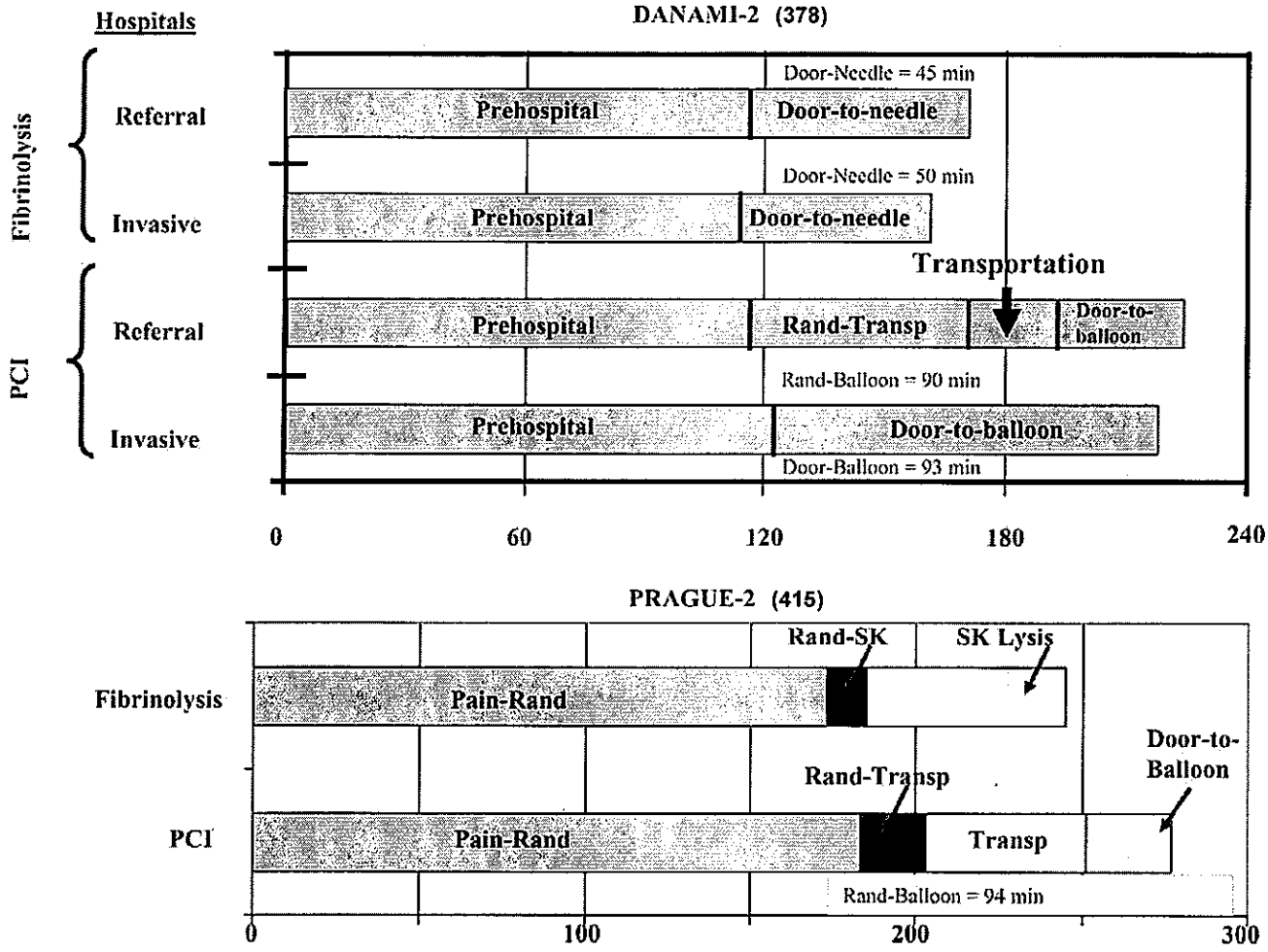

Figure 8. Comparison of elapsed time to fibrinolysis versus primary PCI. Time is presented as a continuous variable in minutes on the horizontal axis. For DANAMI-2, times reflect components of delay from symptom onset to randomization (vertical bar) and are further separated according to whether patients presented at community referral hospitals or those equipped for primary PCI. For those patients randomized to PCI at a referral hospital, the 3 components of delay after randomization are related to duration of stay at referral hospital, time for transport to PCI hospital, and delay from arrival at PCI hospital to balloon inflation. Lysis indicates fibrinolysis; PCI, percutaneous coronary intervention; Rand, randomization; SK, streptokinase; and Transp, transportation. Top graph reprinted with permission from Anderson et al. N Engl J Med 2003;349:733-42 (378). Copyright 2003 Massachusetts Medical Society. All rights reserved. Bottom graph reprinted from Widimsky et al. Eur Heart J 2003;24:94-104 (415) with permission from the European Society of Cardiology.

33% relative risk reduction with primary PCI compared with a 9% relative risk reduction with fibrinolytic therapy (447-449). Primary PCI in patients with anterior STEMI reduces mortality compared with fibrinolytic therapy, but there is no difference in patients with nonanterior STEMI (450,451).

Despite the evidence supporting primary PCI in the treatment of STEMI, there is serious concern that a routine policy of primary PCI for patients with STEMI will result in unacceptable delays in achieving reperfusion in a substantial number of patients and less than optimal outcomes if performed by less experienced operators. The mean time delay for PCI instead of fibrinolysis in the randomized trials was only 40 min (364). Strict performance criteria must be mandated for primary angioplasty programs so that excessive delays in reperfusion and performance by low-volume or poor-outcome operators/centers do not occur. The physicians, nursing, and technical catheterization laboratory staff must be experienced in handling acutely ill patients, must be skilled in all aspects of interventional equipment and procedures, and must participate in a 24-hours-per-day, 365-days-per-year call schedule. Interventional cardiologists and centers should strive for 1) balloon dilation within 90 min of admission and diagnosis of STEMI (452); 2) TIMI 2 to 3 flow attained in more than 90% of patients; 3) emergency CABG rate less than 2% among all patients undergoing the procedure; 4) actual performance of PCI in 85% of patients brought to the laboratory; and 5) a risk-adjusted in-hospital mortality rate less than 7% in patients without cardiogenic

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1st Door to Data: 9 min. (4-16 min.)

Data (Transport) to Cath Lab Arrival: 132 min. (88-219 min.)

Cath Lab to Balloon: 37 min. (28-50 min.)



Total Door 1 to Balloon Time: 185 minutes (137-276 minutes)
Percent of Patients with Door to Balloon Time Less Than 90 Minutes: 3.0%

Sample Size: 1,346; Time Period: January 2002 – December 2002

Figure 9. Door-to-balloon times: patients transferred in NRMI 4. Data are expressed in minutes as median time (25th percentile to 75th percentile). Cath Lab indicates catheterization laboratory. Modified, with permission, from NRMI-4 Investigators: The National Registry of Myocardial Infarction-4 Quarterly Report. Genentech, South San Francisco, Calif; March, 2003:2 (428).

shock. Otherwise, the focus of treatment should be the early use of fibrinolytic therapy, with further referral to PCI when indicated.

5.4.2. PCI in Fibrinolytic-Ineligible Patients

Class I

Primary PCI should be performed in fibrinolytic-ineligible patients who present with STEMI within 12 hours of symptom onset. ***(Level of Evidence: C)***

Class IIa

It is reasonable to perform primary PCI for fibrinolytic-ineligible patients with onset of symptoms within the prior 12 to 24 hours and 1 or more of the following:

a. **Severe congestive heart failure.** ***(Level of Evidence: C)***
b. **Hemodynamic or electrical instability.** ***(Level of Evidence: C)***
c. **Evidence of persistent ischemia.** ***(Level of Evidence: C)***

Randomized, controlled clinical trials evaluating the outcome of PCI for patients who present with STEMI but who are ineligible for fibrinolytic therapy have not been performed. Nevertheless, these patients are at increased risk for mortality (453), and there is a general consensus that PCI is an appropriate means for achieving reperfusion in those who cannot receive fibrinolytic drugs because of an increased risk of bleeding (401,454-456). Other reasons also exclude STEMI patients from fibrinolytic therapy, and the outcome of PCI in these patients may differ from those eligible for fibrinolytic therapy. Few data are available to characterize the value of primary PCI for this subset of STEMI patients (Table 22) (332,401).

Table 20. Transport of Patients With STEMI for Primary PCI

Study (Reference)	Number Transported	Distance, km	Time Between Randomization and First Balloon Inflation, min
Vermeer et al. (412)	75	25 to 50	85*
PRAGUE-1 (407)	101	5 to 74	80*
AIR-PAMI (381)	71	52*	155†
PRAGUE-2 (415)	429	5 to 120	97*
DANAMI-2 (378)	567	3 to 150	90†
Total	1243	3 to 150	

min indicates minutes; km, kilometer; PCI, percutaneous coronary intervention; and STEMI, ST-elevation myocardial infarction.
*Mean.
†Median.

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Table 21. Studies Comparing PTCA with Stents in Acute Myocardial Infarction

Study	Year	Follow-Up (mo)	n, Stent/PTCA	Success (%)	Early Events (0-30 days), %					Late Events (Cumulative) %				
					Crossover	Death	Reinfarction	TVR	Any Event	Restenosis	Death	Reinfarction	TVR	Any Event
FRESCO (434)	1998	6	75/75	99*	NA	0/0	1.3/2.6	1.3/12	3/15	17/43	1/0	1/3	7/25	13/32
GRAMI (438)	1998	12	52/52	98/94.2	25*	3.8/7.6	0/7.6	0/5.7	3.8/19.2	NA	NA	NA	14/21	17/35
Surrapranata et al. (439)	2001	4	112/115	98/96	2/13	2/3	1/4	NA	NA	NA	3/3	1/9	13/34	16/38
PASTA (436)	1999	12	67/69	99/97	1/10	3/7	3/4	6/13	6/19	17/37.5	5/9	NA	NA	22/49
Stent-PAMI (433)	1999	6	452/448	89.4/92.7	1.5/15	3.5/1.8	0.4/1.1	1.8/3.8	4.6/5.8	20.3/33.5	4.2/2.7	2.4/2.2	7.7/1.7	12.6/20.1
STENTIM-2 (435)	2000	12	101/110	95/94.5	3/36.4	1/0	4/3.6	5/5.4	5/5.4	25.3/39.6	3/1.9	4.0/5.5	17.8/28.2	12.9/20.0
PSAAMI (437)	2001	710 plus or minus 282 days	44/44	NA	1/27	2/5	0/2	0/9	5/11	24/61	9/18	2/9	16/34	23/43
CADILLACa (64)	2002	6	512/518	94.5/94.7	16†	2.2/2.5	1.0/0.8	3.2/5.6	5.7/8.3	22.2/40.8§	3.0/4.5	1.6/1.8	8.3/15.7	11.5/20.0
CADILLACb (64)	2002	6	524/528	96.9/96.1	14‡	2.7/1.1	0.8/0.8	1.6/3.4	4.4/4.8	NA	4.2/2.5	2.2/2.7	5.2/13.8	10.2/16.5

n indicates number of patients; NA, data not gathered for that category; and TVR, target-vessel revascularization. All data are presented as values for stent/PTCA groups.
CADILLACa = Stent alone and PTCA alone arms.
CADILLACb = Stent plus abciximab and PTCA plus abciximab arms.
*Success rate of 99% before randomization.
†Values for crossovers from PTCA to stent treatment.
‡Values for crossovers from PTCA or stenting alone to combination with abciximab treatment.
§7-month follow-up; n = 636; independent of abciximab use.
Modified from Al SJ et al. JAMA 2000;284:1828-36 (106).

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Table 22. Contraindications and Cautions for Fibrinolysis in STEMI*

Absolute contraindications
Any prior intracranial hemorrhage
Known structural cerebral vascular lesion (e.g., AVM)
Known malignant intracranial neoplasm (primary or metastatic)
Ischemic stroke within 3 months, EXCEPT acute ischemic stroke within 3 hours
Suspected aortic dissection
Active bleeding or bleeding diathesis (excluding menses)
Significant closed head or facial trauma within 3 months
Relative contraindications
History of chronic severe, poorly controlled hypertension
Severe uncontrolled hypertension on presentation (SBP greater than 180 mm Hg or DBP greater than 110 mm Hg)†
History of prior ischemic stroke greater than 3 months, dementia, or known intracranial pathology not covered in contraindications
Traumatic or prolonged (greater than 10 minutes) CPR or major surgery (less than 3 weeks)
Recent (within 2 to 4 weeks) internal bleeding
Noncompressible vascular punctures
For streptokinase/anistreplase: prior exposure (more than 5 days ago) or prior allergic reaction to these agents
Pregnancy
Active peptic ulcer
Current use of anticoagulants: the higher the INR, the higher the risk of bleeding

AVM indicates arteriovenous malformation; CPR, cardiopulmonary resuscitation; DBP, diastolic blood pressure; INR, international normalized ratio; SBP, systolic blood pressure; and STEMI, ST-elevation myocardial infarction.

*Viewed as advisory for clinical decision making and may not be all inclusive or definitive.

†Could be an absolute contraindication in low-risk patients with STEMI (see Section 6.3.1.6.3.2 in the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction, available at: http://www.acc.org/clinical/guidelines/stemi/index.pdf).

Reprinted from Antman et al. J Am Coll Cardiol 2004;44:e1-e211 (332).

5.4.3. Facilitated PCI

Class IIb

Facilitated PCI might be performed as a reperfusion strategy in higher-risk patients when PCI is not immediately available and bleeding risk is low. ***(Level of Evidence: B)***

Facilitated PCI refers to a strategy of planned immediate PCI after an initial pharmacological regimen such as a full-dose fibrinolytic, a half-dose fibrinolytic, a GP IIb/IIIa inhibitor, or a combination of reduced-dose fibrinolytic therapy and a platelet GP IIb/IIIa inhibitor. Facilitated PCI should be differentiated from primary PCI without fibrinolysis; from primary PCI with a GP IIb/IIIa inhibitor started at the time of PCI; from immediate, early, or delayed PCI after successful full-dose fibrinolysis; and from rescue PCI after unsuccessful fibrinolysis. Potential advantages include earlier time to reperfusion, improved patient stability, greater procedure success rates, higher TIMI flow rates, and improved survival rates (419,420,442,457-460). However, preliminary studies have not demonstrated any benefit in reducing infarct size or improving outcomes. It is unlikely that this strategy would be beneficial in low-risk patients.

A strategy of facilitated PCI holds promise in higher-risk patients when PCI is not immediately available. Potential risks include increased bleeding complications, especially in older patients, and potential limitations include added cost. Several randomized trials of facilitated PCI with a variety of pharmacological regimens are in progress.

5.4.4. PCI After Failed Fibrinolysis (Rescue PCI)

Class I

1. **Rescue PCI should be performed in patients less than 75 years old with ST elevation or left bundle-branch block who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock, unless further support is futile because of the patient's wishes or contraindications/unsuitability for further invasive care.** ***(Level of Evidence: B)***
2. **Rescue PCI should be performed in patients with severe congestive heart failure and/or pulmonary edema (Killip class 3) and onset of symptoms within 12 hours.** ***(Level of Evidence: B)***

Class IIa

1. **Rescue PCI is reasonable for selected patients 75 years or older with ST elevation or left bundle-branch block or who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock. Patients with good prior functional status who are suitable for revascularization and agree to invasive care may be selected for such an invasive strategy.** ***(Level of Evidence: B)***
2. **It is reasonable to perform rescue PCI for patients with 1 or more of the following:**
   a. **Hemodynamic or electrical instability.** ***(Level of Evidence: C)***
   b. **Evidence of persistent ischemia.** ***(Level of Evidence: C)***

Class III

Rescue PCI in the absence of 1 or more of the above class I or IIa indications is not recommended. ***(Level of Evidence: C)***

PCI Immediately After Failed Fibrinolysis

Intravenous fibrinolytic therapy successfully restores antegrade coronary flow at 90 min in 50% to 80% of patients with acute STEMI (461). In those in whom it is unsuccessful, antegrade coronary flow can usually be restored with PCI. Several studies have demonstrated the marked beneficial effect of infarct-related artery patency (obtained via endogenous, pharmacological, or mechanical recanalization) on survival in patients with acute STEMI (462). Survivors of STEMI with a patent infarct-related artery demonstrated at 90 min after treatment have an improved long-term outcome

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compared with those with an occluded infarct-related artery, even when LV systolic function is similar (463,464). The REACT trial (Rapid Early Action for Coronary Treatment) was a randomized trial comparing medical therapy, immediate PCI, or repeat fibrinolytic in patients previously treated with fibrinolytic therapy. Preliminary data at 30 days demonstrated a significant advantage to rescue PCI [A.H. Gershlick, oral presentation, American Heart Association Scientific Sessions, New Orleans, LA, November 2004.]

Rescue (also known as salvage) PCI is defined as PCI within 12 h after failed fibrinolysis for patients with continuing myocardial ischemia. Rescue PCI has resulted in higher rates of early infarct-artery patency, improved regional infarct-zone wall motion, and greater freedom from adverse in-hospital clinical events compared with a deferred PCI strategy or medical therapy (465). The Randomized Evaluation of Rescue PCI with Combined Utilization Endpoints (RESCUE) trial demonstrated a reduction in rates of in-hospital death and combined death and HF that was maintained up to 1 year after study entry for patients presenting with anterior wall STEMI who failed fibrinolytic therapy when performed a mean of 8 h after symptom onset (466,467). Improvement in TIMI grade flow from 2 to 3 may offer additional clinical benefit. Similar data are not available for patients with nonanterior STEMI.

A major problem in adopting a strategy of rescue PCI lies in the limitation of accurate identification of patients in whom fibrinolytic therapy has not restored antegrade coronary flow. Unless unsuccessful fibrinolysis is recognized and corrected quickly (within 3 to 6 h of onset of symptoms), salvage of ischemic myocardium is unlikely. Unfortunately, clinical markers of reperfusion, such as relief of ischemic-type chest discomfort, partial resolution of ST-segment elevation, and reperfusion arrhythmias, have limited predictive value in identifying failure of fibrinolysis (468). Immediate catheterization of all patients after fibrinolytic therapy to identify those with an occluded infarct-related artery in a prior era in which the practice of PCI was less mature failed to show a significant benefit and was associated with bleeding complications. However, there was no specific study using stents and current pharmacotherapy. This strategy is being re-evaluated in clinical trials testing facilitated PCI in the contemporary PCI setting.

Even in the patient with documented failure of fibrinolysis, rescue PCI has limitations. First, because extensive myocardial necrosis occurs when coronary occlusion has been present for more than 3 h (469), PCI may not salvage a substantial amount of myocardium, considering the time delay associated with presentation of the patient to the hospital after onset of symptoms, infusion of the fibrinolytic agent, recognition of failed fibrinolysis, and subsequent initiation of PCI. Second, rescue PCI fails to reestablish antegrade coronary flow in about 10% of patients, and reocclusion of the infarct-related artery occurs in as many as 20% of the remainder (470), although GP IIb/IIIa inhibitors and stent implantation may have improved these results. Third, unsuccessful rescue PCI is associated with a high mortality (471,472). Finally, coronary reperfusion occurs over the subsequent h after fibrinolytic therapy in many patients. Although infarct-related artery patency is achieved in only 50% to 85% of patients 90 min after fibrinolytic therapy, it rises to 90% by 24 h (473). Such "late" reperfusion may improve survival without the risk of invasive procedures coupled with fibrinolytic therapy. Confounding the issue, both fibrinolysis and PCI may successfully restore flow in the epicardial artery but fail to improve microvascular perfusion.

Hours to Days After Failed Fibrinolysis

Patency of the infarct-related artery is an important predictor of mortality in survivors of STEMI (462,463,474). Compared with those with a patent infarct artery, survivors of STEMI with a persistently occluded artery after fibrinolysis, PCI, or no reperfusion therapy have 1) increased LV dilatation (475), 2) a greater incidence of spontaneous and inducible ventricular arrhythmias (476), and 3) a poorer prognosis (477). On the basis of observational and experimental data, it has been hypothesized that infarct artery patency may favorably influence LV remodeling and electrical stability, even if accomplished at a time when salvage of ischemic myocardium is unlikely (i.e., more than 12 h to days after coronary artery occlusion). Five small randomized trials, which enrolled a total of 562 patients, have directly tested the hypothesis that mechanical opening of persistent total occlusions late after MI will improve long-term LV remodeling and clinical outcomes (the late open artery hypothesis). Most studies enrolled a combination of patients, including those who had failed fibrinolysis and those who had not received reperfusion therapy (478-480), with a range from almost no fibrinolytic therapy (481) to fibrinolytic therapy in nearly all patients (482). There was wide variation in the effect of routine PCI compared with medical therapy only on LV size and function. Most studies showed no significant differences between the treatment groups (478,479). One single-center study of 83 patients with LAD occlusions reported improved LV volumes and clinical outcomes (composite of HF, MI, and death) at 6 months in the PCI group (481). In contrast, a multicenter study of 66 patients with LAD occlusions reported significantly worse LV remodeling, with progressive LV dilation at 1 year and more clinical events in the PCI group than in those assigned to optimal medical therapy alone (482). The latter included very high rates of beta-blocker and angiotensin converting enzyme inhibitor use. The largest multicenter study, DECOPI (DEsobstruction COronaire en Post-Infarctus), enrolled 212 patients and reported no difference in the primary end point, the composite of death, ventricular tachycardia, and MI at 6 months (483). Stents were used in 80% of patients in the PCI group, and GP IIb/IIIa antagonists were used in 9%. The study reached less than one third of the target sample size and was severely underpowered, as were all the other studies, to assess clinical events.

Selection of patients for revascularization based on viability testing has gained a great deal of investigational support, i.e., delayed enhancement or low-dose dobutamine cardiac

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MRI assessment. If viability is shown, outcomes are excellent, whereas if transmural MI is present, it is not, and revascularization is not recommended (484-486).

There are no convincing data to support the routine use of late adjuvant PCI days after failed fibrinolysis or for patients who do not receive reperfusion therapy. Nevertheless, this is being done in some STEMI patients as an extension of the invasive strategy for NSTEMI patients. The Occluded Artery Trial (OAT) is currently randomizing patients to test whether routine PCI days to weeks after MI improves long-term clinical outcomes in asymptomatic high-risk patients with an occluded infarct-related artery (487).

5.4.5. PCI After Successful Fibrinolysis or for Patients Not Undergoing Primary Reperfusion

Class I

1. **In patients whose anatomy is suitable, PCI should be performed when there is objective evidence of recurrent MI.** ***(Level of Evidence: C)***
2. **In patients whose anatomy is suitable, PCI should be performed for moderate or severe spontaneous or provocable myocardial ischemia during recovery from STEMI.** ***(Level of Evidence: B)***
3. **In patients whose anatomy is suitable, PCI should be performed for cardiogenic shock or hemodynamic instability.** ***(Level of Evidence: B)***

Class IIa

1. **It is reasonable to perform routine PCI in patients with LV ejection fraction less than or equal to 0.40, HF, or serious ventricular arrhythmias.** ***(Level of Evidence: C)***
2. **It is reasonable to perform PCI when there is documented clinical heart failure during the acute episode, even though subsequent evaluation shows preserved LV function (LV ejection fraction greater than 0.40).** ***(Level of Evidence: C)***

Class IIb

PCI might be considered as part of an invasive strategy after fibrinolytic therapy. ***(Level of Evidence: C)***

PCI Immediately After Successful Fibrinolysis

In early studies, asymptomatic patients undergoing routine PCI of the stenotic infarct-related artery immediately after successful fibrinolysis showed no benefit with regard to salvage of jeopardized myocardium or prevention of reinfarction or death. In addition, in some studies, this approach was associated with an increased incidence of adverse events, including bleeding, recurrent ischemia, emergency CABG surgery, and death (488-491). However, these studies have not been repeated in the modern interventional era with improved equipment, improved antiplatelet and anticoagulant therapy, and coronary stents. Notwithstanding this, routine PCI immediately after fibrinolysis may increase the chance for vascular complications at the catheterization access site and hemorrhage into the infarct-related vessel wall (491).

Hours to Days After Successful Fibrinolysis

It was initially suggested that elective PCI of the stenotic infarct-related artery hours to days after fibrinolysis might allow sufficient time for development of a more stable hemostatic milieu at the site of previous thrombotic occlusion. In this setting, PCI would be safer and more effective in reducing the incidence of reocclusion and improving survival. Two large randomized, prospective trials from an earlier PCI era tested this hypothesis, with both concluding that 1) there are fewer complications if PCI is delayed for several days after fibrinolytic therapy, and 2) routine PCI in the absence of spontaneous or provocable ischemia does not improve LV function or survival (226,489,490,492). Thus, in unselected patients receiving fibrinolytic therapy, PCI of the stenotic infarct-related artery in the absence of evidence of recurrent ischemia within 48 h did not appear to be beneficial.

Great improvements in equipment, operator experience, and adjunctive pharmacotherapy have increased PCI success rates and decreased complications. More recently, the invasive strategy for patients with NSTEMI has been given a class I recommendation by the ACC/AHA 2002 Guideline Update for the Management of Patients With UA/NSTEMI (493). Patients with STEMI are increasingly being treated similarly as an extension of this approach. Although 7 published reports (474,480,494-498) support this strategy, randomized studies similar to those in NSTEMI are needed.

One study supports the policy of performing catheterization and subsequent revascularization for patients who do have spontaneous or inducible angina after STEMI. The DANAMI trial (499) randomly assigned 1008 survivors of a first acute MI treated with fibrinolytic therapy within 12 h of onset of symptoms to catheterization and subsequent revascularization or standard medical therapy if they showed evidence of spontaneous or inducible angina. Those who underwent revascularization had less UA and fewer nonfatal MIs during a 2.5-year period of follow-up than those patients randomly assigned to medical treatment only (18% and 5.6% vs 30% and 10.5%, respectively). Among 500 patients undergoing fibrinolysis for STEMI, the GRACIA-1 (randomized trial comparing stenting within 24 hours of thrombolysis versus ischemia-guided approach to thrombolysed acute myocardial infarction with ST elevation) trial compared a strategy of angiography and intervention within 6 to 24 h of fibrinolysis to an ischemia-guided conservative approach for intervention. Eighty percent of patients assigned to angiography and intervention underwent stenting of the culprit artery compared with 20% in the ischemia-guided group. At 1 year, patients in the invasive group had a lower frequency of the primary end point (death, reinfarction, or revascularization; 9% vs 21%, P equals 0.008), and they tended to have a reduced rate of death or reinfarction (7% vs 12%, P equals

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0.07). In the angiography and intervention group, 81% had TIMI-3 flow before PCI was performed (494).

Days to Weeks After Successful Fibrinolysis

Continued thrombus lysis and remodeling of the infarct artery stenosis occur over the days to weeks after successful fibrinolysis, which makes the underlying residual coronary stenosis more stable and less prone to rethrombosis and reocclusion. Thus, a delay in performing PCI for days to weeks after fibrinolysis might improve survival, even though earlier routine PCI does not. To date, there have not been adequately sized trials to evaluate this treatment strategy. Two older, small, randomized trials (488,500) demonstrated similar LV function, rates of reinfarction, and mortality in patients randomized to PCI or conservative therapy.

5.4.6. PCI for Cardiogenic Shock

Class I

Primary PCI is recommended for patients less than 75 years old with ST elevation or left bundle-branch block who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock, unless further support is futile because of the patient's wishes or contraindications/unsuitability for further invasive care. *(Level of Evidence: A)*

Class IIa

Primary PCI is reasonable for selected patients 75 years or older with ST elevation or left bundle-branch block who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock. Patients with good prior functional status who are suitable for revascularization and agree to invasive care may be selected for such an invasive strategy. *(Level of Evidence: B)*

Observational studies support the value of PCI for patients who develop cardiogenic shock in the early hours of MI. For patients who do not have mechanical causes of shock, such as acute mitral regurgitation or septal or free wall rupture, mortality among those having PCI is lower than among those treated by medical means (366). However, undergoing cardiac catheterization alone, with or without PCI, is associated with a lower mortality because of patient selection bias (501).

Two randomized clinical trials (366,502) have further clarified the role of emergency revascularization in STEMI complicated by cardiogenic shock. Both showed a statistically insignificant, but clinically important, absolute 9% reduction in 30-day mortality. In the SHOCK trial (366), the survival curves continued to progressively diverge such that at 6 months and 1 year, there was a significant mortality reduction with emergency revascularization (53% vs 66%, *P* less than 0.03) (503). The prespecified subgroup analysis of patients less than 75 years old showed an absolute 15% reduction in 30-day mortality (*P* less than 0.02), whereas there was no apparent benefit for the small cohort (n equals 56) of patients more than 75 years old. These data strongly support the approach that patients younger than 75 years with STEMI complicated by cardiogenic shock should undergo emergency revascularization and support measures. Three registries (504-506) have demonstrated a marked survival benefit for elderly patients who are clinically selected for revascularization (approximately 1 of 5 patients), so age alone should not disqualify a patient for early revascularization (see Section 3.5.9).

Several additional discussions elsewhere in this guideline are important to consider in these patients. Intra-aortic balloon pump support or ventricular assist devices can stabilize hemodynamics so that revascularization procedures can be performed (see Section 3.5.8). Post hoc analyses (507-509) have suggested that GP IIb/IIIa inhibitors may reduce mortality, but the studies are limited by lower than expected mortality rates, larger than expected mortality reduction, and small sample sizes. Although PCI in a noninfarct artery is not recommended in stable patients, it can be beneficial in hemodynamically compromised patients if the stenotic artery perfuses a large area of myocardium and the procedure can be performed efficiently. In patients with significant left main disease or severe 3-vessel disease and without right ventricular infarction or major comorbidities such as renal insufficiency or severe pulmonary disease, CABG can be considered as the revascularization strategy (Figure 10) (510).

5.4.7. PCI in Selected Patient Subgroups

5.4.7.1. Young and Elderly Postinfarct Patients

Although not supported by randomized trials, routine cardiac catheterization after fibrinolytic therapy for STEMI has been a frequently performed strategy in all age groups. Young patients (less than 50 years old) often undergo cardiac catheterization after fibrinolytic therapy owing to a "perceived need" to define coronary anatomy and thus establish psychological as well as clinical outcomes. In contrast, older patients (greater than 75 years of age) have higher in-hospital and long-term mortality rates and enhanced clinical outcomes when treated with primary PCI (511-514). In addition, patients thought to be candidates for implantable cardioverter-defibrillator placement and those with small infarcts may undergo cardiac catheterization for further evaluation after STEMI.

In a secondary analysis of the TIMI-IIB study that compared angiographic findings and clinical outcomes among 841 young (aged less than 50 years) and 859 older (aged 65 to 70 years) patients randomly assigned to an invasive or conservative post-lytic management strategy (515), the younger patients assigned to the invasive strategy commonly had insignificant (i.e., less than 60% diameter stenosis) and single-vessel CAD. Severe 3-vessel or left main coronary disease findings were infrequent (3-vessel incidence, 4%; left main, 0%). Fatal and nonfatal MI and death through-

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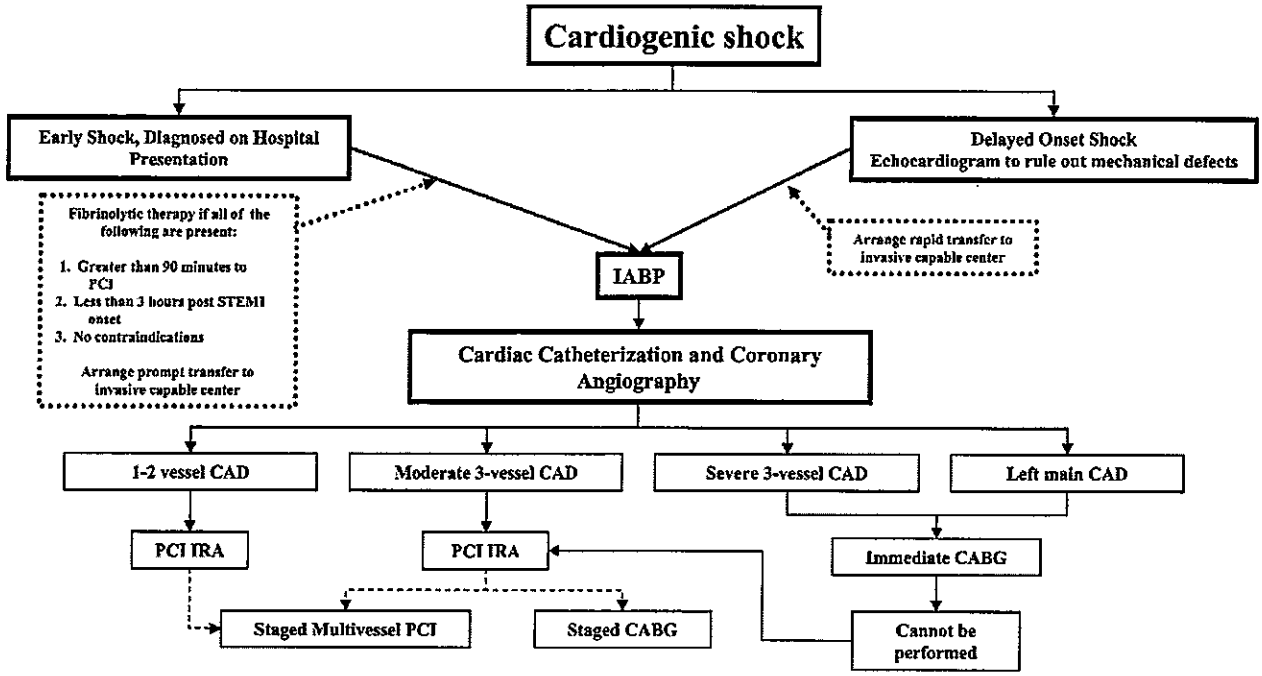

Figure 10. Recommendations for initial reperfusion therapy when cardiogenic shock complicates STEMI. Early mechanical revascularization with PCI/CABG is a Class I recommendation for candidates less than 75 years of age with ST elevation or left bundle-branch block who develop shock less than 36 hours from STEMI and in whom revascularization can be performed within 18 hours of shock, and it is a Class IIa recommendation for patients 75 years of age or older with the same criteria. Eighty-five percent of shock cases are diagnosed after initial therapy for STEMI, but most patients develop shock within 24 hours. IABP is recommended when shock is not quickly reversed with pharmacological therapy, as a stabilizing measure for patients who are candidates for further invasive care. Dashed lines indicate that the procedure should be performed in patients with specific indications only. Recommendations for staged CABG and PCI are discussed in the text, as are definitions of moderate and severe 3-vessel CAD. CABG indicates coronary artery bypass graft surgery; CAD, coronary artery disease; IABP, intra-aortic balloon pump; IRA, infarct-related artery; and STEMI, ST-elevation myocardial infarction. Modified with permission from Hochman. Circulation 2003;107:2998-3002 (510).

out the first year after study entry were also infrequent. There were no differences in the rates of in-hospital recurrent ischemia, reinfarction, or death among patients assigned to the conservative strategy of selective cardiac angiography and coronary revascularization compared with an invasive strategy, which consisted of routine post-lytic coronary angiography. Compared with younger patients, older patients had a higher prevalence of multivessel CAD (i.e., 44%) and higher 42-day rates of reinfarction and death.

In spite of these observations, there was no difference in the 42-day rates of reinfarction or death among the older patient subgroup, regardless of the post-lytic management strategy. The TIMI-II data of younger and older infarct patients are consistent with the overall results of other randomized trials of fibrinolysis/PTCA. More recent studies have examined PCI compared with fibrinolysis in young and elderly patients. The Primary Angioplasty in Myocardial Infarction (PAMI) investigators reviewed 3362 patients with ST-elevation MI enrolled in the various PAMI trials. All underwent primary angioplasty. Hospital mortality was higher for older patients, but the improvement in survival was also significant. Patients with high-risk infarction, including those with age greater than 70 years, had an improved outcome when treated with primary PTCA compared with fibrinolysis (512). In a review of more than 37 000 patients with STEMI from a national cohort of the Medicare database, after age adjustment, fibrinolytic therapy was not associated with a better 30-day survival than no therapy, whereas primary angioplasty was (OR 0.79, 95% CI 0.66 to 0.94). The benefit of primary angioplasty was noted at 1 year as well (513). In the GUSTO-IIB (Global Use of Strategies to Open occluded coronary arteries in acute coronary syndromes) angioplasty study, 1138 patients were randomized to receive primary angioplasty or fibrinolytic therapy. Irrespective of treatment, the risk of hospital mortality increased with age. For each 10-year increment in patient age, outcome was improved with angioplasty compared with fibrinolytic therapy. After adjustment for baseline characteristics, each increment of 10 years of age increased the risk of death or MI by a factor of 1.3 (95% CI 1.04 to 1.76, *P* equals 0.022). Advancing age was found to be associated with worse outcomes, and the risks increased in proportion to age. Primary angioplasty improved outcome compared with fibrinolysis but was not incrementally better in older than in younger patient groups (514). Given the current data, with the exception of patients presenting with cardiogenic shock, use of

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PCI should be determined by clinical need without special consideration of age.

5.4.7.2. Patients With Prior MI

A prior MI is an independent predictor of death, reinfarction, and need for urgent coronary bypass surgery (516). In fibrinolytic trials, 14% to 20% of enrolled patients had a history of prior MI (490,517,518), and patients with prior MI have higher rates of reinfarction after fibrinolytic therapy (519).

In the TIMI-II study, patients with a history of prior MI had a higher 42-day mortality (8.8% vs 4.3%; *P* less than 0.001), higher prevalence of multivessel CAD (60% vs 28%; *P* less than 0.001), and a lower LV ejection fraction (42% vs 48%; *P* less than 0.001) than patients with a first MI (520). Among patients assigned to the conservative post-lytic strategy, those with a prior MI had a significantly higher 42-day mortality than patients with a first MI (11.5% vs 3.5%; *P* less than 0.001), whereas in the invasive strategy, the mortality outcome was essentially the same in the 2 patient groups. Mortality tended to be lower among patients with a prior MI undergoing the invasive versus the conservative strategy, a benefit that persisted up to 1 year after study entry (492).

In a registry involving almost 12 000 patients with acute coronary syndromes, with and without ST-segment elevation, a history of prior MI was noted in almost one third of patients. There was no significant increase in relative risk for hospital mortality in this group (521). Some analyses of predictors of mortality for angioplasty after fibrinolytic therapy have found relatively little importance for prior infarction and emphasized the much greater importance of time delays in achieving reperfusion among patients with failed fibrinolysis (418).

Given the above findings and current practice, PCI should be based on clinical need. The presence of prior MI places the patient in a higher-risk subset and should be considered in the PCI decision.

5.5. Percutaneous Intervention in Patients With Prior Coronary Bypass Surgery

Class I

1. **When technically feasible, PCI should be performed in patients with early ischemia (usually within 30 days) after CABG.** ***(Level of Evidence: B)***
2. **It is recommended that distal embolic protection devices be used when technically feasible in patients undergoing PCI to saphenous vein grafts.** ***(Level of Evidence: B)***

Class IIa

1. **PCI is reasonable in patients with ischemia that occurs 1 to 3 years after CABG and who have preserved LV function with discrete lesions in graft conduits.** ***(Level of Evidence: B)***
2. **PCI is reasonable in patients with disabling angina secondary to new disease in a native coronary circulation after CABG. (If angina is not typical, objective evidence of ischemia should be obtained.)** ***(Level of Evidence: B)***
3. **PCI is reasonable in patients with diseased vein grafts more than 3 years after CABG.** ***(Level of Evidence: B)***
4. **PCI is reasonable when technically feasible in patients with a patent left internal mammary artery graft who have clinically significant obstructions in other vessels.** ***(Level of Evidence: C)***

Class III

1. **PCI is not recommended in patients with prior CABG for chronic total vein graft occlusions.** ***(Level of Evidence: B)***
2. **PCI is not recommended in patients who have multiple target lesions with prior CABG and who have multivessel disease, failure of multiple SVGs, and impaired LV function unless repeat CABG poses excessive risk due to severe comorbid conditions.** ***(Level of Evidence: B)***

5.5.1. Early Ischemia After CABG

Recurrent ischemia early (less than 30 days) postoperatively usually reflects graft failure, often secondary to thrombosis (522-524), and may occur in both saphenous vein and arterial graft conduits (525). Incomplete revascularization and unbypassed native vessel stenoses or stenoses distal to a bypass graft anastomosis may also precipitate recurrent ischemia. Urgent coronary angiography is indicated to define the anatomic cause of ischemia and to determine the best course of therapy. Emergency PCI of a focal graft stenosis (venous or arterial) or recanalization of an acute graft thrombosis may successfully relieve ischemia in the majority of patients. Balloon dilatation across suture lines has been accomplished safely within days of surgery (526-528). Intracoronary fibrinolytic therapy should be administered with caution during the first week postoperatively (529-532), and if required, residual thrombus may be "targeted" in low doses through a local drug delivery system. Conversely, mechanical thrombectomy with newer catheter technologies may be effective without the attendant risk of fibrinolysis (533). Adjunctive therapy with abciximab for percutaneous intervention during the first week after bypass surgery has been limited but intuitively may pose less risk for hemorrhage than fibrinolysis. Because flow in vein graft conduits is pressure dependent, IABP support should be considered in the context of systemic hypotension or severe LV dysfunction. If feasible, PCI of both bypass graft and native vessel offending stenoses should be attempted, particularly if intracoronary stents can be deployed successfully.

When ischemia occurs 1 to 12 months after surgery, the cause is usually perianastomotic graft stenosis. Distal anastomotic stenoses (both arterial and venous) respond well to balloon dilation alone and have a more favorable long-term prognosis than stenoses involving the midshaft or proximal vein graft anastomosis (250,251,534-537). Midshaft vein graft stenoses occurring during this time frame are usually

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due to intimal hyperplasia. Restenosis may be less frequent and event-free survival may be enhanced after angioplasty of SVGs dilated within 6 months of surgery compared with grafts of older age. The immediate results of PCI in midshaft ostial or distal anastomotic vein graft stenoses may be enhanced by coronary stent deployment (537,538). Ablative technologies such as directional atherectomy or excimer laser coronary angioplasty may facilitate angioplasty and stent deployment in patients with aorto-ostial vein graft stenoses (539,540).

Stenoses in the midportion or origin of the IMA graft are uncommon but respond to balloon dilation (541,542) with stent deployment as feasible. Long-term follow-up of patients after IMA angioplasty has demonstrated sustained benefit and relief of ischemia in the majority of patients (543,544). Balloon angioplasty with or without stent deployment can be performed successfully in patients with distal anastomotic stenoses involving the gastroepiploic artery bypass graft and in patients with free radial artery bypass grafts (545). Percutaneous intervention has also been effective in relieving ischemia for patients with stenosis of the subclavian artery proximal to the origin of a patent left IMA bypass graft (546,547).

5.5.2. Late Ischemia After CABG

Ischemia occurring more than 1 year postoperatively usually reflects the development of new stenoses in graft conduits and/or native vessels that may be amenable to PCI (548). At 3 years or more after SVG implantation, atherosclerotic plaque is frequently evident and is often progressive. These lesions may be friable and often have associated thrombus formation, which may contribute to the occurrence of slow flow, distal embolization, and periprocedural MI after attempted percutaneous intervention (56). Slow flow occurs more frequently in grafts that have diffuse atherosclerotic involvement, angiographically demonstrable thrombus, and irregular or ulcerative lesion surfaces, and with long lesions that have large plaque volume (549,550). Although a reduced incidence of distal embolization has been reported after the use of the extraction atherectomy catheter to recanalize stenoses in older vein graft conduits (551-555), embolization may still complicate adjunctive balloon dilation. Distal embolic protection devices have significantly reduced the occurrence of complications of embolization in SVGs and should be used when possible (254,255). Slow flow with signs and symptoms of myocardial ischemia may be ameliorated by the intragraft administration of agents such as adenosine, diltiazem, nitroprusside, and verapamil (549,556-559). The adjunctive administration of abciximab during vein graft intervention was evaluated in a meta-analysis of 5 studies that demonstrated no improvement in outcomes after PCI and in the absence of distal protection and was associated with a high incidence of death and nonfatal ischemic events (252).

Although postprocedural minimum lumen diameter is larger after directional coronary atherectomy (243,560,561) or stent deployment (244,245,562-569) than with balloon angioplasty of SVG stenoses, long-term prognosis remains guarded, and late recurrent ischemic events may be due to both restenosis of the target lesion and diffuse vein graft disease (570-572). Final patency after PCI is greater for distal SVG lesions than for ostial or mid-SVG lesions (535), and stenosis location appears to be a better determinant of final patency than graft age or the type of interventional device used.

Percutaneous intervention for chronic vein graft occlusion has been problematic. Balloon angioplasty alone has been associated with high complication rates and low rates of sustained patency (572). Although prolonged intragraft infusion of fibrinolytic therapy was reported to successfully recanalize 69% of a selected group of patients with chronic SVG occlusion of less than 6 months' duration, long-term patency rates with or without adjunctive stent deployment were low (573-575). In addition, prolonged fibrinolytic therapy has been associated with thromboembolic MI (576-579), intracranial hemorrhage (580), and intramyocardial hemorrhage (581), as well as vascular access-site complications. Favorable results have been obtained with both local "targeted" and more prolonged infusion of fibrinolytic agents for nonocclusive intragraft thrombus (582,583). Fibrinolytic catheter-based systems appear to successfully treat SVG thrombosis as well as or better than fibrinolytic agents (584).

5.5.3. Early and Late Outcomes of Percutaneous Intervention

Before the general availability of coronary stenting, overall angioplasty procedural success rates exceeded 90%, and adverse outcomes of emergency repeat coronary bypass surgery (2.3%) and death (0.8%) were infrequent as reported in combined series of over 2000 patients with prior bypass surgery undergoing percutaneous intervention (250,585-597). These results are comparable to those achieved in patients without prior bypass surgery, an observation confirmed by NHLBI registry data (7). The most common complications observed in this population are NSTEMI and atheroembolism, particularly after SVG intervention (538,598).

Patients with prior bypass surgery who undergo successful PCI have a long-term outcome that is dependent on patient age, the degree of LV dysfunction, and the presence of multivessel coronary atherosclerosis. The best long-term results are observed after recanalization of distal anastomotic stenoses occurring within 1 year of operation. Angioplasty of distal anastomotic stenoses involving IMA grafts has been associated with similar, favorable long-term patency rates (543,544). Conversely, event-free survival is less favorable after angioplasty of totally occluded SVGs, ostial vein graft stenoses, or grafts with diffuse or multicentric disease (570-572). Coexistent multisystem disease, the presence of which may have prompted the choice of a percutaneous revascularization strategy, may also influence long-term outcomes in this population.

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5.5.4. General Considerations

Aged, diffuse, friable, and degenerative SVG disease in the absence of a patent arterial conduit to the LAD represents a prime consideration for repeat surgical revascularization. In contrast, the presence of a patent arterial conduit to the LAD favors a percutaneous interventional approach to other vessels (599). The overall risk of repeat operation, especially the presence of comorbidities such as concomitant cerebrovascular, renal, or pulmonary disease and the potential for jeopardizing patent, nondiseased bypass conduits, must be considered carefully. Isolated, friable stenoses in vein grafts may be approached with primary stenting or the combination of extraction atherectomy and stenting in an attempt to reduce the likelihood of distal embolization. Distal embolic protection devices have reduced the occurrence of complications of embolization significantly and should be used when possible (254,255) (see Sections 5.5.2 and 6.1.1).

Another therapeutic option for patients with prior coronary bypass surgery that has become available is grafting with the IMA through a "minimally invasive" surgical approach (273,600-604). This strategy, which avoids both the risk of cardiopulmonary bypass (stroke or coagulopathy) and repeat median sternotomy, may be particularly applicable to patients with chronic native-vessel LAD coronary occlusion and friable atherosclerotic disease that involves a prior SVG to this vessel. The role of combining a minimally invasive surgical approach with PCI requires further study (605,606).

In general, patients with multivessel disease, failure of multiple SVGs, and moderately impaired LV function derive the greatest benefit from the durability provided by surgical revascularization with arterial conduits. Regardless of repeat revascularization strategy, risk factor modification with cessation of smoking (607,608) and lipid-lowering therapy (609,610) should be implemented in patients with prior CABG surgery. An aggressive lipid-lowering strategy that targets a low-density lipoprotein cholesterol level substantially less than 100 mg per dL (optional therapeutic target for low-density lipoprotein cholesterol less than 70 mg per dL in very-high-risk patients) (611) can be effective in reducing recurrent ischemic events and the need for subsequent revascularization procedures (610).

5.6. Use of Adjunctive Technology (Intracoronary Ultrasound Imaging, Flow Velocity, and Pressure)

The limitations of coronary angiography for diagnostic and interventional procedures can be reduced by the use of adjunctive technology such as intracoronary ultrasound imaging, flow velocity, and pressure. Information obtained from the adjunctive modalities of intravascular imaging and physiology can improve PCI methods and outcomes.

5.6.1. Intravascular Ultrasound Imaging

Class IIa

IVUS is reasonable for the following:

a. **Assessment of the adequacy of deployment of coronary stents, including the extent of stent apposition and determination of the minimum luminal diameter within the stent.** *(Level of Evidence: B)*
b. **Determination of the mechanism of stent restenosis (inadequate expansion versus neointimal proliferation) and to enable selection of appropriate therapy (vascular brachytherapy versus repeat balloon expansion).** *(Level of Evidence: B)*
c. **Evaluation of coronary obstruction at a location difficult to image by angiography in a patient with a suspected flow-limiting stenosis.** *(Level of Evidence: C)*
d. **Assessment of a suboptimal angiographic result after PCI.** *(Level of Evidence: C)*
e. **Establishment of the presence and distribution of coronary calcium in patients for whom adjunctive rotational atherectomy is contemplated.** *(Level of Evidence: C)*
f. **Determination of plaque location and circumferential distribution for guidance of directional coronary atherectomy.** *(Level of Evidence: B)*

Class IIb

IVUS may be considered for the following:

a. **Determination of the extent of atherosclerosis in patients with characteristic anginal symptoms and a positive functional study with no focal stenoses or mild CAD on angiography.** *(Level of Evidence: C)*
b. **Preinterventional assessment of lesional characteristics and vessel dimensions as a means to select an optimal revascularization device.** *(Level of Evidence: C)*
c. **Diagnosis of coronary disease after cardiac transplantation.** *(Level of Evidence: C)*

Class III

IVUS is not recommended when the angiographic diagnosis is clear and no interventional treatment is planned. *(Level of Evidence: C)*

IVUS imaging provides a tomographic 360-degree sagittal scan of the vessel from the lumen through the media to the vessel wall. IVUS measurements of arterial dimensions (minimal and maximal diameters, cross-sectional area, and plaque area) complement and enhance angiographic information. IVUS has been used to refine device selection through plaque characterization (e.g., calcified) and artery sizing. IVUS has contributed to the understanding of the mechanisms of coronary angioplasty in general and specifically to the advancement of coronary stenting without long-term anticoagulation (612-617). In a large observational study, IVUS-guided angioplasty resulted in a decreased final residual plaque area from 51% to 34%, despite a final angiographic percent stenosis of 0% (612). IVUS-facilitated stent deployment was associated with a subacute thrombosis rate of 0.3% without systemic anticoagulation, although

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antiplatelet agents are still required for stenting (612). In the placement of coronary stents, because radiographic contrast material can be located between stent struts and the vascular wall, an angiographic appearance of a large lumen may exist when the stent has not been fully deployed. IVUS documents full apposition of stent struts to the vessel wall (612).

IVUS is not necessary for all stent procedures. The results of the French Stent Registry study of 2900 patients treated without warfarin and without IVUS reported a subacute closure rate of 1.8% (618). In the Stent Anticoagulation Regimen Study (STARS) (619), a subacute closure rate of 0.6% in patients having optimal stent implantation supports the approach that IVUS does not appear to be required routinely in all stent implantations. However, the use of IVUS to evaluate results in high-risk procedures (e.g., those patients with multiple stents, impaired TIMI grade flow or coronary flow reserve, and marginal angiographic appearance) appears warranted.

The long-term outcomes when adjunctive IVUS is used are currently under study. In the Multicenter Ultrasound Stent In Coronaries (MUSIC) trial of 161 patients (620), which evaluated optimal stent expansion (defined as complete apposition of the stent over its length) with symmetrical expansion (defined as a ratio of minimum to maximum luminal diameter greater than 0.7) and minimal luminal area (compared with greater than 80% of the reference area), the subacute closure rate was 1.3% with monotherapy of aspirin. The angiographic restenosis rate was less than 10% when stent cross-sectional areas were greater than 9.0 mm^2.

Fitzgerald et al. reported that the degree of stent expansion as measured by IVUS directly correlates to clinical outcomes in the CRUISE (Can Routine Ultrasound Influence Stent Expansion) study (621). This multicenter study compared 270 patients with IVUS-guided stent implantation with IVUS-documented, but not guided, stent implantation in 229 patients. At 9-month follow-up, there was no difference in rates of death or MI, but the target-lesion revascularization rate was substantially lower in the IVUS-guided group (8.5% vs 15.3%; P equals 0.019). These data suggest that ultrasound guidance of stent implantation may result in more effective stent expansion than angiographic guidance alone and subsequently reduce the need for late target-lesion revascularization.

In several instances, IVUS has been useful in determining the reason for reduced efficacy of new technology. In the RESCUT (REStenosis CUTting balloon evaluation) trial comparing cutting balloon with PTCA for ISR, IVUS examinations showed that there was stent underexpansion when a cutting balloon was used at low pressure compared with high-pressure balloons (91).

IVUS has also identified complications of PCI that require further therapy. Postprocedure hematomas that were not identifiable by angiography were identified by IVUS (622).

Stent underexpansion was also shown to be common in diabetic patients assessed with angiography. This can be revealed by IVUS so that further expansion of the stent can be accomplished (623). IVUS increasingly is also being used to measure the volume of intimal hyperplasia in experimental studies to evaluate the efficacy of systemic and locally delivered antirestenotic therapies (624-628) or in clinical research trials to assess the effect of therapies for dyslipidemia on vascular wall and plaque structure.

5.6.2. Coronary Artery Pressure and Flow: Use of Fractional Flow Reserve and Coronary Vasodilatory Reserve

Class IIa

It is reasonable to use intracoronary physiologic measurements (Doppler ultrasound, fractional flow reserve) in the assessment of the effects of intermediate coronary stenoses (30% to 70% luminal narrowing) in patients with anginal symptoms. Coronary pressure or Doppler velocimetry may also be useful as an alternative to performing noninvasive functional testing (e.g., when the functional study is absent or ambiguous) to determine whether an intervention is warranted. ***(Level of Evidence: B)***

Class IIb

1. **Intracoronary physiologic measurements may be considered for the evaluation of the success of PCI in restoring flow reserve and to predict the risk of restenosis.** ***(Level of Evidence: C)***
2. **Intracoronary physiologic measurements may be considered for the evaluation of patients with anginal symptoms without an apparent angiographic culprit lesion.** ***(Level of Evidence: C)***

Class III

Routine assessment with intracoronary physiologic measurements such as Doppler ultrasound or fractional flow reserve to assess the severity of angiographic disease in patients with a positive, unequivocal noninvasive functional study is not recommended. ***(Level of Evidence: C)***

Historically, translesional pressure gradients were used as end points for early interventional cardiology procedures. The use of a translesional pressure gradient measured at rest was abandoned because of difficult technique and improved angiographic imaging. Pijls et al. (545) introduced the concept of fractional flow reserve (FFR) of the myocardium, the ratio of distal coronary pressure to aortic pressure measured during maximal hyperemia, which correlates with the fraction of normal blood flow through the stenotic artery (629,630). The coronary pressure measuring technique is relatively simple, especially with pressure guidewires, a method superior to small catheters. The normal FFR value for all vessels under all hemodynamic conditions, regardless of the status of microcirculation, is 1.0. FFR values less than 0.75 are associated with abnormal stress tests (631). Unlike coronary flow velocity reserve (CVR), the FFR is relatively independent of microcirculatory disturbances. FFR does not use measurements in a reference vessel and is thought to be epicardial lesion-specific. FFR provides no information on

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the microcirculation or on the absolute magnitude of the change in coronary flow.

On the other hand, CVR is the ratio of hyperemic to basal flow and reflects flow resistance through the epicardial artery and the microvascular bed. CVR less than 2.0 is positively correlated to abnormal stress perfusion imaging (632-634). In some cases, the uncertainty as to whether the impaired flow reserve is due to the target stenosis or to an abnormal microcirculation may be reduced by use of relative coronary flow reserve (rCVR, which is equal to CVR of the target vessel divided by CVR of the reference vessel). From preliminary studies, rCVR greater than 0.8 may have prognostic values similar to those of negative stress testing (635). There is a correlation between rCVR and pressure-derived FFR (629,635). An abnormal CVR indicates that the stenosis in the epicardial artery is significant when the microcirculation is normal. For coronary lesion assessment, the best measurement appears to be FFR.

CVR measurement of less than 2 after stent placement was an independent predictor of target-vessel revascularization. CVR after PCI in DEBATE-2 (Doppler Endpoints Balloon Angioplasty Trial Europe) also predicted early MACE due to microcirculatory disturbances (636). However, because of the complexity in the interpretation of CVR, pressure-derived FFR is the preferred measurement for lesion assessment and outcome of PCI. Coronary physiologic measurements associated with major clinical outcomes are supported by numerous studies (Table 23) (632,637).

Strong correlations exist between myocardial stress testing and FFR or CVR (633,638-649). An FFR of less than 0.75 identified physiologically significant stenoses associated with inducible myocardial ischemia with high sensitivity (88%), specificity (100%), positive predicted value (100%), and overall accuracy (93%). An abnormal CVR (less than 2.0) corresponded to reversible myocardial perfusion imaging defects with high sensitivity (86% to 92%), specificity (89% to 100%), predictive accuracy (89% to 96%), and positive and negative predictive values (84% to 100% and 77% to 95%, respectively).

The clinical outcomes of deferring coronary intervention for intermediate stenoses with normal physiology are remarkably consistent, with clinical event rates of less than 10% over a 2-year follow-up period (639,647-651). Bech et al. (649) studied 325 patients with intermediate coronary stenosis without documented myocardial ischemia and randomly assigned those with FFR greater than 0.75 to a deferral group of 91 patients or a performance group of 90 patients. PTCA was performed as planned in 144 patients with FFR less than 0.75. At clinical follow-up of 1, 3, 6, 12, and 24 months, event-free survival was similar between the deferral and performance groups (92% vs 89% at 12 months and 89% vs 83% at 24 months). However, these rates were significantly lower in the reference (PTCA) group (80% at 12 months and 78% at 24 months). The percentage of patients free from angina was similar between the deferral and the performance group at 12 and 24 months, but there was a significantly higher incidence of angina in the refer-

Table 23. Catheter-Based Anatomic and Physiological Criteria Associated With Clinical Outcomes

Application	IVUS	CVR	rCVR	FFR
Ischemia detection	Less than 3 to 4 mm^2	Less than 2.0	Less than 0.8	Less than 0.75
Deferred angioplasty	NA	Greater than 2.0	NA	Greater than 0.75
End point of stenting	Greater than 9 mm^2 Greater than 80% reference area, full apposition (depending on vessel size and volume plus morphology of plaque in target-vessel segment)			Greater than 0.94 (depending on diffuse disease in persistent segment)

CVR indicates coronary flow velocity reserve; FFR, fractional flow reserve; IVUS, intravascular ultrasound; NA, not applicable; and rCVR, relative coronary flow velocity.
Modified with permission from Kern. Circulation 2000;101:1344-51 (637).

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ence group (67% vs 50% at 12 months and 80% vs 50% at 24 months). These data indicated that in patients with coronary stenosis without evidence of ischemia, coronary pressure–derived FFR identifies those patients who will benefit from PCI as well as those who will not.

FFR after stenting predicts adverse cardiac events at follow-up. Pijls et al. (648) examined 750 patients with postprocedural FFR and related these findings to MACE at 6 months. In 76 patients (10.2%), 1 adverse event occurred. Five patients died, 19 experienced MI, and 52 underwent at least 1 repeat target-vessel revascularization. Fractional flow reserve immediately after stenting was an independent variable related to all types of events. In 36% of patients, FFR normalized (greater than 0.95) with an event rate of 5%. In 32% of patients with poststenting FFR between 0.90 and 0.95, the event rate was 6%. In the remaining 32% with FFR less than 0.90, event rates were 20%. In 6% of patients with FFR less than 0.80, the event rate was 30% (Table 23) (637). FFR after stenting is a strong predictor of outcome at 6 months. These data suggest that both edge stent subnormalization and diffuse disease are associated with worse long-term outcome.

6. MANAGEMENT OF PATIENTS UNDERGOING PCI

6.1. Evolution of Technologies

The introduction of coronary stents and other devices has broadened the scope of patients who can be approached by PCI beyond those who could be safely treated by PTCA alone. Coronary stenting has become the dominant final therapy in patients undergoing PCI. The NHLBI registry, which collects sampling of unselected patients from 15 medium- to large-volume institutions, shows increasing use of stenting over the past 5 years. In the most recent wave of this registry, 83.6% of PCI patients received stents, and stents were placed in 79.4% of all lesions treated. Stenting has been more successful than balloon angioplasty in mid-sized coronary lesions, chronic total occlusions (652,653), and SVGs (562). Directional coronary atherectomy has been used successfully in proximal anterior descending lesions and bifurcation lesions (638). Rotational atherectomy successfully treats calcific and diffusely diseased coronary vessels (654) and ostial stenoses (655,656). Excimer laser has been used to treat diffuse disease (657). Vascular brachytherapy has been successful in treating restenosis occurring within stents (92,658,659). Other adjunctive therapies for ISR have shown mixed results. The cutting balloon has been used successfully; however, a recent trial did not show superiority for the cutting balloon compared with the normal balloon (95). Rotary ablation, excimer laser, and restenting have also been used for ISR; however, there are no data to indicate that these methods are better than balloon angioplasty.

Intracoronary brachytherapy with both gamma and beta radiation sources has been effective in treatment of ISR, and both radiation sources were approved by the FDA as therapy approved specifically for ISR (92,658-660).

Beta-radiation systems have been used most widely, resulting in an approximately 50% reduction in the need for reintervention over the 9 months after the procedure (92,659). In-stent restenosis is now significantly less than in prior years, but even with drug-eluting stenting, the problem still exists. Early observation of the use of DES to treat ISR has shown mixed results. Studies are currently under way comparing placement of DES to brachytherapy for ISR. Results of those trials are not available at this time.

6.1.1. Acute Results

Class I

It is recommended that distal embolic protection devices be used when technically feasible in patients undergoing PCI to saphenous vein grafts. *(Level of Evidence: B)*

Historically, one of the important limitations of balloon angioplasty has been its high rate of abrupt closure (4% to 7%) and less than optimal acute angiographic result (30% residual diameter stenosis, with frequent evidence of dissections). Significant reductions in acute complication rates for PTCA have resulted from the wide use of stenting, which has been shown to reduce abrupt closure and periprocedural emergency surgery rates. Improved acute outcomes in terms of reduced target-lesion residual diameter stenosis have also been seen with the use of coronary stents, directional coronary atherectomy, and other adjunctive therapies. The GuardWire distal protection device, as studied in the SAFER (Saphenous vein graft Angioplasty Free of Emboli Randomized) trial, has reduced the incidence of MI in patients treated for SVG lesions (255), and the FilterWire was shown not to be inferior to the GuardWire in the FIRE (FilterWire EX Randomized Evaluation) trial (254) (see Section 5.5.2.). However, "embolic" protection devices have not shown a similar benefit in the setting of primary PCI for STEMI, as noted in the EMERALD (Enhanced Myocardial Efficacy and Recovery by Aspiration of Liberated Debris) trial (GuardWire), in which distal protection did not convey significant benefit (661). Thus, the use of distal embolic protection devices for STEMI patients undergoing PCI requires further evaluation (253,661).

6.1.2. Late-Term Results

PCI devices, especially coronary stents, offer the possibility of lower restenosis than with PTCA in the native coronary circulation. Lower restenosis rates have been demonstrated for balloon-expandable stents in large (3 mm) native coronary arteries (80,83) and in saphenous vein lesions (562).

The use of stents in smaller arteries has shown mixed results. Use of stenting in the treatment of chronic total occlusions has been superior to balloon angioplasty alone (652,653). The use of vascular brachytherapy has been shown to reduce restenosis rates and improve clinical outcomes in patients with ISR (92,658,660).

Directional coronary atherectomy, when applied aggressively, produces a larger lumen and has been associated with

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a lower angiographic restenosis rate (85). Despite the improvement in acute results seen for rotational atherectomy and excimer laser, there is no evidence that these devices improve late outcomes in lesions that can be safely treated with balloon angioplasty or stenting alone (662-664).

6.2. Antiplatelet and Antithrombotic Adjunctive Therapies for PCI

6.2.1. Oral Antiplatelet Therapy

Class I

1. **Patients already taking daily chronic aspirin therapy should take 75 to 325 mg of aspirin before the PCI procedure is performed.** *(Level of Evidence: A)*
2. **Patients not already taking daily chronic aspirin therapy should be given 300 to 325 mg of aspirin at least 2 hours and preferably 24 hours before the PCI procedure is performed.** *(Level of Evidence: C)*
3. **After the PCI procedure, in patients with neither aspirin resistance, allergy, nor increased risk of bleeding, aspirin 325 mg daily should be given for at least 1 month after bare-metal stent implantation, 3 months after sirolimus-eluting stent implantation, and 6 months after paclitaxel-eluting stent implantation, after which daily chronic aspirin use should be continued indefinitely at a dose of 75 to 162 mg.** *(Level of Evidence: B)*
4. **A loading dose of clopidogrel should be administered before PCI is performed.** *(Level of Evidence: A)* **An oral loading dose of 300 mg, administered at least 6 hours before the procedure, has the best established evidence of efficacy.** *(Level of Evidence: B)*
5. **In patients who have undergone PCI, clopidogrel 75 mg daily should be given for at least 1 month after bare-metal stent implantation (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks), 3 months after sirolimus stent implantation, and 6 months after paclitaxel stent implantation, and ideally up to 12 months in patients who are not at high risk of bleeding.** *(Level of Evidence: B)*

Class IIa

1. **If clopidogrel is given at the time of procedure, supplementation with GP IIb/IIIa receptor antagonists can be beneficial to facilitate earlier platelet inhibition than with clopidogrel alone.** *(Level of Evidence: B)*
2. **For patients with an absolute contraindication to aspirin, it is reasonable to give a 300-mg loading dose of clopidogrel, administered at least 6 hours before PCI, and/or GP IIb/IIIa antagonists, administered at the time of PCI.** *(Level of Evidence: C)*
3. **When a loading dose of clopidogrel is administered, a regimen of greater than 300 mg is reasonable to achieve higher levels of antiplatelet activity more rapidly, but the efficacy and safety compared with a 300-mg loading dose are less established.** *(Level of Evidence: C)*
4. **It is reasonable that patients undergoing brachytherapy be given daily clopidogrel 75 mg indefinitely and daily aspirin 75 to 325 mg indefinitely unless there is significant risk for bleeding.** *(Level of Evidence: C)*

Class IIb

In patients in whom subacute thrombosis may be catastrophic or lethal (unprotected left main, bifurcating left main, or last patent coronary vessel), platelet aggregation studies may be considered and the dose of clopidogrel increased to 150 mg per day if less than 50% inhibition of platelet aggregation is demonstrated. *(Level of Evidence: C)*

Aspirin reduces the frequency of ischemic complications after PCI. Although the minimum effective aspirin dosage in the setting of PCI has not been established, for those patients not already taking chronic aspirin therapy (75 to 162 mg per day), an empiric dose of aspirin (300 to 325 mg) given at least 2 h and preferably 24 h before the PCI procedure is generally recommended (665-668). Although other antiplatelet agents have antiplatelet effects similar to aspirin (669), only the thienopyridine derivatives (670) ticlopidine and clopidogrel have been used routinely as alternative antiplatelet agents in aspirin-sensitive patients during coronary angioplasty. Glycoprotein IIb/IIIa antagonists might also be substituted for aspirin before PCI. However, aspirin desensitization can be performed safely in selected patients (671,672). A strategy of pretreatment with clopidogrel in patients who have not already had their coronary anatomy defined is controversial, because patients who undergo CABG within 5 to 7 days of clopidogrel treatment have an increased risk of bleeding (665,673).

Clopidogrel and ticlopidine have similar side effects, which include gastrointestinal distress (20%), cutaneous rashes (4.8% to 15%), and abnormal liver function tests (674). Severe neutropenia has been reported to occur in approximately 1% of patients taking ticlopidine (674,675). Rare (less than 1:1000) but fatal episodes of thrombotic thrombocytopenic purpura have also been reported (676-678). Patients receiving ticlopidine should be monitored for the occurrence of this untoward sequela. A shorter duration (10 to 14 days) of ticlopidine therapy may reduce untoward side effects of therapy while maintaining therapeutic efficacy (679). For these reasons, clopidogrel has become the preferred thienopyridine for patients undergoing PCI. Available data show that approximately 4% to 30% of patients treated with conventional doses of clopidogrel do not display adequate platelet response (680). Preliminary data suggests that clopidogrel "nonresponders" may be at higher risk for thrombotic events. Thus, in patients in whom stent thrombosis may be catastrophic or lethal (ULM, bifurcating left main, and last patent coronary vessel), platelet aggregation studies may be considered and the dose of clopidogrel increased to 150 mg per day if less than 50% inhibition of platelet aggregation is demonstrated.

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Before the advent of potent combination antiplatelet therapy in recent years, enthusiasm for stenting during MI (with or without ST elevation) or UA was tempered by the sudden and often unpredictable occurrence of subacute stent thrombosis, which developed in 3.5% to 8.6% of stent-treated patients (80,83,681,682). Anatomic factors (e.g., underdilation of the stent, proximal and distal dissections, poor inflow or outflow obstruction, less than 3-mm vessel diameter) were believed to predispose some patients to the occurrence of subacute stent thrombosis (612,683,684). With the advancements in PCI technology and adjunctive antiplatelet therapy (aspirin plus thienopyridine) after PCI, the incidence of stent thrombosis is now approximately 1% (685,686). The potential risk of stent occlusion should be considered when discontinuation of antiplatelet therapy is contemplated in patients undergoing stent implantation (687,688).

The efficacy of combination antiplatelet therapy in patients undergoing urgent and elective stent implantation has been shown by the Intracoronary Stenting and Antithrombotic Regimen (ISAR) trial of 517 patients treated with BMS for MI, suboptimal angioplasty, or other high-risk clinical and anatomic features. Patients were randomly assigned to treatment with aspirin plus ticlopidine or aspirin, intravenous heparin, and phenprocoumon after successful stent placement (689). The primary end point of cardiac death, MI, coronary bypass surgery, or repeat angioplasty occurred in 1.5% of patients assigned to antiplatelet therapy and 6.2% of those assigned to anticoagulant therapy (relative risk 0.25; 95% CI 0.06 to 0.77) (689).

In the STARS trial (619), the efficacy of aspirin (325 mg daily), the combination of aspirin (325 mg daily) plus ticlopidine (500 mg daily for 1 month), and aspirin (325 mg daily) plus warfarin on ischemic end points at 30 days in 1653 in low-risk patients after optimal BMS placement demonstrated more adverse events in patients not receiving ticlopidine as part of the therapeutic regimen. The primary 30-day composite end point of death, target-lesion revascularization, subacute thrombosis, or MI was 3.6% in patients assigned to aspirin only, 2.7% in those assigned to aspirin plus warfarin, and 0.5% in those assigned to aspirin plus ticlopidine (aspirin plus ticlopidine vs aspirin alone, *P* less than 0.001; aspirin plus ticlopidine vs aspirin plus warfarin, *P* equals 0.014) (619). Pretreatment with ticlopidine without a loading dose for more than 72 h may allow more effective inhibition of platelet activation than shorter durations of therapy (691,692).

In the CURE (Clopidogrel in Unstable angina to prevent Recurrent Events) trial, the effects of clopidogrel in addition to aspirin were tested in 12 562 patients with non–ST-elevation acute coronary syndromes with either positive biomarkers of myocardial injury or new ECG changes (665). The patients were randomized to receive an immediate 300-mg loading dose of clopidogrel in the emergency room followed by 75 mg a day for 1 year or to a matching placebo.

The primary end points of MI, stroke, and cardiovascular death from randomization to 1 year were reported. There was a 20% RRR in the primary outcome of MI, stroke, or cardiovascular death, a highly significant result at 12 months in patients treated with clopidogrel. The most pronounced benefit was observed in the reduction of MIs, with the largest reductions of 40% in Q-wave or ST-elevation MI, also statistically significant. In parallel with the reduction in large MI was a 43% reduction in the use of fibrinolytic therapy after randomization and an 18% reduction in radiologically confirmed HF, both of which reached statistical significance. In PCI CLARITY, patients treated with fibrinolysis for STEMI who underwent PCI 2 to 8 days after receiving a 300 mg loading dose of clopidogrel, had reduced incidence of CV death or ischemic complications when compared to those receiving 300 mg clopidogrel immediately prior to PCI (665a). In another trial (ISAR-REACT [Intracoronary Stenting and Antithrombotic Regimen-Rapid Early Action for Coronary Treatment]), a higher loading dose of clopidogrel (600 mg) was used before elective, low-risk stent procedures with favorable results compared with routine abciximab administration (693). However, the sample size was such that it may have been underpowered to show a benefit of abciximab administration in low-risk populations.

After PCI with BMS implantation, short term (at least 1 month) clopidogrel therapy in addition to aspirin leads to greater protection from thrombotic complications than aspirin alone. The benefits of long-term treatment with clopidogrel after PCI and the benefit of initiating pretreatment with clopidogrel with a preprocedural loading dose in addition to aspirin therapy were tested in CREDO (Clopidogrel for the Reduction of Events During Observation), a randomized, double-blind, controlled trial of early and sustained dual oral antiplatelet therapy after PCI (666). In this trial of 2116 patients undergoing PCI from 99 North American centers, the patients received either a 300-mg loading dose of clopidogrel (n equals 1053) or placebo (no loading dose; n equals 1063) 3 to 24 h before PCI. All patients thereafter received clopidogrel 75 mg daily through day 28. For the following 12 months, patients in the loading dose group received clopidogrel and those in the control group received placebo. All patients received aspirin (325 mg per day through day 28, 81 to 325 mg daily thereafter) throughout the study. At 1 year, long-term clopidogrel therapy was associated with a 27% RRR in the combined risk of death, MI, or stroke for an absolute reduction of 3% (*P* equals 0.02). Clopidogrel pretreatment did not significantly reduce MACE at 28 days. However, in a prespecified subgroup analysis, the patients who received clopidogrel at least 6 h before PCI had a RRR of 39% (*P* equals 0.051) for the combined end point compared with no reduction with treatment less than 6 h before PCI. Major bleeding risk at 1 year increased but not significantly (8.8% with clopidogrel vs 6.7% with placebo, *P* equals 0.07). These data suggest that after PCI, long-term clopidogrel therapy (1 year) significantly reduced the risk of adverse ischemic events. A 300-mg loading dose of clopidogrel given at least 3 h before the procedure did not reduce events at 28 days, but longer intervals between the loading dose and PCI appeared to be associated with a highly favorable trend toward reduced events.

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Importantly, the CREDO trial did not have a control group that was given a loading dose at the time of the procedure.

The effects of pretreatment with clopidogrel and aspirin followed by long-term therapy in patients undergoing PCI was also evaluated in the PCI CURE study (667). The PCI CURE study examined 2658 patients with non–ST-elevation acute coronary syndromes undergoing PCI assigned randomly to double-blind treatment with clopidogrel (n equals 1313) or placebo (n equals 1345). The patients were pretreated with aspirin and the study drug for 6 days before PCI during initial hospital admission and for 10 days overall. After PCI, 80% of patients in both groups received open-label clopidogrel for 4 weeks, after which the study drug was restarted for a mean of 8 months. Fifty-nine patients (4.5% in the clopidogrel group) experienced the primary end point of cardiovascular death, MI, or urgent target-lesion revascularization within 30 days compared with 6.4% in the placebo group (*P* equals 0.03). Long-term clopidogrel administration after PCI conferred a lower rate of cardiovascular death, MI, or any revascularization (*P* equals 0.03) and cardiovascular death or MI (*P* equals 0.047). Including events before and after PCI, there was an overall reduction of 31% in cardiovascular death and MI (*P* equals 0.002).

The use of clopidogrel in patients with diabetes had especially favorable results. The CAPRIE (Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events) trial showed a 9% RRR that favored clopidogrel versus aspirin for cardiovascular events. A subgroup analysis in patients who had prior cardiac surgery and who had been randomized to clopidogrel revealed a significant reduction in risk of MI, stroke, and cardiovascular death compared with those taking aspirin. In patients with diabetes in the CAPRIE substudy, the benefit of clopidogrel appeared larger compared with aspirin alone, especially in those who required insulin (694). Tabulation of the number of adverse events prevented per 1000 patients treated for 1 year with clopidogrel compared with aspirin revealed 9 events prevented in the patients without diabetes, with 21 events in all patients with diabetes and 38 in insulin-requiring patients with diabetes.

Further trials are needed to identify the optimum loading dose and timing of clopidogrel administration before PCI. A strategy of administering a 300-mg loading dose 6 h before PCI has the best established evidence of efficacy (666). Higher loading doses increase the magnitude and speed of inhibition of platelet aggregation; however, no large-scale randomized trials have been conducted to date comparing the efficacy and safety of different loading doses of clopidogrel. Furthermore, an important consideration in the decision for pretreatment is the increased risk of bleeding in patients managed with CABG. The ARMYDA-2 trial (Antiplatelet therapy for the Reduction of MYocardial Damage during Angioplasty) is a randomized, prospective, double-blind study of patients with stable angina or UA/NSTEMI and indications for coronary angiography. In this trial, 126 patients were randomized to a 600-mg loading dose and 129 patients to a 300-mg loading dose 4 to 8 h before PCI. The primary end point of death, MI (defined as CK-MB greater than 3 times the upper limit of normal), or target-vessel revascularization up to 30 days after the procedure occurred in 4% of patients in the 600-mg loading dose group and 12% in the 300-mg loading dose group (*P* equals 0.041) owing to a reduction in periprocedural MI. This was a small study of relatively low-risk patients, with only a few patients receiving IIb/IIIa inhibitors. Thus, whether the results would also apply to higher-risk patients taking IIb/IIIa blockers is unknown (695). Some insights may be derived from the CLEAR PLATELETS study (Clopidogrel Loading With Eptifibatide to Arrest the Reactivity of Platelets), which evaluated a 300-mg and 600-mg clopidogrel loading dose with or without eptifibatide in 120 patients undergoing elective stenting procedures. Clopidogrel was administered immediately after stenting. Aggregometry and flow cytometry were used to assess platelet reactivity. The authors concluded that a strategy of eptifibatide administration was associated with superior platelet inhibition and lower cardiac biomarker release than high-dose (600 mg) or standard-dose (300 mg) clopidogrel at the time of PCI (696). Further study is needed to determine the relationship of platelet reactivity to clinical outcomes such as bleeding, myocardial necrosis, and stent thrombosis, which could not be derived from this small, pharmacodynamic study.

Continuation of combination treatment with aspirin and clopidogrel after PCI appears to reduce rates of cardiovascular ischemic events (666,667,697,698). On the basis of randomized clinical trial protocols, aspirin 325 mg daily should be given for at least 1 month after BMS implantation (unless there is a risk of bleeding, in which case it should be given for 2 weeks), 3 months after SES implantation, and 6 months after paclitaxel-eluting stent (PES) implantation, after which daily chronic aspirin should be continued indefinitely at a dose of 75 to 162 mg. Likewise, clopidogrel 75 mg daily should be given for at least 1 month after BMS implantation, 3 months after SES implantation, and 6 months after PES implantation and ideally up to 12 months in patients who are not at high risk of bleeding. To reduce the incidence of bleeding complications associated with dual antiplatelet therapy, lower-dose aspirin (75 to 162 mg daily) is recommended for long-term therapy (665).

6.2.2. Glycoprotein IIb/IIIa Inhibitors

Class I

In patients with UA/NSTEMI undergoing PCI without clopidogrel administration, a GP IIb/IIIa inhibitor (abciximab, eptifibatide, or tirofiban) should be administered. *(Level of Evidence: A)

Class IIa

1. **In patients with UA/NSTEMI undergoing PCI with clopidogrel administration, it is reasonable to administer a GP IIb/IIIa inhibitor (abciximab, eptifibatide, or tirofiban). *(Level of Evidence: B)****
2. **In patients with STEMI undergoing PCI, it is reasonable to administer abciximab as early as possible.**

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(Level of Evidence: B)

3. **In patients undergoing elective PCI with stent placement, it is reasonable to administer a GP IIb/IIIa inhibitor (abciximab, eptifibatide, or tirofiban).** ***(Level of Evidence: B)***

Class IIb

In patients with STEMI undergoing PCI, treatment with eptifibatide or tirofiban may be considered. ***(Level of Evidence: C)***

*It is acceptable to administer the GP IIb/IIIa inhibitor before performance of the diagnostic angiogram ("upstream treatment") or just before PCI ("in-lab treatment").

Aspirin is only a partial inhibitor of platelet aggregation (699,700), because it affects only cyclooxygenase, thereby preventing the formation of thromboxane A_2. Functionally active GP IIb/IIIa receptors aggregate platelets through fibrin bound at the receptor sites. These receptors are activated by a variety of agonists, including thromboxane A_2, serotonin, adenosine diphosphate, and collagen, among others. The binding of fibrinogen and other adhesive proteins to adjacent platelets by means of the GP IIb/IIIa receptor serves as the "final common pathway" of platelet-thrombus formation and can be effectively attenuated by GP IIb/IIIa antagonists. These agents have reduced the frequency of ischemic complications after coronary angioplasty. Individual studies evaluating the impact of intravenous GP IIb/IIIa receptor antagonists on survival for patients undergoing PCI have not had adequate power to examine a difference in mortality. Two meta-analyses of GP IIb/IIIa trials (abciximab, eptifibatide, and tirofiban) have been performed to examine this potential benefit. In 1 meta-analysis involving 12 trials of 20 186 patients, overall 30-day mortality was significantly reduced by GP IIb/IIIa inhibition, although no individual trial showed a mortality benefit. At 6 months, the survival benefit was not significant. The trials included in this analysis encompassed a range of patient characteristics (e.g., UA, NSTEMI, and STEMI), therapeutic regimens (e.g., elective PCI, primary PCI), and adjunctive drugs. In another meta-analysis, which involved 19 trials of 20 137 patients, 30-day and 6-month mortality were both significantly reduced for those receiving IIb/IIIa receptor antagonists (Tables 24a and 24b) (64,111,112,191,195,198,200,201,442,443,701-717). Thus, patients undergoing PCI can expect a lower 30-day mortality when GP IIb/IIIa therapy is utilized. The RRR appears to be similar in trials of patients with or without acute MI and for trials using stents or another PCI as the intended primary procedure. Similar reductions in nonfatal MI are seen in association with the use of GP IIb/IIIa receptor antagonists.

There is no consistent evidence that the GP IIb/IIIa inhibitors reduce the frequency of late restenosis in patients without diabetes. In EPISTENT, patients with diabetes who received abciximab therapy in conjunction with stent deployment had a 51% reduction in target-vessel revascularization at 6 months (230,718). This trial is the only one that has shown a reduction in target-vessel revascularization in the diabetic group.

A long-term mortality benefit of abciximab in patients with diabetes undergoing PCI was demonstrated in a pooled analysis of 3 trials (EPIC, EPILOG, and EPISTENT; 4.5% vs 2.5%, P equals 0.03) (718). A meta-analysis showed that the 30-day mortality benefit in patients with diabetes in the setting of UA/NSTEMI was greater in patients undergoing PCI (719).

In a meta-analysis of invasive versus conservative therapy of patients with UA/NSTEMI, men demonstrated a clear survival advantage with routine invasive therapy with GP IIb/IIIa inhibitors and intracoronary stents; however, with similar therapy, the results for women were not improved significantly (205).

On the basis of the numerous trials to date, intravenous GP IIb/IIIa receptor inhibitors should be considered in patients undergoing PCI, particularly those with UA/NSTEMI or with other clinical characteristics of high risk (Table 25). Detailed discussion of the trials applicable to UA/NSTEMI and STEMI patients can be found in the respective ACC/AHA guidelines (332,493).

6.2.2.1. Abciximab

Trials of GP IIb/IIIa inhibitors have utilized different definitions for adjuncting end points. These should be considered when the results are evaluated.

The clinical safety and efficacy of abciximab have been evaluated extensively in many randomized trials of patients with acute coronary syndromes with and without high-risk clinical features. These studies include EPIC (Evaluation of 7E3 for the Prevention of Ischemic Complications) (704), EPILOG (Evaluation of Percutaneous transluminal coronary angioplasty to Improve Long-term Outcome with abciximab GP IIb/IIIA blockade) (705), and EPISTENT (Evaluation of Platelet IIb/IIIa Inhibition in STENTing) (111). Despite early problems with excessive bleeding when weight-adjusted heparin dosing was not employed, abciximab was superior to placebo in all settings for reducing MACE.

ISAR-REACT randomly compared abciximab (n equals 1079) versus placebo (n equals 1080) in low-risk PCI patients pretreated with high-dose clopidogrel (600 mg orally) 2 h before the procedure, then with 75 mg BID for 3 days followed by 75 mg per day for 3 months (693). At 30 days, there was no difference between the groups. Thus, in that trial of low-risk patients having elective PCI, there was no benefit to the use of abciximab in patients receiving high-dose pretreatment with clopidogrel. The sample size was such that it may have been underpowered to show a benefit in low-risk populations (693).

Heeschen et al. (192), for the CAPTURE (Chimeric c7E3 AntiPlatelet Therapy in Unstable angina REfractory to standard treatment) investigators, demonstrated that troponin T, but not C-reactive protein, was predictive of cardiac risk during the initial 72-h period in the treatment of UA patients with standard therapy or with abciximab. Hamm et al. (193),

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Table 24a. Eligible Trials of Intravenous Glycoprotein IIb/IIIa Inhibitors Used in Evaluation of Mortality After PCI

Trial (Reference)	n	PCI	AMI, % (Time)	Post-PCI Heparin	Male, %	Mean Age, y	Past Medical History, %				
							DM	HTN	MI	PCI	CABG
Abciximab											
RAPPORT (443)	483	PTCA or DCA	100 (less than 12 h)	Yes	72	61	22	48	19	14	
ADMIRAL (442)	300	Stenting	100 (less than 12 h)	Yes	82	61	18	38	11	14	12
CADILLAC (64)	2082	PTCA/stenting	100 (less than 12 h)	No	73	60	17	48	14	11	2
EPIC (702-704)	2099	PTCA or DCA	30 (less than 12 h)	Yes	72	61	24	55	38	22	15
EPILOG (705,706)	2792	PTCA or DCA	0	No	72	60	23	ND	27	ND	13
EPISTENT (111,112,191)	1603	Stenting	0	No	75	59	20	53	51	ND	9
CAPTURE (195)	1266	PTCA	0	Yes	73	61	14	42	40	13	3
ERASER (280)	225	Stenting	Negligible*	No	79	59	14	50	ND	14	ND
Petronio et al. (708)	89	PTCA	100 (less than 24 h)	No	65	60	18	ND	10	ND	1
Simoons et al. (710)	60	PTCA	0	No	73	61	ND	ND	42	15	4
Kini et al. (711)	100	HSRA	0	No	75	64	26	44	18	ND	15
Tamburino et al. (712)	107	Stenting	0	No	87	62	27	34	67	ND	ND
ISAR-2 (707)	401	Stenting	100	Yes	76	60	15	64	ND	7	4
Eptifibatide											
IMPACT (713)	150	PTCA or DCA	0	Yes	75	61	21	53	43	39	17
IMPACT-II (198)	4010	Various†	3 (less than 24 h)	No	75	61	23	54	41	30	16
ESPRIT (200,201)	2064	Stenting	0	No	73	62	20	59	32	23	10
Harrington et al. 73 (714)		Various†	0	No	75	60	29	68	45	ND	26
Tirofiban											
RESTORE (715,716)	2141	PTCA or DCA	32 (less than 72 h)	No	72	59	20	55	34	21	7
Kereiakis et al. (717)	93	PTCA	0	Yes	82	59	24	53	47	23	15

AMI indicates acute MI; CABG, coronary artery bypass graft surgery; DCA, directional coronary atherectomy; DM, diabetes mellitus; h, hour; HSRA, high-speed rotational atherectomy; HTN, hypertension; MI, myocardial infarction; n, number of patients; ND, no data; PCI, percutaneous coronary intervention (originally intended procedure[s] in each trial); PTCA, percutaneous transluminal coronary angioplasty; and y, year. For expansion of study names, see corresponding reference.

*14% of patients had unstable angina or AMI within less than 48 h.

†PTCA, DCA, and HSRA (also excimer laser in IMPACT-II).

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Table 24b. Subgroup Analyses for Mortality After PCI in Trials of Glycoprotein IIb/IIIa Inhibitors (See Table 24a for eligible trials)

	30 Days		6 Months	
	No. of Studies	**RR (95% CI)**	**No. of Studies**	**RR (95% CI)**
	20 (20 137)*	**0.69 (0.53 to 0.90)***	**14 (15 651)***	**0.79 (0.64 to 0.97)***
Population				
AMI	6 (3355)	0.69 (0.45 to 1.05)	6 (3355)	0.76 (0.55 to 1.05)
Mixed	2 (4240)	0.95 (0.54 to 1.68)	2 (4240)	0.97 (0.65 to 1.44)
Non-AMI	12 (12 542)	0.59 (0.39 to 0.89)	6 (8056)	0.71 (0.49 to 1.03)
Procedure				
Stent	7 (5736)	0.69 (0.43 to 1.09)	7 (5736)	0.70 (0.49 to 1.01)
Other	13 (14 401)	0.70 (0.51 to 0.96)	7 (9915)	0.84 (0.65 to 1.09)
Postprocedure				
Heparin	7 (4791)	0.72 (0.47 to 1.09)	5 (4548)	0.83 (0.60 to 1.13)
No heparin	13 (15 346)	0.68 (0.49 to 0.95)	9 (11 103)	0.77 (0.58 to 1.01)
Agent				
Abciximab	14 (11 606)	0.69 (0.51 to 0.94)	12 (11 446)	0.77 (0.61 to 0.96)
Tirofiban	2 (2234)	1.05 (0.42 to 2.61)	1 (2141)	1.27 (0.65 to 2.48)
Eptifibatide	4 (6297)	0.60 (0.33 to 1.06)	1 (2064)	0.56 (0.24 to 1.34)

AMI indicates acute myocardial infarction; CI, confidence interval; No., number; and RR, risk ratio (fixed effects).
There was no statistically significant heterogeneity in any case, and random effects estimates were similar (data not shown).
*Refers to all patients.
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for the CAPTURE investigators, also reported that among the 1265 patients with UA enrolled in the CAPTURE trial, troponin T and CK-MB from 890 patients correlated with subsequent 6-month adverse cardiac risk. In patients without elevated troponin T levels, there was no benefit of treatment with respect to the relative risk of death or MI at 6 months (OR 1.26, CI 95% 0.74 to 2.31; *P* equals 0.47). Serum troponin T level, which is considered to be a surrogate marker for thrombus formation, identified a high-risk subgroup of patients with refractory UA suitable for coronary intervention who would particularly benefit from antiplatelet treatment with abciximab (192).

One putative limitation of abciximab is the potential for immune-mediated hypersensitivity reactions after subsequent readministration. Thrombocytopenia after readministration occurs in 3.5% to 6.3% of patients, which is similar to the rate of occurrence in patients receiving abciximab for the first time. Therefore, the absence of thrombocytopenia after a first abciximab exposure does not guarantee protection against its occurrence upon re-exposure. Moreover, the prevalence of severe thrombocytopenia (2.8%) and profound thrombocytopenia (2.0%) is greater with readministration than the incidence observed after first-time administration (1.0% and 0.4% for severe and profound thrombocytopenia, respectively) (202). With the first administration, human antichimeric antibodies (HACA) form in approximately 6% of patients (702). The implications of HACA, however, are unclear. Among 500 patients enrolled in the ReoPro Readministration Registry (R3), there were no cases of anaphylaxis or other allergic manifestations whether or not HACA was present, and HACA was not predictive of any other measure of complication or success. From the R3 study, HACA has been shown to be an IgG (not IgE) immunoglobulin that does not neutralize abciximab. The more worrisome clinical phenomenon associated with readministration is the potential for increased rates of thrombocytopenia. In the 500-patient R3, a 4.4% incidence in thrombocytopenia (to a platelet count of less than 100 × 109 per liter) was observed, with half of the patients developing acute profound thrombocytopenia (to a platelet count of less than 20 × 109 per liter). This potential complication should always be monitored when treating a patient with abciximab (194-197). Abciximab readministration poses greater risk within 2 weeks of original abciximab dose.

6.2.2.2. Eptifibatide

The clinical utility of eptifibatide, a short-acting cyclic heptapeptide that also inhibits the GP IIb/IIIa receptor, was evaluated in the Integrilin to Manage Platelet Aggregation to prevent Coronary Thrombosis-II (IMPACT-II) trial, a double-blind, randomized, placebo-controlled multicenter trial that enrolled 4010 patients undergoing coronary angioplasty (198). Patients were assigned to treatment with aspirin, heparin and placebo, aspirin, heparin, and eptifibatide bolus (135 mcg per kg) followed by a low-dose eptifibatide infu-

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Table 25. Recommendations for Use of GP IIb/IIIa Inhibitors in Patients Undergoing PCI

UA/NSTEMI and Clopidogrel Used	UA/NSTEMI and Clopidogrel Not Used	STEMI	Elective PCI
Abciximab, eptifibatide, or tirofiban	Abciximab, eptifibatide, or or tirofiban	Abciximab	Abciximab, eptifibatide, or tirofiban
Class IIa; LOE: B	*Class I; LOE: A*	*Class IIa; LOE: B*	*Class IIa; LOE: B*
		Eptifibatide or tirofiban	
		Class IIb; LOE: C	

LOE indicates level of evidence; PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction; and UA/NSTEMI, unstable angina/non–ST-elevation myocardial infarction.

sion (0.5 mcg per kg per min for 20 to 24 h), or aspirin, heparin, and eptifibatide bolus (135 mcg per kg) and higher-dose infusion (0.75 mcg per kg per min for 20 to 24 h) (198). The 30-day composite primary end point of death, MI, unplanned surgical or repeat percutaneous revascularization, or coronary stent implantation for abrupt closure occurred in 11.4% of placebo-treated patients compared with 9.2% in the 135/0.5-mcg eptifibatide group (*P* equals 0.063) and 9.9% in the 135/0.75-mcg eptifibatide group (*P* equals 0.22) (198). The frequency of major bleeding events and transfusions was similar among the 3 groups.

A higher bolus and infusion of eptifibatide was evaluated in 10 948 patients with UA/NSTEMI who were assigned to treatment with placebo or 1 of 2 doses of eptifibatide: 180 mcg per kg bolus plus 1.3 mcg per kg per min infusion (180/1.3) or 180 mcg per kg bolus plus 2.0 mcg per kg per min infusion (180/2.0) (199). Compared with placebo, patients receiving 180/2.0-mcg eptifibatide had a lower frequency of 30-day death or MI (15.7% vs 14.2%; *P* equals 0.042). In patients undergoing early (less than 72 h) coronary intervention, 30-day composite events occurred less often in patients receiving 180/2.0-mcg eptifibatide (11.6% and 16.7% in placebo-treated patients; *P* equals 0.01) (200, 201).

The ESPRIT (Enhanced Suppression of the Platelet IIb/IIIa Receptor with Integrilin Therapy) trial evaluated the efficacy and safety of eptifibatide treatment as adjunctive therapy during nonemergency coronary stent implantation. A total of 2064 patients were enrolled from June 1999 to February 2000 in this multicenter, randomized, double-blind, parallel-group, placebo-controlled (crossover-permitted) clinical trial. A double-bolus regimen of eptifibatide (180 mcg per kg bolus followed by a 2.0 mcg per kg per min infusion, with a second 180 mcg per kg bolus given 10 min after the first bolus) was compared with placebo treatment. The 48-h primary composite end point of death, MI, urgent target-vessel revascularization, or bailout treatment with open-label GP IIb/IIIa inhibitor therapy was reduced 37% from 10.5% to 6.6% (*P* equals 0.0015). There was a consistent treatment benefit across all components of the end point and across all subgroups of patients. At 30 days, the key secondary composite end point of death, MI, and urgent target-vessel revascularization was also improved 35% from 10.4% to 6.8% (*P* equals 0.0034) (200,201).

6.2.2.3. Tirofiban

Tirofiban is a nonpeptidyl tyrosine derivative that produces a dose-dependent inhibition of GP IIb/IIIa–mediated platelet aggregation (720). The clinical effect of tirofiban during coronary angioplasty was evaluated in the Randomized Efficacy Study of Tirofiban for Outcomes and Restenosis (RESTORE) trial, a double-blind, placebo-controlled trial of 2139 patients with UA or acute MI defined by CK measured at the end of 36 h or at the time of discharge (715). Patients were randomly assigned to aspirin, heparin, and a tirofiban bolus (10 mcg per kg over 3 min) plus infusion (0.15 mcg per kg per minute), or to aspirin, heparin, and a placebo bolus plus infusion for 36 h. The primary end point of the trial was the occurrence of major events at 30-day, including death due to any cause, MI, coronary bypass surgery due to angioplasty failure or recurrent ischemia, repeat target-vessel angioplasty for recurrent ischemia, or insertion of a stent due to threatened abrupt closure (715). The rate of primary 30-day end point was reduced from 12.2% in the placebo group to 10.3% in the tirofiban group (*P* equals 0.160). Patients treated with tirofiban had a 38% relative reduction in the composite end point at 48 h (*P* less than 0.005) and a 27% relative reduction at 7 days (*P* equals 0.022). The incidence of major bleeding was similar in the 2 groups with the TIMI criteria (2.4% in tirofiban-treated patients and 2.1% in placebo-treated patients; *P* equals 0.662) (715), although major bleeding tended to be higher in tirofiban-treated patients (5.3% vs 3.7% in placebo-treated patients; *P* equals 0.096). Thrombocytopenia was similar in both groups (0.9% for the placebo group vs 1.1% for the tirofiban group; *P* equals 0.709) (721). A larger clinical benefit with tirofiban was seen in patients with UA undergoing coronary angioplasty in the PRISM-PLUS study, a randomized trial of 1570 patients with UA or non–Q-wave MI assigned to 48- to 108-h treatment with heparin plus tirofiban or heparin alone (722). Coronary angioplasty was performed in 30.5% of patients between 49 to 96 h after randomization (722). The composite end point of death, MI, or refractory ischemia was reduced significantly in the heparin plus tirofiban group compared with the heparin alone group (10.0% vs 15.7%; *P* less than 0.01) (722).

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6.2.3. Antithrombotic Therapy

6.2.3.1. Unfractionated Heparin, Low-Molecular-Weight Heparin, and Bivalirudin

Class I

1. **Unfractionated heparin should be administered to patients undergoing PCI.** ***(Level of Evidence: C)***
2. **For patients with heparin-induced thrombocytopenia, it is recommended that bivalirudin or argatroban be used to replace heparin.** ***(Level of Evidence: B)***

Class IIa

1. **It is reasonable to use bivalirudin as an alternative to unfractionated heparin and glycoprotein IIb/IIIa antagonists in low-risk patients undergoing elective PCI.** ***(Level of Evidence: B)***
2. **Low-molecular-weight heparin is a reasonable alternative to unfractionated heparin in patients with UA/NSTEMI undergoing PCI.** ***(Level of Evidence: B)***

Class IIb

Low-molecular-weight heparin may be considered as an alternative to unfractionated heparin in patients with STEMI undergoing PCI. ***(Level of Evidence: B)***

Intravenous unfractionated heparin prevents clot formation at the site of arterial injury (723) and on coronary guidewires and catheters used for coronary angioplasty (724). Although the intensity of anticoagulation with unfractionated heparin is generally determined with activated partial thromboplastin times, these values are less useful for monitoring anticoagulation during coronary angioplasty, because higher levels of anticoagulation are needed than can be discriminated with the activated partial thromboplastin time alone. Instead, the activated clotting time (ACT) has been more useful to follow heparin therapy during coronary angioplasty (725). The Hemochron and HemoTec devices are commonly used to measure ACT values during coronary angioplasty (725-727). The Hemochron ACT generally exceeds the HemoTec ACT by 30 to 50 s, although considerable measurement variability exists.

Empiric recommendations regarding heparin dosage during coronary angioplasty have been proposed (728,729), but ACT levels after a fixed dose of unfractionated heparin may vary substantially due to differences in body size (730), concomitant use of other medications, including intravenous nitroglycerin (731,732), and in the presence of acute coronary syndromes that increase heparin resistance.

The relationship between the level of the ACT and development of ischemic complications during coronary angioplasty has been controversial. Whereas some studies have identified an inverse relationship between the initial ACT and the risk of ischemic events (733,734), others found either no relationship or a direct relationship between the degree of anticoagulation and occurrence of complications (735). It is generally believed that very high levels (ACTs greater than 400 to 600 s) of periprocedural anticoagulation are associated with an increased risk for bleeding complications (736).

The safety of low-dose heparin during coronary angioplasty has also been shown in a recent study. Fatal complications (0.3%), emergency bypass surgery (1.7%), MI (3.3%), or repeat angioplasty within 48 h (0.7%) were uncommon after an empiric bolus of heparin 5000 U at the beginning of the procedure (618). In a smaller randomized study of 400 patients assigned to fixed-dose heparin (15 000 international units [IU]) or weight-adjusted heparin (100 IU per kg), there were no differences in procedural success or bleeding complications between the 2 groups (737), although use of the weight-adjusted heparin resulted in earlier sheath removal and more rapid transfer to a step-down unit (737). Another advantage of weight-adjusted heparin dosing is that "overshooting" of the ACT value can be avoided.

Two analyses of ACT and PCI-related complications have not detected any relationship between ACT level and ischemic complications, which suggests that the degree of anticoagulation during PCI may be less of a factor in determining complications than in the earlier era of balloon angioplasty (738,739). The results of these limited studies suggest that heparin is an intraprocedural component for PCI, despite dosing uncertainties and an unpredictable therapeutic response with the unfractionated preparation. It appears that weight-adjusted heparin dosing may provide a clinically superior anticoagulation method to fixed heparin dosing, although definitive studies are lacking.

Routine use of unfractionated heparin after an uncomplicated coronary angioplasty is no longer recommended (72,740-743) and may be associated with more frequent bleeding events (72,740), particularly when platelet GP IIb/IIIa inhibitors are used (72,740). Subcutaneous administration of unfractionated heparin (741) may provide a safer and less costly means of extending antithrombin therapy than intravenous unfractionated heparin if there are clinical reasons to continue anticoagulation, such as residual thrombus or significant residual dissections.

In the SYNERGY (Superior Yield of the New strategy of Enoxaparin, Revascularization and Glycoprotein IIb/IIIa Inhibitors) study, patients with NSTEMI were randomized to treatment with either unfractionated heparin or subcutaneously administered enoxaparin. In patients who underwent PCI within 8 h of the last subcutaneous dose, no additional anticoagulation was administered. In those patients who underwent PCI 8 to 12 h after the last subcutaneous dose, an additional intravenous dose of enoxaparin 0.3 mg per kg was administered at the time of PCI. The rates of major ischemic complications in those patients undergoing PCI were similar between those treated with unfractionated heparin and those treated with enoxaparin (744). Bleeding was observed to be higher in those patients who "crossed over" from one anticoagulant to the other. Some of these crossover patients were those who received a different anticoagulant than what they had been randomized to and had received before. On the basis of this observation, it appears prudent to not give an additional anticoagulant to patients who are receiving one

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form of anticoagulant (e.g., not to give unfractionated heparin to those who have received subcutaneous enoxaparin within the last 12 h and not to give intravenous enoxaparin to those receiving intravenous heparin).

The safety and efficacy of low-molecular-weight heparin therapy in patients undergoing PCI has been evaluated. In all but 1 of these studies, the agent studied has been enoxaparin. These studies have found bleeding and ischemic complication rates to be low and comparable to those observed in PCI patients who had been treated with unfractionated heparin.

In those patients who have received subcutaneous enoxaparin for the treatment of NSTEMI and are to undergo PCI within 8 h of the last subcutaneous dose, no additional anticoagulant should be administered. In those who undergo PCI 8 to 12 h after the last subcutaneous dose, an additional intravenous dose of 0.3 mg per kg should be administered immediately before device activation.

Bivalirudin, a hirudin analog, is a direct thrombin inhibitor. It has been tested against heparin and a GP IIb/IIIa inhibitor in the REPLACE-2 trial of patients undergoing PCI without high-risk features. The primary end point at 30 days included major bleeding plus the usual end points of death, MI, and urgent revascularization. These events occurred in 9.2% of the bivalirudin group and 10% of the group given unfractionated heparin plus GP IIb/IIIa inhibitors (nonsignificant). The secondary end point was freedom from death, MI, and urgent revascularization and occurred in 7.6% of the bivalirudin group and 7.1% of the group given unfractionated heparin plus GP IIb/IIIa inhibitors (also nonsignificant), but bleeding (combined major and moderate bleeding) was significantly reduced in the bivalirudin group (from 7.1% to 2.4%, *P* less than 0.001). Although a small, nonsignificant increase in periprocedural NSTEMI was seen in the bivalirudin-treated patients, by 1 year mortality was not significantly increased in the bivalirudin group (1.89% vs 2.46 %) (744a). These results established that bivalirudin is not superior to standard therapy, but it appears to be a reasonable alternative in non-high-risk patients (745). Bivalirudin is a good anticoagulant for use in patients with heparin-induced thrombocytopenia and those with renal failure (746). Argatroban is also an effective therapy for heparin-induced thrombocytopenia (747). More data are needed to establish its use for patients with STEMI, NSTEMI, and diabetes.

6.2.3.2. Heparin Dosing Guidelines

In those patients who do not receive GP IIb/IIIa inhibitors, sufficient unfractionated heparin should be given during coronary angioplasty to achieve an ACT of 250 to 300 s with the HemoTec device and 300 to 350 s (200,201) with the Hemochron device. A weight-adjusted bolus heparin (70 to 100 IU per kg) can be used to avoid excess anticoagulation. If the target values for ACT are not achieved after a bolus of heparin, additional heparin boluses (2000 to 5000 IU) can be given. Early sheath removal should be performed when the ACT falls to less than 150 to 180 s.

The unfractionated heparin bolus should be reduced to 50 to 70 IU per kg when GP IIb/IIIa inhibitors are given in order to achieve a target ACT of 200 s with either the HemoTec or Hemochron device. The currently recommended target ACT for eptifibatide and tirofiban is less than 300 s during coronary angioplasty. Postprocedural heparin infusions are not recommended during GP IIb/IIIa therapy (748-750).

Transitioning of patients with acute coronary syndromes who have been treated with enoxaparin from the medical floor to the cardiac catheterization laboratory is based on pharmacokinetic data, clinical experience, and expert opinion. In patients who received the last subcutaneously administered dose of enoxaparin within 8 h, no additional anticoagulant therapy is needed before PCI is performed. In patients who received the last subcutaneously administered dose of enoxaparin between 8 and 12 h before PCI, an additional 0.3 mg per kg dose of enoxaparin should be administered intravenously before PCI (whether or not the patient is to be treated with a GP IIb/IIIa inhibitor). Alternatively, in the latter group of patients, supplemental anticoagulation with unfractionated heparin can be used. Unfractionated heparin 50 U per kg (with a target ACT of 200 to 250 s) may be administered in those patients to be treated with a GP IIb/IIIa inhibitor; 60 U per kg unfractionated heparin (with a target ACT of 250 to 300 s) may be administered in those patients who are not concomitantly treated with a GP IIb/IIIa inhibitor. A higher risk of bleeding may result if patients cross over between different anticoagulant therapies during the index admission.

Low-molecular-weight heparins have little effect on measurements of ACT. Therefore, the ACT should not be used as a guide to anticoagulation therapy in patients currently being treated with a low-molecular-weight heparin. Sheath removal when followed by manual groin compression may be performed 4 h after the last intravenous dose of enoxaparin or 6 to 8 h after the last subcutaneous dose of enoxaparin (751,752).

6.3. Post-PCI Management

After PCI, in-hospital care should focus on monitoring the patient for recurrent myocardial ischemia, achieving hemostasis at the catheter insertion site, detecting and preventing contrast-induced renal failure, and monitoring results of the vascular closure device, if used (753). Attention should also be directed toward implementing appropriate secondary atherosclerosis prevention programs. The patient should understand and adhere to recommended medical therapies and behavior modifications known to reduce subsequent morbidity and mortality from coronary heart disease.

Most patients can be safely discharged from the hospital within the next calendar day after an uncomplicated elective PCI. Special skilled nursing units have been developed by many institutions to facilitate post-PCI management. Specific protocols for sheath removal, continuation of anticoagulation or antiplatelet therapies, and observation for recurrent myocardial ischemia/infarction and contrast-induced renal failure are of particular assistance in ensuring appropriate outcomes during this period. Pilot studies suggest that selected patients may be discharged on the same day

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after PCI (754,755) especially when the procedure is performed by the percutaneous radial or brachial approach (756). However, confirmation by larger studies is necessary before widespread endorsement of this strategy.

In the prior setting of aggressive systemic anticoagulation, vascular complications may occur in as many as 14% of patients after PCI, but those requiring surgical repair occur in 3.5% (736) of patients, although lower rates of vascular complications can now be expected with reduced anticoagulation and smaller sheath sizes (757-762). Major factors associated with vascular complications include use of fibrinolytic or platelet inhibitor therapy, coexisting peripheral vascular disease, female gender, prolonged heparin use with delayed sheath removal, and older age (736,758,760-764). Although most bleeding complications at the vascular access site are obvious and readily managed, physicians and nurses should remain alert for retroperitoneal hematoma, the signs and symptoms of which may include hypotension, marked suprainguinal tenderness, and severe back or lower-quadrant abdominal pain (765). Post-PCI hematocrit should be monitored for a decrease greater than absolute 5% to 6%. Computed tomography can confirm the diagnosis of retroperitoneal hematoma, and more than 80% of patients can be treated conservatively with transfusions without surgery (764). Pseudoaneurysms may be treated effectively with ultrasound-directed compression in the majority of patients who are not bleeding and do not require continued anticoagulation (763,766,767). Arteriovenous fistulas, generally occurring late after a procedure, are detected by a continuous murmur over the puncture site and, in rare cases, may be associated with high-output failure. In general, repeat use of the access site should be avoided because of the possibility of making the fistula larger, accessing the vein when attempting to access the artery, and increasing potential issues with hemostasis. Both pseudoaneurysm and arteriovenous fistula can occur secondary to cannulation of the superficial rather than the common femoral artery (768). Arterial compression systems and percutaneous vascular closure devices reduce the incidence of vascular complications (753,756). A meta-analysis involving 37 000 patients undergoing diagnostic coronary arteriography and PCI compared manual compression with 3 closure devices (VasoSeal™, AngioSeal™, and PerClose™). No difference was seen in access-related complications between manual compression, PerClose™, and AngioSeal™; however, there were more complications associated with VasoSeal™ than with manual compression. The complications evaluated included pseudoaneurysm requiring ultrasound-guided compression or surgical repair; arteriovenous fistula; retroperitoneal hematoma causing hemodynamic compromise and necessitating surgery, blood transfusion, prolonged hospitalization, and/or death; femoral artery thrombosis (vessel occlusion requiring surgery or thrombolysis); surgical vascular repair; access-site infection necessitating treatment with antibiotics or surgical drainage; and blood transfusion. The study was performed with early generations of devices. Potential benefits of newer adjunctive therapies are not well established (753,769). However, the degree to which these technologies reduce length of hospital stay and cost remains to be determined (764,770-772).

Patients with pre-existing renal insufficiency, diabetes, and dehydration are at higher risk and should be monitored for contrast-induced nephropathy, generally defined as an increase of greater than 25% or greater than 0.5 mg per dL in serum creatinine that occurs within 48 h after PCI. In addition, those patients receiving higher contrast loads or a second contrast load within 72 h and those undergoing IABP placement should have renal function assessed. A risk score based on 8 variables (hypotension, IABP, HF, chronic renal insufficiency, diabetes, age more than 75 years, anemia, and contrast volume) has been developed to assist in the identification of patients at risk for contrast-induced nephropathy after PCI (773). Whenever possible, nephrotoxic drugs (certain antibiotics, nonsteroidal anti-inflammatory agents, and cyclosporine) and metformin (especially in those with pre-existing renal dysfunction) should be withheld for 24 h before PCI is performed, and consideration should be given to withholding angiotensin converting enzyme inhibitors and angiotensin receptor blockers on the day of the procedure (774-776). Although data on the prevention of contrast-induced nephropathy are inconclusive, several measures including preprocedural and postprocedural hydration, use of low and iso-osmolar contrast agents, and pretreatment with acetylcysteine or sodium bicarbonate may be helpful in reducing the incidence of contrast-induced nephropathy among higher-risk patients (774,775,777).

6.3.1. Postprocedure Evaluation of Ischemia

After PCI, chest pain may occur in as many as 50% of patients. ECG evidence of ischemia identifies those with significant risk for acute vessel closure (6,118,119,778-780). When angina pectoris or ischemic ECG changes occur after PCI, the decision to proceed with further interventional procedures, CABG surgery, or medical therapy should be individualized on the basis of factors such as hemodynamic stability, amount of myocardium at risk, and the likelihood that the treatment will be successful.

A 12-lead ECG should be obtained before and soon after PCI and again if symptoms should occur. Angina-like symptoms with ECG changes will assist in determining the need for repeat angiography and for additional therapy.

As discussed in Section 6.2.2, coronary stents and platelet GP receptor inhibitors have reduced the incidence of acute closure significantly. Factors that correlate with a poor outcome after acute coronary closure include age greater than 70 years, large ischemic burden, presentation with acute coronary syndromes, and LV ejection fraction less than 30% (778-780).

Elevated levels of CK or the MB subfraction (CK-MB) or ECG abnormalities are reported to occur in 5% to 30% of patients after PCI (23). The mechanisms associated with CK release include side-branch occlusion, distal embolization, intimal dissection, and coronary spasm (781). A more frequent requirement for revascularization procedures and a

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higher risk of death or subsequent MI are associated with elevated cardiac biomarkers, increasing as a continuous function with no obvious threshold effect. Both acute and chronic complications are more common among patients with elevated cardiac biomarkers. Even in patients with low-level elevations of CK-MB in whom the in-hospital risk is low, the intermediate- and long-term risks are also increased. Postprocedural increases in CK and CK-MB are not specific for a particular technique and have been reported after balloon angioplasty, directional and rotablator atherectomy, excimer laser angioplasty, and stent placement. Kong et al. (782) found that increased levels of CK are a significant independent predictor of cardiac mortality and subsequent MI (56). Cardiac mortality after elective PCI was significantly higher for patients with high (more than 3.0 times normal) and intermediate (1.5 to 3.0 times normal) CK compared with those with low CK (more than 1.0 but less than 1.5 times normal) elevations and control patients (P equals 0.007). (See Section 3.2, Acute Outcome: Procedural Complications.)

CK and CK-MB measurements should be obtained in patients with suspected ischemia (prolonged chest pain, side-branch occlusion, recurrent ischemia, or hemodynamic instability) during PCI. Ideally, the European Society of Cardiology and the ACC recommend that small infarcts may and should be detected by serial blood sampling and analysis before and after the procedure (6 to 8 h before and 24 h after, respectively) (21). In patients in whom a clinically driven CK-MB determination is made, a CK-MB index increase of more than 5 times the upper limit of normal should be treated as signifying an MI, and the patient should be referred for further observation. The results of CK-MB should be considered for the discharge management strategies for these patients.

The troponin isoforms I and T have a high level of sensitivity and specificity for the diagnosis of acute MI. Troponin T or I elevation occurs frequently after PCI. The timing of the peak elevation after PCI is unclear (25). Minor elevations do not appear to have prognostic value, whereas marked (more than 5 times) elevations are associated with worsened 1-year outcome (26,27).

6.3.2. Risk Factor Modifications

All patients should be instructed about necessary behavior and risk factor modification, and the appropriate medical therapies should be initiated for the secondary prevention of atherosclerosis before the patient leaves the hospital. The interventional cardiologist should emphasize the importance of these measures directly to the patient, because failure to do so may suggest that secondary prevention therapies are not necessary. The interventional cardiologist should interact with the primary care physician to ensure that the necessary secondary prevention therapies initiated during hospitalization are maintained by patients after discharge from the hospital. Secondary prevention measures are an essential part of long-term therapy because they can reduce future morbidity and mortality associated with the atherosclerotic process.

Depending on the risk factors and contraindications present, advice should include antithrombotic therapy (aspirin and/or clopidogrel or ticlopidine), control of hypertension, diabetic management, aggressive control of serum lipids, maintenance of a low-density lipoprotein cholesterol level substantially below 100 mg per dL (optional therapeutic target less than 70 mg per dL in very-high-risk patients [611]), abstinence from tobacco use, weight control, regular exercise, beta-blocker use, and inhibition of the renin-angiotensin-aldosterone system as recommended in the ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction (Table 26) (332,783). Given the natural history and pathophysiology of CAD among patients undergoing PCI, the clinically indicated secondary prevention measures (Table 26) (332,783), which usually include aspirin, statin therapy, beta-blockers, and inhibitors of the renin-angiotensin-aldosterone system, should be continued indefinitely except in those patients intolerant to these agents (242,783-792). Patients should receive instructions on participation in cardiac rehabilitation and the timing of return to full activities, be informed to contact their physician or seek immediate medical attention if symptoms recur, and have made plans for a follow-up visit to assess compliance with secondary prevention therapies.

6.3.3. Exercise Testing After PCI

The published ACC/AHA practice guidelines for exercise testing (793) provide an excellent summary of the available information on exercise testing after PTCA. Although restenosis remains the major limitation of PCI, symptom status is an unreliable index to development of restenosis, with 25% of asymptomatic patients documented as having ischemia on exercise testing (794). (See Section 5.1, Patients With Asymptomatic Ischemia or CCS Class I or II Angina for further information.)

To identify restenosis rather than predict the probability of its occurrence, patients may be tested later (3 to 6 months after PCI). Table 27 reviews the predictive value of exercise testing for restenosis (794-802). Variability is attributed predominantly to differences in the populations studied and criteria for restenosis.

Because myocardial ischemia, whether painful or silent, worsens prognosis (803), some authorities have advocated routine testing. However, the ACC/AHA practice guidelines for exercise testing favor selective evaluation in patients considered to be at particularly high risk (e.g., patients with decreased LV function, multivessel CAD, proximal LAD disease, previous sudden death, diabetes mellitus, left main disease, hazardous occupations, and suboptimal PCI results) (793). The exercise ECG is an insensitive predictor of restenosis, with sensitivities ranging from 40% to 55%, significantly less than those obtainable with single photon emission computed tomography (SPECT) (804,805) or exercise echocardiography (806-808). This lower sensitivity of the exercise ECG and its inability to localize disease limit its usefulness in patient management both before and after PCI (797,804,809). For these reasons, stress imaging is preferred

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Table 26. Comprehensive Risk Reduction for Patients With Coronary and Other Vascular Disease After PCI

Goals	Intervention Recommendations
Smoking: Goal Complete cessation. No exposure to environmental tobacco smoke	Ask about tobacco status at every visit. Strongly encourage patient and family to stop smoking and to avoid environmental tobacco smoke. Assess the tobacco user's willingness to quit. Assist by counseling and developing a plan for quitting. Arrange follow-up, referral to special programs, orpharmacological therapy (including nicotine replacement and buproprion). Urge avoidance of exposure to environmental tobacco smoke at work and home.
Blood pressure control: Goal Less than 140 over 90 mm Hg or less than 130 over 80 mm Hg if chronic kidney disease or diabetes is present	*If blood pressure is 120 over 80 mm Hg or greater:*· • Initiate or maintain lifestyle modification (weight control, increased physical activity, alcohol moderation, moderate sodium restriction, and emphasis on fruits, vegetables, and low-fat dairy products) in all patients. *If blood pressure is 140 over 90 mm Hg or greater (or 130 over 80 mm Hg or greater for individuals with chronic kidney disease or diabetes):* • Add blood pressure medication, emphasizing the use of beta-blockers and inhibitors of the renin-angiotensin-aldosterone system.
Lipid management: (TG less than 200 mg per dL) Primary goal LDL-C substantially less than 100 mg per dL (optional target less than 70 mg per dL for very-high-risk patients)¶	Start dietary therapy in all patients (less than 7% of total calories as saturated fat and less than 200 mg of cholesterol per day). Promote physical activity and weight management. Encourage increased consumption of omega-3 fatty acids in fish# or 1 g per day omega-3 fatty acids from supplements for risk reduction (for treatment of elevated TG, higher doses are usually necessary for risk reduction). Assess fasting lipid profile in all patients, preferably within 24 h of an acute event. For patients hospitalized, initiate lipid-lowering medication as recommended below before discharge according to the following guide: LDL-C less than 100 mg per dL (baseline or on-treatment): • Statins preferred to lower LDL-C. LDL-C greater than or equal to 100 mg per dL (baseline or on-treatment): • Initiate or intensify LDL-C–lowering therapy with drug treatment. May require combination therapy with standard-dose ezetimide, bile acid sequestrant, or niacin‡.
Lipid management: (TG 200 mg per dL or greater) Primary goal Non–HDL-C* substantially less than 130 mg per dL	If TG is greater than or equal to 150 mg per dL or HDL-C is less than 40 mg per dL: • Emphasize weight management and physical activity. Advise smoking cessation. If TG is 200-499 mg per dL: • After LDL-C–lowering therapy†**, consider adding fibrate or niacin‡. If TG is greater than or equal to 500 mg per dL: • Consider fibrate or niacin‡ before LDL-C–lowering therapy.†** • Consider omega-3 fatty acids as adjunct for high TG.
Physical activity: Minimum goal 30 minutes 5 days per week; optimal daily	Assess risk, preferably with exercise test, to guide prescription. Encourage minimum of 30 to 60 minutes of activity, preferably daily or at least 5 times weekly (brisk walking, jogging, cycling, or other aerobic activity) supplemented by an increase in daily lifestyle activities (e.g., walking breaks at work, gardening, household work). Encourage resistance training 2 days per week. Cardiac rehabilitation programs are recommended, particularly for those patients with multiple modifiable risk factors and/or those moderate- to high-risk patients in whom supervised exercise training is warranted.

Continued on next page

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Table 26. *Continued*

Goals	Intervention Recommendations
Weight management: Goal BMI 18.5 to 24.9 kg per m^2 Waist circumference: Women: Less than 35 inches Men: Less than 40 inches	Calculate BMI and measure waist circumference as part of evaluation. Monitor response of BMI and waist circumference to therapy. Start weight management and physical activity as appropriate. Desirable BMI range: 18.5 to 24.9 kg per m^2. If waist circumference is 35 inches or greater in women or 40 inches or greater in men, initiate lifestyle changes and consider treatment strategies for metabolic syndrome.
Diabetes management: Goal HbA1c less than 7%	Appropriate glucose-lowering therapy to achieve near-normal fasting plasma glucose as indicated by HbA1c. Treatment of other risk factors (e.g., physical activity, weight management, blood pressure cholesterol management).
Antiplatelet agents/ anticoagulants:	For all post-PCI stented patients, aspirin 325 mg daily should be given for at least 1 month after bare metal stent implantation, 3 months after sirolimus stent, and 6 months after paclitaxel stent, after which daily chronic aspirin†† (75 to 162 mg per day) should be continued indefinitely in all patients if not contraindicated. For post-PCI stented patients, clopidogrel 75 mg per day should be given for at least 1 month after bare metal stent implantation, 3 months after sirolimus stent, and 6 months after paclitaxel stent, after which clopidogrel should ideally be continued up to 12 months in all stented patients who are not at high risk of bleeding. Use warfarin in combination with clopidogrel and low-dose aspirin with great caution and when INR is carefully regulated (2.0 to 3.0). Manage warfarin to INR 2.5 to 3.5 for post-MI patients when clinically indicated or for those not able to take aspirin or clopidogrel.
Renin-angiotensin-aldosterone system blockers:	Consider ACE inhibitors for all CHD patients indefinitely; start early after MI in stable high-risk patients (anterior MI, previous MI, Killip class greater than or equal to II [S_3 gallop, rales, radiographic HF]). Continue indefinitely in for all patients with LV dysfunction (ejection fraction less than or equal to 0.40) or symptoms of heart failure. Use as needed to manage blood pressure or consider for chronic therapy in all other patients. Use angiotensin receptor blockers in post-STEMI patients who are intolerant of ACE inhibitors and who have either clinical or radiological signs of heart failure or LVEF less than 0.40. Aldosterone blockade in post-STEMI patients without significant renal dysfunction§ or hyperkalemia¦ who are already receiving therapeutic doses of an ACE inhibitor, have an LVEF less than or equal to 0.40, and have either diabetes or heart failure.
Beta-blockers:	Start in all post-MI and acute patients (arrhythmia, LV dysfunction, inducible ischemia). Continue for a minimum of 6 months; continue indefinitely in patients with STEMI. Observe usual contraindications. Use as needed to manage angina, rhythm, or blood pressure in all other patients.

ACE indicates angiotensin-converting enzyme; BMI, body mass index; HF, congestive heart failure; CHD, coronary heart disease; HDL-C, high-density lipoprotein cholesterol; INR, international normalized ratio; LDL-C, low-density lipoprotein cholesterol; LV, left ventricular; LVEF, left ventricular ejection fraction; MI, myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction; and TG, triglyceride.

*Non–HDL-C equals total cholesterol minus HDL cholesterol.

†Treat to a goal of non–HDL-C substantially less than 130 mg per dL.

‡Dietary supplement niacin must not be used as a substitute for prescription niacin.

§Creatinine should be less than or equal to 2.5 mg per dL in men and less than or equal to 2.0 mg per dL in women.

¦Potassium should be less than or equal to 5.0 mEq per liter.

¶Patients with acute coronary syndromes and other very-high-risk patients (e.g., established CHD plus multiple major risk factors [especially diabetes] or severe and poorly controlled risk factors [especially continued cigarette smoking and/or metabolic syndrome]) should be considered for optional LDL-C goal less than 70 mg per dL.

#Pregnant and lactating women should limit their intake of fish to minimize exposure to methylmercury.

**The use of resin is relatively contraindicated when TGs are greater than 200 mg per dL.

††Some recommend avoiding regular use of ibuprofen, which may limit the cardioprotective effects of aspirin. Use of cyclo-oxygenase-2 inhibitors may be associated with increased incidence of cardiovascular events.

Modified with permission from Smith et al. Circulation 2001;104:1577-9 (810) (at dosing and at writing an initial release) and Antman et al. J Am Coll Cardiol 2004;44:e1-e211 (362).

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Table 27. Predictive Value of Exercise ECG Testing for Identification of Restenosis After PCI

Author	Year	Ref	n	Clinical	Post-PCI, mo	Restenosis, %	Positive PV, %	Negative PV, %	Definition of Restenosis
Dadel	1989	(795)	398	Consecutive	Up to 6	33	66	75	Greater than 70% luminal diameter stenosis
Honan	1989	(796)	144	Post-MI	6	40	57	64	Greater than 75% luminal diameter stenosis
Schroeder	1989	(797)	111	Asymptomatic	6	12	53	63	Greater than 70% luminal diameter stenosis
Lnarman	1990	(798)	141	Asymptomatic	1 to 6	12	15	87	Greater than 50% luminal diameter stenosis
el-Tamimi	1990	(799)	31	Consecutive	6	45	100	94	Loss of more than 50% initial gain of lumen diameter
Bengston	1990	(794)	200	Asymptomatic (n=127)	6	44	46	63	Greater than 75% luminal diameter stenosis
			200	Symptomatic (n=66)	6	59	76	47	Greater than 75% luminal diameter stenosis
Roth	1994	(800)	78	1-vessel CAD	6	28	37	77	Greater than 50% luminal diameter stenosis
Desmet	1995	(801)	191	Asymptomatic	6	33	52	70	Greater than 50% luminal diameter stenosis

CAD indicates coronary artery disease; MI, myocardial infarction; mo, month; n, number of patients; PCI, percutaneous coronary intervention; PV, predictive value; and Ref, reference.

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to evaluate symptomatic patients after PCI. If the patient's exertional capacity is significantly limited, coronary angiography may be more efficacious to evaluate symptoms of typical angina. Exercise testing after discharge is helpful for activity counseling and exercise training as part of cardiac rehabilitation. Neither exercise testing nor radionuclide imaging is indicated for the routine, periodic monitoring of asymptomatic patients after PCI without specific indications.

6.3.4. Left Main CAD

Class IIa

It is reasonable that patients undergoing PCI to unprotected left main coronary obstructions be followed up with coronary angiography between 2 and 6 months after PCI. ***(Level of Evidence: C)***

Careful postprocedure surveillance with coronary angiography is needed to prevent fatal MI or sudden death that may be associated with ISR with a large area of myocardium in jeopardy; however, the frequency and best method of follow-up is unknown (162). Early experience in the ULTIMA registry using BMS for ULM lesions suggested a high early mortality (2% per month) after PCI, which led the study's authors to suggest routine surveillance angiography at 2 and 4 months after PCI (153). Others advocate routine stress testing or cardiac catheterization at 3 and 6 months even in asymptomatic patients (148,150). In view of these observations and suggestions, the Committee recommends routine surveillance angiography at 2 to 3 months for all patients after ULM PCI. Studies from the DES era have reported the performance of routine angiography 4 to 8 months after PCI or earlier if clinically indicated by symptoms or documented myocardial ischemia (159,160).

7. SPECIAL CONSIDERATIONS

7.1. Ad Hoc Angioplasty—PCI at the Time of Initial Cardiac Catheterization

Ad hoc coronary intervention is defined as PCI performed at the same time as diagnostic cardiac catheterization. During the past several years, in an effort to reduce hospital length of stay and potentially reduce costs, PCI has increasingly been performed immediately after the diagnostic coronary angiographic procedure (811), with reported incidence ranging from 52% to 83% (812-814). The indications for diagnostic catheterization and coronary angiography in different catheterization laboratory settings are discussed in the ACC/SCAI Expert Consensus Document on Catheterization Laboratory Standards (Table 28) (309,815).

Ad hoc angioplasty has several inherent advantages. It expedites patient care, avoids a second invasive procedure with its associated risks and recognized morbidity, and reduces total X-ray exposure and therefore cost, but only in settings in which intrinsic risks are low (813). However, ad hoc intervention is associated with a higher procedural contrast use and should be avoided in situations where excessive

Table 28. Exclusion Criteria for Invasive Cardiac Procedures in Settings Without Full-Support Services

Location	Type of Patient	Diagnostic Procedures	Therapeutic Procedures
Hospitals	Adult	Age greater than 75 years NYHA class III or IV heart failure Acute, intermediate, or high-risk ischemic syndromes Recent MI with postinfarction ischemia Pulmonary edema thought to be caused by ischemia Markedly abnormal noninvasive test indicating a high likelihood of left main or severe multivessel coronary disease Known left main coronary artery disease Severe valvular dysfunction, especially in the setting of depressed LV performance	All valvuloplasty procedures, complex adult congenital heart disease diagnostic or therapeutic procedures Diagnostic pericardiocentesis when the effusion is small or moderate in size and there is no tamponade Elective coronary intervention
	Pediatric	No procedures approved	No procedures approved
Freestanding laboratories	Adult	All of the above plus high-risk patients by virtue of comorbid conditions, including need for anticoagulation, poorly controlled hypertension or diabetes, contrast allergy, or renal insufficiency	
	Pediatric	No procedures approved	No procedures approved

LV indicates left ventricular, MI, myocardial infarction; and NYHA, New York Heart Association.
Modified from Bashore et al. J Am Coll Cardiol 2001;37:2170-214.

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contrast has been used and when adequate pretreatment with aspirin or antiplatelet agents has not been achieved (814).

In contrast to ad hoc angioplasty, a staged approach also has several advantages. It allows ample time to review the angiogram and plan the procedural strategy; discuss the risks, benefits, and alternatives with the patient and family; and obtain consultation from cardiothoracic surgical colleagues. It is far more difficult to adequately inform the patient of risks, benefits, and alternatives without knowledge of the anatomy and the extent of coronary disease. A staged approach also allows for optimal hydration and pretreatment with oral antiplatelet agents. Explicit and clear informed consent, especially for ad hoc PCI, should be discussed by the interventional cardiologist with the patient and family.

Studies evaluating the outcome of patients undergoing ad hoc coronary intervention have reported that informed patients with suitable anatomy have a shorter hospital stay, less radiation exposure, and lower costs without an increase in procedural complications compared with patients undergoing a staged approach (812,813,816,817). In a multicenter cohort study of 35 700 patients undergoing elective coronary angioplasty between 1992 and 1995, the risk of a major complication (MI, emergency CABG, or death) from combined ("ad hoc") versus staged procedures was 2% and 1.6%, respectively. After adjustment for clinical and angiographic differences between groups, the risk from combined procedures was not significantly different. However, patients with multivessel disease, women, patients older than 65 years, and patients undergoing multilesion coronary angioplasty were at increased risk of an adverse outcome (818). In an analysis of patients in the New York State PCI Registry, in-hospital mortality was similar in patients undergoing ad hoc and staged procedures, although patients with HF had a significantly lower mortality when undergoing staged procedures. These studies suggest that it is safe to perform PCI after diagnostic catheterization in selected patients (819).

Ad hoc coronary intervention is particularly suitable for patients with clinical evidence of restenosis 6 to 12 months after the initial procedure (820), patients undergoing primary angioplasty for MI, and patients with refractory UA in need of urgent revascularization (821). Before the procedure, these patients should be treated with aspirin and clopidogrel (822) only when PCI with stent placement is highly likely, and they should give appropriate informed consent for anticipated PCI. Ad hoc PCI should be performed only in a well-informed patient, particularly in the setting of single-vessel disease without morphologic features predictive of an adverse outcome, when it is clear that this treatment strategy is the best alternative. However, ad hoc percutaneous revascularization should not be performed in patients in whom the angiographic findings are unanticipated or in whom the indication, suitability, or preference for percutaneous revascularization is unclear (823). Patient safety should be the paramount consideration when ad hoc intervention is being considered. This Committee endorses the recommendations from the SCAI that ad hoc PCI be individualized and not be a standard or required strategy for all patients (824). The Writing Committee encourages future studies to further evaluate the outcomes associated with ad hoc angioplasty and its cost effectiveness.

7.2. PCI in Cardiac Transplant Patients

Allograft atherosclerosis and vasculopathy are the main cause of death in cardiac transplant recipients. Because no medical therapy is known to prevent graft atherosclerosis, and retransplantation is associated with decreased survival, palliative therapy with PCI has been proposed and performed (825). No single medical center has performed PCI in many patients, and thus, the responses and outcomes of a large cohort are unavailable for review. However, pooled information from 11 medical centers retrospectively analyzing results of coronary angioplasty in cardiac transplant patients has been reported (826). These investigators concluded that although high procedural success can be achieved and PCI may be applied in a selected cardiac transplant population with success and complication rates comparable to the routine patient population, it remains unknown whether PCI prolongs allograft survival.

Coronary stenting in cardiac allograft vascular disease has been performed in small numbers of patients with favorable results (827). Heublein et al. (828) compared angioplasty and stenting in 27 patients who received 48 stents, 5.7 plus or minus 2.9 years after heart transplantation. Coronary angioplasty resulted in a minimal increase in luminal dimensions compared with stenting (2.04 plus or minus 0.36 mm for angioplasty vs 2.53 plus or minus 0.38 mm for stenting). There were no stent thromboses or bleeding complications. At a mean follow-up period of 8 plus or minus 5 months (range 2 weeks to 23 months), all patients were clinically event-free. Six of 24 stented vessels in 16 patients had restenosis greater than 50% by ultrasound or angiography 6 months after the procedure. These somewhat disappointing results highlight the need for a better understanding of the mechanism of graft vasculopathy and the development of refined, specific PCI-related therapies with better outcomes. The largest reported experience of PCI in cardiac transplant recipients to date showed that PCI with stents is effective in relieving focal stenoses in patients with allograft coronary disease (829). Between 1990 and 2000, 62 patients (1.5 to 15 years after transplant) underwent 151 procedures that resulted in PCI of 219 lesions. Periprocedural mortality was low at 2% (4 of 151 procedures). Two-year freedom from allograft coronary disease death or graft loss was 74% for 1-vessel disease at first PCI, 75% for 2-vessel disease, and 27% for 3-vessel disease (P equals 0.009). There were no incidences of acute stent thrombosis. Freedom from repeat PCI of the same vessel ranged from 75% at 6 months to 57% at 4 years. Freedom from restenosis ranged from 95% at 1 month to 57% at 6 months. Multivariate predictors of freedom from restenosis were the use of stents, higher antiproliferative immunosuppressant dose, and an era effect (e.g., procedural advances and widespread use of periprocedural GP IIb/IIIa inhibitors and thienopyridines, among others). Long-term

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survival effects remain under examination (Table 29) (826,830-833).

7.3. Clinical Restenosis: Background and Management

7.3.1. Background on Restenosis After PTCA

Angiographic restenosis after PTCA has been reported to occur in 32% to 40% of patients within 6 months after the procedure (80,85). Initial procedural success rates after PTCA of restenotic lesions appear similar to those after PTCA for de novo lesions. The risk for repeat angiographic restenosis after repeat PTCA for a single episode of restenosis also appears similar to the restenosis risk for de novo lesions (834,835). The risk of recurrent symptoms progressively increases with the number of restenosis episodes, approaching 50% to 53% for patients undergoing a fourth PTCA for a third episode of restenosis (836,837).

7.3.2. Clinical and Angiographic Factors for Restenosis After PTCA

A number of factors are associated with lesion recurrence among patients undergoing a second PTCA for restenosis. These factors include an interval less than 60 to 90 days between the initial angioplasty and the treatment of restenosis (834-838), LAD lesion location (837), multivessel versus single-vessel redilations (838), the presence of diabetes mellitus (834,838), hypertension (834), UA (834), need for higher (7 atm) balloon inflation pressures (835), and multiple (3) balloon inflations (835,836). Of these, the most important factor is the time between the initial and subsequent PTCA (839). In a series of 423 patients, restenosis was more common in those having repeat angioplasty less than 3 months after a first angioplasty than in patients undergoing later redilation (56% vs 37%, *P* equals 0.007) (839).

Some studies have suggested that lesions become longer and more severe after repeat PTCA of restenotic lesions (840,841). In a serial angiographic study, the mean stenosis length before the initial angioplasty was 7.0 mm but increased to 8.7 mm at the time of the repeat procedure (an increase of more than 1.7 mm, 95% CI 0.6 to 2.8 mm, *P* less than 0.01) (841). A history of restenosis may also predict the risk for subsequent restenosis after PTCA of a new lesion (104). Multivariate analysis identified that prior restenosis (*P* less than 0.02, OR equals 3.4), LAD location of stenosis (*P* less than 0.04, OR equals 3.0), and severity of stenosis before PTCA (*P* less than 0.02, OR equals 1.8) were independently associated with restenosis after PTCA (104).

7.3.3. Management Strategies for Restenosis After PTCA

Class IIa

It is reasonable to consider that patients who develop restenosis after PTCA or PTCA with atheroablative devices are candidates for repeat coronary intervention with intracoronary stents if anatomic factors are appropriate. ***(Level of Evidence: B)***

Long-term patency of the initial target lesion may be achieved with repeated balloon dilatations. In a series of 1455 de novo lesions treated with PTCA, angiographic restenosis requiring repeat PTCA developed in 32% (842). Late patency was achieved in 93% of lesions with up to 3 PTCA procedures. Only 23 lesions (1.6%) required 4 or more procedures (842).

Although atheroablation devices have been developed in an attempt to lower the second restenosis risk in patients, none has shown an incremental benefit over PTCA. In a study of 1569 patients who underwent excimer laser coronary angioplasty for restenotic (n equals 620 patients) or de novo (n equals 949) lesions (843), procedural success was higher in restenotic patients (92% vs 88% in de novo patients; *P* less than 0.001), although clinical recurrence was high in both groups (49% in restenotic patients and 44% in de novo patients, *P* equals NS) (843).

Stent placement is superior to PTCA for the treatment of restenotic lesions. In the REstenosis STent (REST) Study (844), a randomized clinical trial, late clinical and angiographic outcomes were compared in 351 patients undergoing either PTCA or Palmaz-Schatz stent placement for restenotic lesions. Stent-treated patients had lower rates of target-lesion revascularization (10% vs 32% in balloon-treated patients) and restenosis (18% vs 32% in balloon-treated patients; *P* equals 0.03) (844).

Given these findings, it is recommended that patients who develop restenosis after an initially successful PTCA be considered for repeat PCI with stent placement. Factors that may influence this decision include the technical difficulty of the initial procedure, the potential for the lesion to be treated successfully with a stent, and the severity and extent of the restenotic process. If restenosis presents as a much longer lesion than was originally present, additional procedures may aggravate rather than relieve coronary narrowing. If repeat intervention is performed, treatment with a stent appears to be preferred. Each time restenosis recurs, consideration should be given to alternate methods of revascularization, particularly CABG surgery, as well as continued medical therapy. Patients who have angiographic evidence of restenosis but no symptoms or evidence for ischemia may be able to continue with medical therapy alone. It is recommended that patients who develop restenosis after PTCA or atheroablative device therapy plus PTCA be candidates for repeat coronary intervention with intracoronary stents if anatomy is appropriate. Patients who have no signs or symptoms of ischemia and who have intermediate (50%) stenoses at the time of clinical follow-up may not require PCI and, especially where the anatomy is complex, may be followed up for evidence of ischemia rather than subjected to PCI.

7.3.4. Background on Restenosis After BMS Implantation

Although coronary stents have been shown to reduce the frequency of restenosis compared with conventional balloon angioplasty, lumen renarrowing due to intimal hyperplasia within the stent may develop in 17% to 32% of patients

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Table 29. Coronary Angioplasty Studies in Heart Transplant Patients

First Author	Year	Ref.	n	Procedures	Lesions	Time After Tx, mo	Success Rate, %	Major Complex	Minor Complex	Restenosis Rate at More Than 6 mo, %	1-Year Event-Free Rate, %	Late Death or reTx at More Than 6 mo, n
Haffine	1992	(826)	35	51	95	45 plus or minus 5	93	3	3	NA	60	7
Sanghu	1992	(830)	8	11	13	43 plus or minus 19	85	NA	1	NA	38	4
Swan	1993	(831)	13	31	NA	NA	NA	NA	NA	100	NA	NA
Von Scheidt	1995	(832)	14	38	62	41 plus or minus 25	97	1	NA	61	60	5
Pane	1996	(833)	8	NA	11	NA	91	1	1	NA	50	3

mo indicates month; n, number of patients; NA, not applicable; Ref., reference; reTX, retreatment; and Tx, treatment.

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(80,83,845). A number of factors have been associated with the propensity to develop stent restenosis, including small vessel size (846), smaller postprocedure minimum lumen diameter (847), higher residual percent diameter stenosis (848), lesions located in the LAD (83), stent length, and the presence of diabetes mellitus (721,841,842,844,846-848).

Stent restenosis may occur within the stent, due to intimal hyperplasia, or at the stent margins, due to both intimal hyperplasia and arterial remodeling (849). A serial IVUS study performed in 115 lesions treated with the Palmaz-Schatz stent demonstrated that tissue growth was uniformly distributed throughout the stent at follow-up study, with a slightly higher tendency for neointimal tissue accumulation at the central articulation (850). The stent lumen tended to be smallest at the articulation site, presumably owing to tissue prolapse between the stent struts. For multiple stents, there was no difference in the postintervention or follow-up lumen when overlapped stents were compared with nonoverlapped stents (850). In another series of patients treated with the Palmaz-Schatz stent, 77 (26%) of 301 stent margins were restenotic at follow-up (more than 50% late lumen loss) (849). The dominant periprocedural predictor of stent margin restenosis was the plaque burden of the contiguous reference segment (849).

Balloon angioplasty has been used frequently to treat patients with stent restenosis (851-853). The mechanism of lumen improvement after balloon angioplasty for stent restenosis relates to further stent expansion (851) and extrusion of the tissue through the stent struts (851-854). In an IVUS study of 64 restenotic Palmaz-Schatz stents, 56% plus or minus 28% of the lumen enlargement was the result of additional stent expansion and 44% plus or minus 28% was the result of a decrease in neointimal tissue (851). Despite the use of high-pressure balloon dilation, a relatively high residual stenosis (18% plus or minus 12%) remained after treatment with balloon angioplasty.

The outcome after balloon angioplasty has been variable, depending, in part, on the size of the stented segment and length of the stent restenosis (855). In a consecutive series of 124 patients presenting with stent restenosis successfully treated with repeat percutaneous intervention, clinical follow-up was obtained at 27.4 plus or minus 14.7 months (855). Recurrent clinical events occurred in 25 patients (20%), including death (2%), MI (1%), and target-vessel revascularization (11%) (855). Cumulative event-free survival at 12 and 24 months was 86.2% and 80.7%, respectively (855).

A number of factors have been related to the frequency of clinical recurrence after balloon angioplasty for stent restenosis (855), which include repeat intervention in SVGs, multivessel disease, low ejection fraction, and a 3-month interval between stent implantation and repeat intervention. One preliminary report has shown target-lesion revascularization was related to the length of the stent restenosis, ranging from 10% for focal stent stenosis to 25% for intrastent restenosis, 50% for diffuse stent restenosis, and 80% for stent total occlusions (856).

New coronary devices, including directional (857,858), rotational (859,860), extraction (861-865), and pullback (866) atherectomy, a cutting balloon, and excimer laser-assisted angioplasty, have also been used for stent restenosis before balloon dilation. Although some comparative registry series have suggested an improved angiographic outcome associated with the use of these ablative devices, no long-term studies demonstrating clinical advantage have been completed.

When a significant residual stenosis exists after conventional PTCA of stent restenosis fails to achieve an optimal lumen diameter, additional stents have been used to improve the initial angiographic result (867-869). Although preliminary results of clinical trials failed to demonstrate a benefit using routine BMS placement for the treatment of stent restenosis, favorable results have been shown with DES (see Section 7.3.5 for further discussion) (116,870,871).

Acute platelet inhibition with abciximab does not reduce ISR, as demonstrated in the ERASER (Evaluation of ReoPro And Stenting to Eliminate Restenosis) study (280). In a study of 225 patients randomly allocated to placebo or abciximab before intervention, 215 patients received a stent and the study drug. Of the 191 patients who returned for follow-up more than 4 months after evaluation, there was no difference between tissue volume as measured by IVUS between the placebo and treatment groups. Lack of abciximab benefit was confirmed by quantitative angiography. The investigators concluded that potent platelet inhibition with abciximab as administered in the ERASER study did not reduce ISR.

Since the last (2001) revision of the ACC/AHA PCI guideline, the proportional use of stents in percutaneous interventions has continued to increase. In part, this derives from randomized trial data suggesting that routine stenting is more effective than provisional stenting (636,872-874). In addition, stents are being used in a much wider spectrum of coronary and even graft anatomies (875). Accordingly, ISR has become increasingly important. Because stents prevent elastic recoil and late negative remodeling, the predominant mechanism of ISR is neointimal hyperplasia due to smooth muscle cell proliferation and extracellular matrix production. Two of the biggest changes since the 2001 revision have been the expanding databases of 1) brachytherapy to treat ISR and 2) DES to try to prevent ISR.

7.3.5. Drug-Eluting Stents

Class I

A drug-eluting stent (DES) should be considered as an alternative to the bare-metal stent in subsets of patients in whom trial data suggest efficacy. ***(Level of Evidence: A)***

Class IIb

A DES may be considered for use in anatomic settings in which the usefulness, effectiveness, and safety have not been fully documented in published trials. ***(Level of Evidence: C)***

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All PCI creates injury to the vessel wall, specifically tears or dissection. Larger devices and higher pressures are associated with tears at deeper levels of the vessel wall (media or even adventitia, as opposed to intima and plaque boundary only). All injuries tend to heal; specifically, injury to the vessel wall is associated with re-establishment of an intact endothelial layer. Failure to re-establish an intact, functional endothelial layer is likely to be associated with continued risk of arterial thrombosis and an abnormal balance between vasoconstrictive and vasodilatory mechanisms. In general, deeper injury is associated with more proliferative healing (876-878). The demonstration, by quantitative angiography, that late lumen diameter after balloon angioplasty follows a "normal" or Gaussian distribution supports the concept that restenosis is an exaggerated healing response rather than a distinct biologic process, which occurs in a minority of individuals.

For balloon angioplasty, the healing response includes, on the macroscopic level, negative (narrowing) and positive (dilatation) remodeling, elastic recoil, and neointimal hyperplasia. Because stents block elastic recoil and negative remodeling, ISR is predominantly due to neointimal hyperplasia. Neointimal hyperplasia is the name given to a complex process of multifactorial causation, which leads to vessel lumen encroachment. The causes of neointimal hyperplasia appear to include, but are not limited to, the following inflammatory response involving cells and molecular mediators; growth factors and cytokines; release of mediators and upregulation of signaling systems that stimulate cellular migration and proliferation; activation, adherence, and aggregation of platelets; and thrombosis with release of clotting factors. Neointimal hyperplasia may be distinct from atherosclerosis and negative remodeling, but it shares many of the same causative factors. Accordingly, investigators and clinicians are inclined to try many of the same antithrombotic, antiplatelet, anti-inflammatory, and antiproliferative agents to try to modify atherosclerosis, neointimal hyperplasia, and negative remodeling. Additionally, many therapeutic agents affect multiple mechanisms.

To date, no systemically administered therapeutic agent has consistently reduced restenosis after balloon angioplasty or placement of BMS. Stents have reduced restenosis relative to balloon angioplasty (albeit with increased late loss due to increased neointimal proliferation), and locally delivered radiation (brachytherapy) has reduced ISR. Taken together, these observations and the early success of sirolimus- and paclitaxel-eluting stents have supported the paradigm of blocking elastic recoil and negative remodeling with a mechanical stent and inhibiting neointimal hyperplasia with a locally delivered (higher concentration than can be achieved systemically) antiproliferative and anti-inflammatory agent.

Local delivery of a therapeutic agent with stents has taken 2 forms: simple coating of the stent and adherence of the therapeutic agent to a polymer, which allows for sustained release over time. Diffusion of the therapeutic agent into the tissues and into blood is an additional complexity. For coated stents, the long-term outcome depends on the response to both stent and coating. For DES, the long-term healing response depends on the response to the polymer and the therapeutic agent, as well as the stent. As evidenced by the trials of gold coating and the preliminary experiences (registry) with the QuaDS stent, actinomycin, and batimastat, some combinations are potentially even more proliferative, inflammatory, or thrombogenic than BMS.

Peer-reviewed publications of human DES implantation, including consecutive case series and randomized trials, are available for 3 polymer-based, drug-eluting, balloon-expandable stent systems (Table 30) (236,441,624,628,697,698, 879-888): the antiproliferative, antimigratory, anti-inflammatory macrolide antibiotic rapamycin (sirolimus) affixed to a stent (Bx Velocity); the 7-hexanoyltaxol (QP2)-eluting polymer stent system (QuaDS); and the microtubule inhibitor paclitaxel (TAXUS) affixed to a stent. Each of these systems had undergone rigorous testing in animal models that demonstrated an intact endothelial layer and significant reductions in neointimal hyperplasia and inflammation.

The first reported series of 45 patients who underwent SES implantation in either Sao Paulo, Brazil, or Rotterdam, Holland, demonstrated the virtual absence of intimal hyperplasia at 4 months (889). Subsequent studies of the same cohort at 1 and 2 years continued to document sustained suppression of neointimal hyperplasia as detected with both IVUS and quantitative angiography (628,879). In the Randomized Study With the Sirolimus-Eluting Bx Velocity Balloon-Expandable Stent (RAVEL) trial, 238 patients were randomly allocated between BMS and SES (624). At 6 months the binary restenosis rate was 26% for the bare metal group versus 0% for the DES group, and there were no subacute stent thromboses with a 2-month dual antiplatelet regimen. In 1 year of follow-up, the bare metal group had a 29% rate of MACE versus 5.8% for the sirolimus-eluting group; this difference was driven entirely by target-vessel revascularization.

A 3-year follow-up of the RAVEL trial (890), involving 114 patients from the SES arm and 113 in the BMS arm, documented target-vessel revascularization in 11.4% of the SES group compared with 33.6% of the BMS group. These data support the long-term durability of SES in reducing repeat revascularization compared with BMS.

The SIRIUS (Sirolimus-Eluting Balloon Expandable Stent in the Treatment of Patients With De Novo Native Coronary Artery Lesions) investigators reported 1058 patients randomly allocated at 1 of 53 centers between BMS and SES (93). This cohort included diabetic patients (26%) and somewhat longer lesions (mean 14.4 mm) and smaller-diameter vessels (mean 2.8 mm) than the RAVEL population. Again, the sirolimus-eluting group had lower MACE at 270 days than the BMS group (7.1% vs 18.9%), which was driven by lower rates of target-vessel revascularization (4.1% vs 16.6%). Both quantitative angiography and IVUS were used to document that the mechanism for this salutary effect was decreased neointimal hyperplasia. SIRIUS was the pivotal

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Table 30. Published Randomized Trials and Selected Registry Experiences of Drug-Eluting Stents Compared With Bare Metal Stents

Eluting Drug	Trial (Ref.)	Year	n, Active/Control	Stent	Eluting Drug Dosage	Deaths Active/Control, %	MI, Active/Control, %	Restenosis, Active/Control, %	TLR, Active/Control, %
Sirolimus	FIM (628)	2001	30 in Sao Paulo; 15 in Rotterdam	BxVelocity	140 mcg/cm²	NA	NA	0% at 1 year	Minimal neointimal proliferation at 1 year
	FIM (879)	2002	15 from Rotterdam	BxVelocity	140 mcg/cm²	NA	NA	0% at 2 years	Minimal neointimal proliferation at 2 years
	RAVEL (624)	2002	120/118	BxVelocity	140 mcg/cm²	1.7/1.7	3.3/4.2	0/26.6 at 6 months (*P* less than 0.001)	0/22.9 at 1 year (*P* equals 0.001)
	SIRIUS (698)	2004	533/525	BxVelocity	140 mcg/cm²	0.9/0.6	2.8/3.2	8.9/36.3 at 8 months (*P* less than 0.001)	4.9/20 at 1 year (*P* less than 0.001)
	C-SIRIUS (880)	2004	50/50	BxVelocity	140 mcg/cm²	0/0	2.0/4.0	2.3/51.1	4.0/18.0 at 9 months (*P* less than 0.001)
	E-SIRIUS (881)	2003	175/177	BxVelocity	140 mcg/cm²	1.1/0.6	4.6/2.3	5.9/42.3	4.0/20.9 at 9 months (*P* less than 0.001)
	RESEARCH Registry Overall (236)	2004	508/450	BxVelocity	140 mcg/cm²	1.6/2.0 at 30 days	0.8/1.6 at 30 days	NA	1.0/1.8 at 30 days
	RESEARCH Registry ACS (882)	2003	198/301	BxVelocity	140 mcg/cm²	3.0/3.0 at 30 days	3.0/1.0 at 30 days	NA	1.0/2.7 at 30 days
	RESEARCH Registry STEMI (441)	2004	186/183	BxVelocity	140 mcg/cm²	8.3/8.2 at 300 days	0.5/2.2 at 300 days	NA	1.1/8.2 at 300 days (*P* less than 0.01)
	RESEARCH Registry Chronic Totals (883)	2004	56/28	BxVelocity	140 mcg/cm²	0/0 in hospital	NA	NA	12-month MACE: 5.6/17.2 (*P* less than 0.05)

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Table 30. *Continued*

Eluting Drug	Trial (Ref.)	Year	n, Active/Control	Stent	Eluting Drug Dosage	Deaths Active/Control, %	MI, Active/Control, %	Restenosis, Active/Control, %	TLR, Active/Control, %
Paclitaxel	QuaDS-QP2 (884)	2002	15	QuaDS-QP2	2400 to 3200 mcg total dose	NA	NA	13.3 at 6 months 61.5 at 1 year	20 at 6 months 60 at 1 year
	ASPECT (885)	2003	59 High dose 58 low dose/ 59 control	Supra-G	3.1 mcg/mm² 1.3 mcg/mm²	0.9/0	2.6/1.7	4/12/27 at 4 to 6 months (high dose vs control, *P* less than 0.001)	2/2/2 at 1 to 6 months
	TAXUS I (886)	2003	31/30	NIR	1.0 mcg/mm²	0/0	0/0	0/10 at 6 months (*P* equals 0.012)	0/10 at 1 year (*P* equals 0.237)
	TAXUS II (887)	2003	266/279	NIR	1.0 mcg/mm²	0/0.8	3.1/5.3	7.1/21.9 at 6 months	10.4/21.7 at 12 months
	TAXUS III (888)	2003	28 ISR	NIR	1.0 mcg/mm²	NA	NA	NA	21.4 at 1 year
	TAXUS IV (697)	2004	662/652	EXPRESS	1.0 mcg/mm²	1.4/1.1	3.5/3.7	7.9/26.6 at 9 months (*P* less than 0.0001)	4.4/15.1 at 1 year (*P* less than 0.0001)

ACS indicates cute coronary syndromes; ASPECT, Asian Paclitaxel-Eluting Stent Clinical Trial; FIM, First in Man; ISR, in-stent restenosis; NA, not applicable; RESEARCH, Rapamycin-Eluting and Taxus Stent Evaluated At Rotterdam Cardiology Hospital; SIRIUS, Sirolimus-Eluting Balloon Expandable Stent in the Treatment of Patients With De Novo Native Coronary Artery Lesions (C-SIRIUS indicates Canadian study; E-SIRIUS, European study); and TLR, target-lesion revascularization.

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trial for FDA release of the rapamycin, polymer, Bx Velocity system.

Subsequent studies from the RESEARCH (Rapamycin-Eluting and TAXUS Stent Evaluated At Rotterdam Cardiology Hospital) registry experience at Thoraxcenter, Rotterdam, Netherlands, have documented the short-term safety of using these SES systems in patients with acute coronary syndromes, including STEMI (882,891). An additional small registry experience from the Rotterdam group suggests the potential applicability of the sirolimus DES system to ISR. A consecutive case series of 368 patients with 735 lesions for which 841 SES were implanted documented only 11 cases of restenosis (greater than 50% diameter), and all of those occurred in a focal pattern (892). The operators in that series, which included longer lesions (mean length of lesion 17.48 plus or minus 12.19 mm) and more complex anatomic subsets, learned from earlier studies of DES edge lesions to fully cover diseased segments (mean stent length 27.59 plus or minus 14.02 mm) (892).

TAXUS-I was the first feasibility and safety study of the paclitaxel, polymer, NIR stent system. There were 61 patients randomly allocated between a BMS and DES. At 12 months, the MACE rate was 3% (1 event) in the TAXUS group and 10% in the BMS group (4 events in 3 patients), and there were no subacute stent thromboses. Although these differences were not statistically significantly different, the continuous outcome of minimal lumen diameter was significantly better in the TAXUS group (886).

The ASPECT trial was a 3-center prospective, randomized trial of 177 patients with short (less than 15 mm), favorable (2.25 to 3.5 mm diameter) native vessel lesions who were randomly allocated between bare-metal Cook Supra-G stents and stents bonded with 1 of 2 doses of paclitaxel (885). Interpretation of this trial was complicated by the use of 3 different antiplatelet regimens. Binary restenosis was 4% in the high dose of paclitaxel, 12% in the low dose of paclitaxel, and 27% in the BMS arm. Subsequent mechanistic studies with IVUS documented that the paclitaxel-coated stents reduced neointimal hyperplasia (893).

TAXUS-IV was a prospective, randomized clinical trial of the slow-release; polymer-based paclitaxel-NIR stent system conducted at 73 US centers (94). A total of 1314 patients with native coronary lesions 10 to 28 mm in length and 2.5 to 3.75 mm in diameter were randomly allocated between BMS and the paclitaxel polymer system. At 9 months, angiographic restenosis was reduced from 26.6% to 7.9% with DES, albeit there were no differences in death, MI, or subacute stent thrombosis (0.6% and 0.8%, respectively). It is primarily on the basis of TAXUS-IV that the FDA released the paclitaxel, polymer NIR stent system. TAXUS-III was a registry study that demonstrated the potential efficacy of this DES system for ISR (888).

There is considerable promise and excitement surrounding the release of DES; nevertheless, important reservations remain, including the following:

- Most of the follow-up is still relatively short-term (1 year or less)
- Comparison of the 2 FDA-released systems is needed and should provide clinically useful information. One such trial that supplies information in this regard is ISAR-DESIRE (Intracoronary Stenting and Angiographic Results: Drug-Eluting Stents for In-Stent Restenosis), which is discussed in Section 7.3.6.2.
- Preliminary results from randomized trials (REALITY, SIRTAX) comparing SES and PES (CYPHER versus TAXUS) have not shown large differences in clinical outcomes [M.C. Morice, oral presentation, American College of Cardiology Scientific Session, Orlando, Fla, March 2005; S. Windecker, oral presentation, American College of Cardiology Scientific Session, Orlando, Fla, March 2005].
- Mandated angiographic follow-up applied in trials has increased the reintervention rate, and therefore, the difference between DES and BMS in clinical practice may be less.

The major trials of SES and PES, which were the basis for FDA approval, involved patients with stable or unstable ischemia with documented coronary artery narrowing of 51% to 99%, which stenoses were, for the most part, between 2.75 and 3.5 mm in diameter and 15 to 30 mm in length. Specific clinical exclusions from these landmark trials included the following: MI within 48 h; LV ejection fraction less than 0.25; previous or planned use of brachytherapy; previous PCI of the same lesion; coexisting medical conditions likely to limit life expectancy; contraindications to aspirin, thienopyridines, or stent substances; and severe renal or hematologic comorbidity. Specific angiographic exclusions from these landmark trials included the following: ostial lesions; bifurcation lesions; ULM lesion; SVG lesion; severe calcification; angiographic thrombus; severe tortuosity; and occluded vessel. Babapulle and coworkers have performed a Bayesian meta-analysis of randomized clinical trials of DES that incorporates the results of RAVEL, SIRIUS, C-SIRIUS, and E-SIRIUS regarding rapamycin-eluting stents and TAXUS, I, II, and IV regarding PES (234, 880, 881). These authors also included 4 trials of a nonpolymeric formulation of paclitaxel, which has not been shown to be effective in reducing restenosis or target-lesion or target-vessel revascularization and which has not been released for commercial use (234).

In an effort to extend the application of DES to most of the other clinical angiographic subsets, unstudied in these landmark trials, Serruys and coworkers at Thoraxcenter Rotterdam, the Netherlands, established the RESEARCH Registry (882). In this experience, the rapamycin-eluting stent has been used as the default strategy since it became available, and consecutive prospective cases of particular clinical and angiographic subsets have been compared with

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the immediately prior experience at the same institution with the particular subset (882).

Patients with acute coronary syndromes were considered for SES in a RESEARCH registry comparison of 198 consecutive patients receiving the SES versus a prior consecutive case series of 301 patients with acute coronary syndromes treated with BMS (882). Major adverse cardiac events including death (3.0% vs 3.0%), nonfatal MI (3.0% vs 1.0%), and target-vessel revascularization (1.0% vs 2.7%) were comparable for SES and BMS (total 6.1% vs 6.6%). Lemos and colleagues reported a series of 186 consecutive STEMI patients treated with an SES and compared that group with 183 patients treated with a BMS in terms of both short- and long-term outcomes (441). MACE at 30 days (7.5% vs 10.4%) and stent thrombosis (0% vs 1.6%) were not significantly different for SES compared with BMS patients. By 300 days, both target-vessel revascularization (1.1% vs 8.2%) and MACE (9.4% vs 17.0%) were reduced with SES versus BMS (441). A quantitative study reported by Saia et al demonstrated a binary restenosis rate of 0% at 6 months in a subset of 96 STEMI patients, which documented reduced late loss to a degree comparable to what was seen in the landmark trials of more stable patients with less complex anatomy (891).

Hoye and coauthors compared the outcomes of a consecutive case cohort of 56 patients with chronic total occlusions treated with SES and compared them with a prior consecutive case series of 28 patients with chronic total occlusions treated with BMS (883). By 12 months, MACE was 96.4% with SES and 82.1% with BMS (*P* less than 0.05 by log-rank testing) (883). A consecutive case series of 19 patients with 21 lesions of old SVGs treated with SES had 0% early revascularization and a 1-year (average) MACE of 84% (894). Unlike the other RESEARCH Registry series, this report included no historic control group.

7.3.6. Management Strategies for ISR

Since the last (2001) revision of the ACC/AHA PCI guideline, the proportional use of stents in percutaneous interventions has continued to increase. In part, this derives from randomized trial data suggesting that routine stenting is more effective than provisional stenting (636,872-874). In addition, stents are being used in a much wider spectrum of coronary and even graft anatomies (875). Accordingly, ISR has become increasingly important. Because stents prevent elastic recoil and late negative remodeling, the predominant mechanism of ISR is neointimal hyperplasia due to smooth muscle cell proliferation and extracellular matrix production. Two of the biggest changes since the 2001 revision have been the expanding databases evaluating the use of 1) DES to prevent ISR and 2) brachytherapy to treat ISR (discussed in Sections 7.3.6.2 and 7.3.6.3, respectively).

7.3.6.1. PTCA

PTCA has been used to treat patients with ISR (851-853). The mechanism of lumen improvement after PTCA for ISR relates to further stent expansion (851) and extrusion of the tissue through the stent struts (851-854). In an IVUS study of 64 restenotic Palmaz-Schatz stents, 56% plus or minus 28% of the lumen enlargement was the result of additional stent expansion, and 44% plus or minus 28% was the result of a decrease in neointimal tissue (851). Despite the use of high-pressure balloon dilation, a relatively high residual stenosis (18% plus or minus 12%) remained after treatment with PTCA.

The outcome after PTCA has been variable, depending in part on the size of the stented segment and length of the stent restenosis (855). In a consecutive series of 124 patients presenting with stent restenosis successfully treated with repeat PTCA, clinical follow-up was obtained at 27.4 plus or minus 14.7 months (855). Recurrent clinical events occurred in 25 patients (20%), including death (2%), MI (1%), and target-vessel revascularization (11%) (855). Cumulative event-free survival at 12 and 24 months was 86.2% and 80.7%, respectively (855).

A number of factors have been related to the frequency of clinical recurrence after PTCA for ISR (855), which include repeat intervention in SVGs, multivessel disease, low ejection fraction, and a 3-month interval between stent implantation and repeat intervention. One report involving 245 patients receiving BMS in the pre-DES era has categorized ISR into 4 classifications: focal, diffuse intrastent, diffuse proliferative, and total occlusion. Pattern I contains 4 types (A-D). Patterns II through IV are defined according to geographic position of ISR in relation to the previously implanted stent. Target-lesion revascularization was related to the length of the ISR, ranging from 10% for focal in-stent stenosis (class I) to 25% for intrastent restenosis (class II), 50% for diffuse proliferative ISR (class III), and 80% for ISR with total occlusion (class IV) (856).

A broad array of catheter-based technologies, including directional (857,858), rotational (859,860), extraction (861-865), and pullback (866) atherectomy, a cutting balloon, and excimer laser-assisted angioplasty, have been used to treat ISR in association with PTCA. Although some comparative registry series have suggested an improved angiographic outcome associated with the use of these ablative devices, no long-term studies demonstrating clinical advantage have been completed.

When a significant residual stenosis exists after conventional PTCA for ISR, PCI with stenting has been used to improve the initial angiographic result (867-869). Although preliminary results of clinical trials failed to demonstrate a benefit using routine BMS placement for the treatment of ISR, favorable results have been shown with DES, as summarized in the following section (116,870,871).

7.3.6.2. Drug-Eluting Stents

Class IIa

It is reasonable to perform repeat PCI for ISR with a DES or a new DES for patients who develop ISR if anatomic factors are appropriate. *(Level of Evidence: B)*

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In-stent restenosis represents a clinical challenge of great interest for DES technology. Sousa and coworkers treated 25 consecutive cases of ISR with SES (870). They demonstrated minimal intimal hyperplasia and no delayed malapposition by intracoronary ultrasound (870). Clinically, they reported a remarkable 0 repeat revascularizations, stent thromboses, or deaths (870). Degertekin and colleagues reported a group of 26 consecutive ISR patients treated with SES (871). They also used 3-dimensional ultrasound to document minimal neointimal formation by 4 months (871). This more complex cohort included 1 patient with transplant vasculopathy and 4 with prior brachytherapy, which provided support not only for the effectiveness of SES but also of the need for prolonged antiplatelet therapy and risk factor modification in patients with diffuse coronary disease (871). Saia and coworkers reported a series of 12 patients with ISR refractory to brachytherapy who received SES; 4 of 10 patients who were followed up long-term developed restenosis (895).

The ISAR-DESIRE trial compared the use of balloon angioplasty SES and PES treatment of ISR in 300 patients (896). Angiography at 6 months in 92% of the patients (n equals 275) demonstrated angiographic restenosis in 44.6% (41 of 92) of the balloon-alone group; 14.3% (13 of 91) of the SES group; and 21.7% (20 of 92) of the PES group. Both DES were superior to balloon alone, reducing the incidence of target-vessel revascularization (33% for balloon alone vs 8% for SES and 19% for PES). There was a trend toward superiority of SES over PES in angiographic restenosis that was marginally significant (*P* equals 0.19) and significance for target-vessel revascularization (*P* equals 0.02). These data support the use of either approved DES for the treatment of ISR over a BMS. Additional data for DES and ISR have been reported in the TReatment Of Patients with an In-STENT REstenotic Coronary Artery Lesion (TROPICAL) Study, which assessed outcomes in 155 patients with ISR receiving an SES. In-lesion late loss of 0.08 plus or minus 0.49 and a binary restenosis rate of 9.7% was reported at 6-month follow-up, with a reintervention rate of 7.4% (897). Furthermore, preliminary data suggest that in patients receiving SES for ISR (TROPICAL group), late lesion loss and binary restenosis at 6 months were significantly reduced compared with a historical group receiving brachytherapy for ISR in the GAMMA I and II studies [F.J. Neumann, oral presentation, EuroPCR, Paris, France, May 2004]. The potential benefit of SES compared with brachytherapy remains to be delineated in ongoing randomized trials.

7.3.6.3. Radiation

Class IIa

Brachytherapy can be useful as a safe and effective treatment for ISR. *(Level of Evidence: A)*

Both gamma energy (photons), and beta energy (electrons) have been used in randomized clinical trials and prospective registries to reduce the neointimal proliferation associated with ISR (898-900). In the 2001 revision of the guideline, the initial results of the SCRIPPS trial (Scripps Coronary Radiation to Inhibit Proliferation Post Stenting) were summarized (117). Since then, the 5-year results of the SCRIPPS cohort have been published (901). The Ir-192–treated patients continued to demonstrate improved event-free survival (freedom from death, MI, or target-lesion revascularization) compared with placebo (61.5% vs 34.5%; *P* equals 0.02) (900). As shown in Table 31, this composite end point derived from improvements in each of the 3 component end points (92,116,117,658-660,901-903).

A number of reports of the GAMMA-1 trial have been published since the 2001 revision (622,658,904,905). The initial report of 9 months of follow-up demonstrated a statistically significant reduction in target-lesion revascularization with Ir-192 (42% vs 24 %; *P* less than 0.01). Death and MI were insignificantly higher with radiation.

The WRIST (Washington Radiation for In-Stent Restenosis Trial) investigators randomized 130 patients (65/65) with ISR between placebo and 15 Gy Ir-192 (116). The SVG-WRIST investigators randomized 120 patients (60/60) between placebo and Ir-192 for the treatment of ISR in SVGs (902). Again, the brachytherapy-treated cohort had lower rates of binary restenosis (21% vs 44%; *P* equals 0.005) and target-lesion revascularization (17% vs 57%; *P* less than 0.001).

Among the specific limitations of gamma radiation are the need for long treatment times and the high radiation exposure, which necessitate special shielding and removal of staff from the treatment room during dwell times (906). Beta radiation, in the form of electrons or particulate energy, has also demonstrated effectiveness in randomized trials of ISR, despite its more limited tissue penetration (92,659,660). Taken together, these data support the effectiveness of radiation in reducing restenosis after treatment of ISR. Further investigation into the causes of late stent thrombosis (907) have led to recommendations that 1) new stents not be implanted at the time of brachytherapy unless necessary and 2) antiplatelet therapy with both aspirin and a thienopyridine be continued for at least 6 to 12 months after brachytherapy (898-900,906).

Brachytherapy dosing for ISR is prescribed so as to achieve adequate radiation in the vessel wall to block cellular proliferation. The manufacturer's recommended dosing for the beta radiation source is 18.4 Gy at 2 mm from the source center for vessels from 2.7 to 3.35 mm in diameter and 23 Gy for vessels 3.35 to 4.0 mm in diameter. It is also recommended that radiation be delivered over the entire segment injured by balloon dilation and that at least a 5-mm margin be allowed on each side of the injured segment (908).

To date, the following potential limitations have been observed with the use of brachytherapy to treat ISR: edge stenoses or geographic miss; acute thrombosis; late thrombosis and occlusion (up to 14%); persistent dissections; late stent malapposition; increased plaque burden outside the stent; IVUS echolucent areas or black holes (898-900,906);

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Table 31. Randomized Clinical Trials of Brachytherapy for In-Stent Restenosis

Trial (Ref.)	Year	n XRT/Placebo	Follow-Up, Angiographic/ Clinical	Source	Restenosis, XRT/Placebo	TLR, % XRT/Placebo	MI, XRT/Placebo	Death, XRT/Placebo
SCRIPPS (117)	1997	26/29	6 mo 12 mo	Gamma IR-192	17%/54% (*P* equals 0.01)	12%/45% (*P* equals 0.01)	4%/0% (*P* equals NS)	0%/3 % (*P* equals NS)
PREVENT (660)	2000	80/25	6 mo 12 mo	Beta P-32	22%/50% (*P* equals 0.018)	6%/24% (*P* less than 0.05)	10%/4% (*P* equals NS)	1%/0% (*P* equals NS)
WRIST (116)	2000	65/65	6 mo 12 mo	Gamma IR-192	22%/60% (*P* equals 0.0001)	3%/63% (*P* less than 0.001)	9%/9% (*P* equals NS)	6%/6% (*P* equals NS)
GAMMA-ONE (658)	2001	131/121	6 mo 9 mo	Gamma IR-192	32%/55% (*P* equals 0.01)	24%/42% (*P* less than 0.01)	9.9%/4.1% (*P* equals 0.09)	3.1%/0.8% (*P* equals 0.17)
INHIBIT (659)	2002	166/166	9 mo 290 d	Beta P-32	26%/52% (*P* less than 0.0001)	8%/26% (*P* less than 0.0001)	3%/3% (*P* equals NS)	3%/2% (*P* equals NS)
SCRIPPS (901)	2002	26/29	5 y	Gamma IR-192	NA	23%/48% (*P* equals 0.05)	4%/10% (*P* equals NS)	19%/31% (*P* equals NS)
START (92)	2002	244/232	8 mo	Beta Sr-90/Y-90	29%/45% (*P* equals 0.001)	14%/25% (*P* less than 0.001)	1.7%/3.3% (*P* equals 0.364)	1.3%/0.5% (*P* equals 0.625)
SVG-WRIST (902)	2002	60/60	6 mo 12 mo	Gamma IR-192	21%/44% (*P* equals 0.005)	17%/57% (*P* less than 0.001)	2%/3% (*P* equals NS)	7%/7% (*P* equals NS)
Long WRIST (903)	2003	60/60	6 mo 12 mo	Gamma IR-192	45%/73% (*P* less than 0.05)	39%/62% (*P* less than 0.05)	16.9%/18.3% (*P* equals NS)	6.8%/1.7% (*P* equals NS)

n indicates number of patients; NA, not applicable; NS, not significant; MI, myocardial infarction; TLR, target-lesion revascularization; and XRT, radiation therapy.

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and very late catch-up phenomenon (in studies with more than 1 year of follow-up).

7.3.6.4. Medical Therapy

Acute platelet inhibition with abciximab does not reduce ISR, as demonstrated in the ERASER study (280). In a study of 225 patients randomly allocated to placebo or abciximab before intervention, 215 patients received a stent and the study drug. Of the 191 patients who returned for follow-up more than 4 months after evaluation, there was no difference between tissue volume, as measured by IVUS, between the placebo and treatment groups. Lack of abciximab benefit was confirmed by quantitative angiography. The investigators concluded that potent platelet inhibition with abciximab as administered in the ERASER study did not reduce ISR. In the Oral Sirolimus to Inhibit Recurrent In-Stent Restenosis (OSIRUS) trial, 300 patients were randomly assigned to receive a cumulative loading dose of either placebo (0 mg), usual-dose (8 mg) oral sirolimus, or high-dose (24 mg) oral sirolimus 2 days before and the day of repeat PCI, followed by maintenance therapy of 2 mg per day for 7 days (909). Restenosis was significantly reduced from 42.2% to 36.8% and 22.1% in the placebo, usual-dose, and high-dose groups, respectively (P equals 0.005). The need for target-vessel revascularization was reduced from 25.5% to 24.2% and 15.2%, respectively, although this was not statistically significant (P equals 0.08). Blood concentration of oral sirolimus was significantly correlated with late lumen loss at follow-up (P less than 0.001). The investigators concluded that oral adjunctive sirolimus treatment for treatment of ISR resulted in significant improvement in the angiographic parameters of restenosis. Further elucidation of optimal dosing, need for pretreatment, and duration of oral sirolimus, as well as long-term follow-up, are needed.

7.3.7. Subacute Stent Thrombosis

The issues of subacute stent thrombosis and technical issues with the PES balloon-delivery system were early causes for concern (910). After many more data have been accumulated, as exemplified by the above-cited registry data, there does not appear to be an increased incidence of early thrombosis with either SES or PES. As reported in the FDA editorial (910), Boston Scientific has recalled a number of TAXUS stent systems because of reports of balloon deflation or retrieval problems and is working closely with the FDA to monitor the situation.

7.3.8. Drug-Eluting Stents: Areas Requiring Further Investigation

Both small vessels (less than 2.75 mm) and long lesions (greater than 18 mm) have been included in the C-SIRIUS and E-SIRIUS trials (880,881). In addition, there are increasing numbers of patients entered into prospective registries and compared retrospectively with the following clinical and angiographic subsets, which were not included in randomized comparative trials of DES versus BMS: acute coronary syndromes; STEMI, chronic total occlusions; SVGs; and ISR. Most of the data currently available regarding the use of DES for ostial lesions, bifurcation lesions, ULM arteries, and extremely long segments are in the form of uncontrolled case reports or series. Nonetheless, given the promising results in reducing late target-lesion and target-vessel revascularization in nearly every group, it is to be expected that registry and randomized trial data will continue to accumulate at a rapid pace.

7.4. Cost-Effectiveness Analysis for PCI

Among all diseases worldwide, ischemic heart disease currently ranks fifth in disability burden and is projected to rank first by the year 2020 (911). As healthcare delivery systems in countries with established economic markets continue to incorporate new and expensive technologies, the costs of medical care have seemingly escalated beyond the revenue historically allotted to health care. Given limited healthcare resources, a cost-effectiveness analysis is appropriate to evaluate percutaneous coronary revascularization strategies (912). The results of cost-effectiveness analyses for any comparable treatment are reported in terms of the incremental cost per unit of health gained, such as 1 year of life adjusted to perfect health (quality-adjusted life year, QALY) compared with the standard of care (913). By modeling different treatments, different patient subsets, and different levels of disease, a series of cost-effectiveness ratios may be constructed to show the tradeoffs associated with choosing among competing interventions.

Although there is no established cost-effectiveness ratio threshold, cost-effectiveness ratios of less than $20 000 per QALY (such as seen in the treatment of severe diastolic hypertension or with cholesterol lowering in patients with ischemic heart disease) are considered highly favorable and consistent with well-accepted therapies. Incremental cost-effectiveness ratios that range between $20 000 and $60 000 per QALY may be viewed as reasonably cost-effective and thus acceptable in most countries, whereas ratios greater than $60 000 to $80 000 may be considered too expensive for most healthcare systems. The Committee defines useful and efficacious treatments, in terms of cost-effectiveness, as treatments with acceptable or favorable cost-effectiveness ratios. Cost-effectiveness analysis is not by itself sufficient to incorporate all factors necessary for medical decision making on an individual patient basis, nor is it sufficient to dictate the broad allocation of societal resources for health care. Rather, cost-effectiveness analysis aims to serve mainly as an aid to medical decision making on the basis of comparison with other evaluated therapies.

The results of cost-effectiveness analysis in the field of percutaneous revascularization for ischemic heart disease have been derived from decision models that incorporate literature-based procedure-related morbidity and mortality, coronary disease–related mortality, and estimates of the benefit of selected revascularization procedures. When available,

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results from randomized trials (levels of evidence A and B) are used to estimate the outcomes of each decision tree branch within the decision-analytical model, for example, using data estimating the restenosis rate after uncomplicated coronary stenting of a single, simple lesion. Cost-effectiveness analyses have been used to compare medical therapy with PTCA with CABG (914), balloon angioplasty with coronary stenting (915,916), and routine coronary angiography after acute MI with symptom-driven coronary angiography (917).

In patients with severe angina, normal LV function, and single-vessel disease of the LAD, the cost-effectiveness ratio for PTCA, directional coronary atherectomy, or coronary stenting that can be expected to provide a more than 90% success rate with a less than 3% major acute complication rate is very favorable (less than $20 000 per QALY) compared with medical therapy (914). The rating also applies to patients with symptomatic angina or documented ischemia and 2-vessel coronary disease, in whom percutaneous coronary revascularization can be expected to provide a more than 90% success rate with a less than 3% major acute complication rate. In patients with 3-vessel coronary disease who have comorbidities that increase the operative risk for CABG surgery, PCI that is believed to be safe and feasible is reasonably acceptable ($20 000 to $60 000 per QALY). In patients in the post-MI setting, a strategy of routine, non–symptom-driven coronary angiography and PCI performed for critical (greater than 70% diameter stenosis) culprit coronary lesions amenable to balloon angioplasty or stenting has been proposed to be reasonably cost-effective in many subgroups (917).

In patients with symptomatic angina or documented ischemia and 3-vessel coronary disease, for which bypass surgery can be expected to provide full revascularization and an acute complication rate of less than 5%, the cost-effectiveness of PCI is not well established. Although PTCA for 2- and 3-vessel coronary disease appears to be as safe as but initially less expensive than CABG surgery, the costs of PTCA converge toward the higher costs of bypass surgery after 3 to 5 years (918,919). Thus, whereas PTCA or CABG surgery has been shown to be cost-effective compared with medical therapy, there is no evidence for incremental cost-effectiveness of PTCA over bypass surgery for 2- or 3-vessel coronary disease in patients who are considered good candidates for both procedures. For patients with 1- or 2-vessel coronary disease who are asymptomatic or have only mild angina, without documented left main disease, the estimated cost-effectiveness ratios for PCI are greater than $80 000 per QALY compared with medical therapy and are thus considered less favorable.

The initial mean cost of angioplasty was 65% that of surgery, but the need for repeat interventions increased medical expenses so that after 5 years, the total medical cost of PTCA was 95% that of surgery ($56 225 vs $58 889), a significant difference of $2664 (*P* equals 0.047). Compared with CABG, PTCA appeared less costly for patients with 2-vessel disease but not for patients with 3-vessel disease.

The use of DES is affecting the cost-effectiveness of PCI. In the SIRIUS trial (93), there were 21 fewer repeat revascularization procedures per 100 patients treated with the sirolimus stent. Although the DES group's hospital costs were $2800 more, much of that was negated in follow-up by the high reintervention rate in the BMS group (920). However, the number of repeat procedures in such trials with routine angiographic follow-up is inflated compared with registries of BMS, which suggests only 6 to 7 repeat procedures are avoided by routinely using DES (882). The ultimate cost effectiveness of drug-eluting stenting will depend on the cost of the stents, how many are implanted per patient, and how many repeat procedures are avoided.

Because cost-effectiveness analysis research is new in the field of PCI, its results are limited. The Committee underscores the need for cost containment and careful decision making regarding the use of PCI strategies.

8. FUTURE DIRECTIONS

The field of coronary intervention has expanded dramatically over the past decade and will continue to evolve over the next several years. New directions will focus on strategies that will further improve procedural safety, reduce the recurrence rate after PCI, and expand the procedure to more complex anatomic subsets. Clinical acceptance of these technologies will be based on demonstration of safety and efficacy over conventional therapies in randomized clinical studies. Several novel strategies are summarized below.

Because the widespread use of stent implantation has lessened the risk of need for emergency bypass, future clinical research will focus on remaining obstacles that decrease procedural success or increase risk. Chronic total occlusion remains a stubborn problem. New devices such as the Frontrunner catheter and new ultrastiff guidewires show some promise in improving procedural success; however, new approaches are needed.

Degenerated vein graft disease remains a high-risk subset. The SAFER trial (255) has demonstrated that distal protection with a balloon occlusive device with intraprocedural aspiration decreases procedural risk. Similarly, a number of distal filter devices are undergoing active testing (254). The results of one such multicenter trial comparing a filter-based catheter with a balloon occlusive and aspiration device showed similar results for MACE at 30 days (254). In spite of these approaches, these procedures are still associated with MACE event rates of 8% to10%. More research is still needed in this area. The use of distal protection devices in settings other than degenerative vein graft disease requires further study. For example, initial studies in primary PCI suggested a benefit with the FilterWire™; however, subsequent trials with the GuideWire have failed to show any benefit, instead showing poor outcomes in this setting. Thus, further research is needed before this technology is adopted for use beyond degenerative vein graft disease.

Dramatic advances have been made in the treatment of restenosis. Although the oral agents tranilast (921) and folic

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acid have proven unsuccessful, other catheter-based strategies have dramatically decreased restenosis risk. Brachytherapy (for ISR), rapamycin-eluting stents, and PES have been extremely effective. Subgroups such as diffuse ISR and insulin-dependent diabetes mellitus will require further study. Other therapies, such as photodynamic therapy, cryotherapy, and therapeutic ultrasound, remain interesting but unproven approaches to treat restenosis.

In patients with refractory angina who have no vessels suited for revascularization, a number of new therapies are being tested. Enhanced external counterpulsation appears to decrease symptoms (922). Treatment with fibroblast growth factor by an intracoronary approach also shows promise (923). Percutaneous laser transmyocardial revascularization has shown mixed results. The PACIFIC trial (Potential Class Improvement From Intramyocardial Channels) putatively demonstrated some benefit of percutaneous laser transmyocardial revascularization, but the major limitation of that study was that it was not placebo-controlled; thus, after its failure to address potential concerns, general consensus attributes the results in PACIFIC to a placebo effect. Also, in PACIFIC, diverse outcomes tended to be higher with laser therapy (924). Although the randomized, double-blind BELIEF trial (Blinded Evaluation of Laser PMR Intervention Electively For angina pectoris) of 82 patients appeared to show some benefit of percutaneous laser transmyocardial revascularization versus sham procedure on angina class and quality-of-life measures, the results were inconclusive given the small size of the study (925). To date, data are insufficient for FDA approval of percutaneous laser therapy. A new frontier has been opened with the intra-arterial infusion of marrow-derived stem cells (926) and direct injection of skeletal muscle–derived myoblasts (927) for myogenesis. Studies to date were performed in patients with severe angina; thus, it is uncertain how this technology might apply to other subsets of patients with coronary disease (e.g., acute coronary syndromes, ischemic cardiomyopathy), and rigorous, blinded evaluation of these approaches must occur.

STAFF

American College of Cardiology

Christine W. McEntee, Chief Executive Officer

Katherine D. Doermann, Senior Specialist, Practice Guidelines

Kristina N. Petrie, MS, Associate Director, Evidence-Based Medicine

Dawn R. Phoubandith, MSW, Associate Director, Practice Guidelines

Peg Christian, Librarian, Knowledge Management

American Heart Association

M. Cass Wheeler, Chief Executive Officer

Rose Marie Robertson, MD, FACC, FAHA, Chief Science Officer

Kathryn A. Taubert, PhD, FAHA, Senior Science Advisor

Society for Cardiovascular Angiography and Interventions

Norm Linsky, Executive Director

Wayne Powell, Senior Director, Advocacy and Guidelines

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APPENDIX 1. ACC/AHA/SCAI Committee to Update 2002 Guidelines for Percutaneous Coronary Intervention—Relationships with Industry

Committee Member	Research Grant	Speakers Bureau/ Honoraria	Stock Ownership	Consultant
Dr. Ted E. Feldman	Abbot Boston Scientific Cardia EV3 Evalve Guidant	Boston Scientific	None	None
Dr. John W. Hirshfeld, Jr	None	None	None	None
Dr. Alice K. Jacobs	None	None	None	Wyeth
Dr. Morton J. Kern	None	None	None	None
Dr. Spencer B. King, III	Guidant	BMS-Sanofi Guidant	None	Medtronic Novoste
Dr. Douglass A. Morrison	None	None	None	None
Dr. William W. O'Neill	None	None	None	None
Dr. Hartzell V. Schaff	None	None	None	None
Dr. Sidney C. Smith, Jr	Merck	Bayer	Johnson & Johnson Medtronic	Bristol-Myers Squibb Eli Lilly Pfizer Sanofi-Aventis
Dr. Patrick L. Whitlow	Abbot Cordis, Inc Fox Hollow Technologies Lumend, Inc	None	Medtronic	None
Dr. David O. Williams	None	None	None	None

This table represents the relevant relationships of authors with industry that were reported orally at the initial writing committee meeting in July 2002 and updated in conjunction with all meetings and conference calls of the writing committee. It does not reflect any actual or potential relationships at the time of publication.

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APPENDIX 2. External Peer Reviewers for the ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention*

Peer Reviewer Name†	Representation	Research Grant	Speakers Bureau/ Honoraria	Stock Ownership	Consultant/ Advisory Board
Dr. Michael Cowley	Official Reviewer -- SCAI	None	None	None	None
Dr. David Faxon	Offical Reviewer – ACC/AHA Task Force on Practice Guidelines	None	None	None	None
Dr. Roxana Mehran	Official Reviewer -- SCAI	None	The Medicines Co.	None	None
Dr. E. Magnus Ohman	Official Reviewer – AHA	Berlex Bristol-Myers Squibb Millennium Schering-Plough	None	Inovise Medical Medtronic Response Medical	None
Dr. Richard Pomerantz	Official Reviewer – ACCF Board of Governors		Aventis	Amgen Johnson & Johnson Pfizer Schering-Plough	Medacorp
Dr. Robert D. Safian	Official Reviewer -- AHA	None	None	None	None
Dr. W. Douglas Weaver	Official Reviewer – ACCF Board of Trustees	None	None	None	None
Dr. Jeffrey L. Anderson	Content Reviewer – Individual Review	Sanofi/Bristol-Myers Squibb Novartis	Merck Sanofi/Bristol-Myers Squibb	None	Merck
Dr. Elliott M. Antman	Content Reviewer – Individual Review	Aventis Bayer Biosite Boehringer-Mannheim Bristol-Myers Squibb British Biotech Centor Cor/Millennium Corvas Dade Genentech Lilly Merck Pfizer Sunol	None	None	Aventis
Dr. Larry S. Dean	Content Reviewer – ACCF Cardiac Catheterization and Intervention Committee	None	None	None	None
Dr. Tommaso Gori	Content Reviewer – AHA Diagnostic and Interventional Cardiac Catheterization Committee	None	None	None	None
Dr. Sharon A. Hunt	Content Reviewer – Individual Review	None	None	None	None
Dr. Lloyd Klein	Content Reviewer -- AHA Diagnostic and Interventional Cardiac Catheterization Committee	None	None	None	None
Dr. Glenn Levine	Content Reviewer AHA Diagnostic and Interventional Cardiac Catheterization Committee	None	Aventis	None	None
Dr. Joseph P. Ornato	Content Reviewer – Individual Review	Genentech	None	None	Bristol-Myers Squibb Genentech

This table represents the relevant relationships of peer reviewers with industry to this topic that were disclosed at the time of peer review of this guideline. It does not necessarily reflect relationships with industry at the time of publication.

*Participation in the peer review process does not imply endorsement of the document.

†Names are listed in alphabetical order within each category of review.

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ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention)

Sidney C. Smith, Jr, Ted E. Feldman, John W. Hirshfeld, Jr, Alice K. Jacobs, Morton J. Kern, Spencer B. King, III, Douglass A. Morrison, William W. O'Neill, Hartzell V. Schaff, Patrick L. Whitlow, David O. Williams, Elliott M. Antman, Sidney C. Smith, Jr, Cynthia D. Adams, Jeffrey L. Anderson, David P. Faxon, Valentin Fuster, Jonathan L. Halperin, Loren F. Hiratzka, Sharon Ann Hunt, Alice K. Jacobs, Rick Nishimura, Joseph P. Ornato, Richard L. Page, and Barbara Riegel

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EXHIBIT 3

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery

Thomas Aversano, M.D., Cynthia C. Lemmon, R.N., B.S.N., M.S., and Li Liu, M.D., for the Atlantic CPORT Investigators

ABSTRACT

BACKGROUND

Performance of percutaneous coronary intervention (PCI) is usually restricted to hospitals with cardiac surgery on site. We conducted a noninferiority trial to compare the outcomes of PCI performed at hospitals without and those with on-site cardiac surgery.

METHODS

We randomly assigned participants to undergo PCI at a hospital with or without on-site cardiac surgery. Patients requiring primary PCI were excluded. The trial had two primary end points: 6-week mortality and 9-month incidence of major adverse cardiac events (the composite of death, Q-wave myocardial infarction, or target-vessel revascularization). Noninferiority margins for the risk difference were 0.4 percentage points for mortality at 6 weeks and 1.8 percentage points for major adverse cardiac events at 9 months.

RESULTS

A total of 18,867 patients were randomly assigned in a 3:1 ratio to undergo PCI at a hospital without on-site cardiac surgery (14,149 patients) or with on-site cardiac surgery (4718 patients). The 6-week mortality rate was 0.9% at hospitals without on-site surgery versus 1.0% at those with on-site surgery (difference, −0.04 percentage points; 95% confidence interval [CI], −0.31 to 0.23; P=0.004 for noninferiority). The 9-month rates of major adverse cardiac events were 12.1% and 11.2% at hospitals without and those with on-site surgery, respectively (difference, 0.92 percentage points; 95% CI, 0.04 to 1.80; P=0.05 for noninferiority). The rate of target-vessel revascularization was higher in hospitals without on-site surgery (6.5% vs. 5.4%, P=0.01).

CONCLUSIONS

We found that PCI performed at hospitals without on-site cardiac surgery was noninferior to PCI performed at hospitals with on-site cardiac surgery with respect to mortality at 6 weeks and major adverse cardiac events at 9 months. (Funded by the Cardiovascular Patient Outcomes Research Team [C-PORT] participating sites; ClinicalTrials.gov number, NCT00549796.)

From Johns Hopkins University, Baltimore (T.A., C.C.L.); and Clinical Trials and Surveys, Owings Mills, MD (L.L.). Address reprint requests to Dr. Aversano at Johns Hopkins Cardiology at the Greater Baltimore Medical Center, Suite 5104, 6701 N. Charles St., Baltimore, MD 21204, or at taversan@jhmi.edu.

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THE POTENTIAL NEED FOR EMERGENCY cardiac surgery to treat complications related to percutaneous coronary intervention (PCI) suggests that performance of PCI may be best limited to hospitals with on-site cardiac surgery. Among Grüntzig's first 50 PCI procedures, 10% of patients required emergency coronary-artery bypass grafting (CABG).[1] Although the need for emergency surgery subsequently diminished dramatically (by 2002, the incidence was 0.15%[2]), concern about the safety and quality of PCI performed without the availability of on-site cardiac surgery has persisted. Hospitals in which PCI is performed but that do not have cardiac surgery programs could have more adverse events and poorer outcomes for a number of reasons (including low institutional volume of PCI procedures and inexperienced staff), in addition to the need for emergency CABG.

Despite these concerns, many hospitals without on-site cardiac surgery developed stand-alone programs for the performance of primary PCI after studies showed that primary PCI was associated with better outcomes than medical therapy in the treatment of myocardial infarction with ST-segment elevation[3] and could be performed safely and effectively at such hospitals.[4] Door-to-balloon times may be shorter, and outcomes consequently better, if primary PCI is widely available. It has further been suggested that, given the relatively low volume of primary PCI procedures at some hospitals, the addition of other PCI procedures (including elective PCI and PCI for acute coronary syndromes without ST-segment elevation) could help sustain and improve these programs.

In addition, previous studies have shown that, for patients with acute coronary syndromes presenting to centers without any revascularization capability, appropriate use of PCI and CABG is limited and outcomes are suboptimal.[5-7] Extension of PCI capability to such hospitals could improve access to appropriate care, particularly in areas where recruitment and retention of cardiologists may be difficult[8] and treatment options for patients are limited.

The Cardiovascular Patient Outcomes Research Team (CPORT) Non-Primary PCI (CPORT-E) trial was designed to help address these issues. CPORT-E was a randomized noninferiority trial that compared outcomes of PCI procedures (excluding primary PCI) at hospitals with and those without on-site cardiac surgery.

METHODS

STUDY DESIGN AND OVERSIGHT

The CPORT-E trial was designed by the study chairman and the protocol-development committee and was funded through financial support provided by participating sites to the Johns Hopkins University and through in-kind support that included the provision of local study coordinators at each site. There was no support from the makers of equipment used in catheterization laboratories or of that used for PCI. The protocol was approved by each participating hospital's institutional review board and the Johns Hopkins institutional review board. Data were gathered by local research coordinators, reviewed for accuracy by central study coordinators at Johns Hopkins, and analyzed by the authors. The authors vouch for the accuracy and completeness of the data and the analysis and for the fidelity of this report to the trial protocol, which is available with the full text of this article at NEJM.org.

TRIAL PARTICIPANTS

Patients were eligible for participation in the trial if they presented for diagnostic cardiac catheterization at 1 of 60 participating hospitals without on-site cardiac surgery located in 10 U.S. states (Maryland, New Jersey, Pennsylvania, Ohio, Georgia, Texas, North Carolina, Illinois, Oregon, and Alabama). During the trial period, patients who did not undergo randomization, whether or not they met the inclusion criteria for the trial, were included in a registry that recorded a limited set of data that excluded identifying private information.

Patients 18 years of age or older with stable coronary artery disease or an acute coronary syndrome were included in the trial. Patients with an acute myocardial infarction with ST-segment elevation were excluded, as were those with an ejection fraction of less than 20% and those who required PCI of an unprotected lesion in the left main coronary artery. In addition, interventionalists could exclude any patient whom they deemed to be at too high a risk for PCI. For each trial participant, all lesions requiring PCI had to be considered treatable at the hospital without on-site cardiac surgery before randomization. Patients who had previously participated in the trial were excluded. Full inclusion and exclusion criteria are available in Table S1 in the Supplementary Appendix, available at NEJM.org.

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PARTICIPATING HOSPITALS AND INTERVENTIONALISTS

Interventionalists were required to meet criteria for competency developed by the American College of Cardiology (ACC), the American Heart Association (AHA), and the Society for Cardiac Angiography and Interventions (SCAI).[9] Participating centers were required to have primary PCI programs available 24 hours per day, 7 days per week, and to be capable of performing 200 PCI procedures annually. Most sites required a waiver from the state department of health to participate. All such waivers allowed for a first-year PCI volume of 100 procedures, increasing to 200 in the second year.

Each site had a formal agreement with a tertiary-care hospital partner specifying that the tertiary-care institution would accept emergency transfers from the enrolling site. However, participants in the trial who were randomly assigned to undergo PCI at a hospital with on-site surgery could have the PCI procedure at any tertiary-care hospital. A formal agreement with an advanced cardiac life-support service capable of transporting patients requiring intraaortic balloon counterpulsation was also required, with an anticipated response time of 30 minutes or less.

Before commencing recruitment, all participating sites were required to complete a formal PCI development program. This program included the development of detailed care plans and pathways, order sets, and logistics and the training of staff in the care of patients undergoing PCI. Details of this program are available in the Supplementary Appendix.

TRIAL PROCEDURES

Before undergoing diagnostic catheterization, study participants provided written informed consent. After catheterization, if PCI was required and all lesions were considered to be treatable at the hospital without on-site cardiac surgery, the participant was randomly assigned in a 3:1 ratio to undergo PCI at either the enrolling site (without on-site cardiac surgery) or another facility with on-site cardiac surgery. Randomization was performed with the use of an automated telephone-response system on a per-site basis in random permuted blocks (of 4, 8, or 12). Patients who were considered to be at too high a risk according to the study-exclusion criteria or in the judgment of the treating physician did not undergo randomization but instead underwent PCI, CABG, or other therapy as clinically indicated.

After randomization, all trial participants were to undergo PCI according to their randomized assignment. The timing of the index PCI procedure depended on individual case acuity, the need to perform PCI on a different day than the visit to the catheterization laboratory to minimize procedural risk (i.e., staged procedure), and scheduling and transportation constraints, but the procedure was to be performed as soon as possible for each participant. All treatments, devices, and drugs were administered and laboratory studies carried out according to routine practice; no specific PCI protocol was prescribed. However, the use of cutting balloons was limited to in-stent restenosis and atherectomy devices were not permitted at hospitals without on-site cardiac surgery.

Participants were contacted by telephone (or mail, if necessary) at 6 weeks and 3, 6, and 9 months after study entry to identify adverse events. Medical records required to document identified events were obtained as needed.

TRIAL OUTCOMES

Two coprimary outcomes were identified: all-cause mortality 6 weeks after the index PCI and the composite rate of major adverse cardiac events, including death from all causes, Q-wave myocardial infarction, and target-vessel revascularization, 9 months after the index PCI. Additional outcomes included the PCI success rate and the incidence of cardiac surgery, bleeding, stroke, renal failure, and any subsequent revascularization.

Except as noted, definitions of data elements followed those in the American College of Cardiology National Cardiovascular Data Registry module on cardiac catheterization, version 3.02.[10] Q-wave myocardial infarction was defined as the development of new Q waves in any two contiguous leads. Target-vessel revascularization was defined as any revascularization intervention (PCI or CABG) occurring in a treated vessel at any time after the index intervention. In randomly assigned participants who did not undergo an index PCI, any revascularization was considered a target-vessel revascularization. Bleeding was defined as any bleeding that required blood transfusion, except for transfusions associated with cardiac surgery. Vascular repair included thrombin injection, ultrasound-guided compression, and surgical repair. Further details of study definitions are available in the Supplementary Appendix.

All events were reported by the enrolling site to the central coordinating center and were con-

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firmed by coordinating-center staff with the source medical records submitted. Occasionally, a review of source documents resulted in the identification of unreported events or the withdrawal of submitted events. A central review committee reviewed electrocardiographic findings without knowledge of the participant's randomized assignment.

STATISTICAL ANALYSIS

The CPORT-E trial was designed as a noninferiority trial. On the basis of previous studies, the 6-week all-cause mortality rate was estimated at 0.8%[11,12] and the rate of major adverse cardiac events at 9 months was estimated at 12.0%.[13-16] Noninferiority margins for the difference in event rates were set at 0.4 percentage points for the 6-week end point and 1.8 percentage points for the 9-month end point. With dual primary end points, the required number of participants for a one-sided test for noninferiority with an alpha level of 0.05 and a beta level of 0.80 was determined to be 18,360.

The primary outcome analysis was performed on data from the intention-to-treat population. Asymptotic normal approximations to the sample proportions were used to generate confidence intervals and P values for noninferiority. Categorical variables were compared with the use of Fisher's exact test or a chi-square test. A per-protocol analysis was also performed, which included only participants who underwent PCI at the site to which they were assigned. All statistical analyses were performed with the use of SAS software, version 9.2.

States that required a waiver from the department of health for trial participation typically specified that the participating hospitals should stop performing PCI when trial enrollment was completed. To allow the creation of a follow-up registry in these states, enrollment continued after the recruitment goal of 18,360 participants was reached. Ultimately, 18,867 participants underwent randomization.

RESULTS

STUDY POPULATION

Enrollment began on April 7, 2006, and ended on March 31, 2011. During that period, there were 99,479 patient visits for diagnostic catheterization at the participating hospitals. Among the 76.1% of patients who provided consent to participate, 21,165 were judged to require PCI after catheterization, and 18,867 underwent randomization (Fig. 1). Excluded were 2298 patients (10.9%) who required PCI but were judged to be at too high a risk for study participation. Reasons for the judgment that the risk was too high are shown in Figure S1 in the Supplementary Appendix. Overall, patients in the registry had fewer risk factors and less severe coronary disease than randomly assigned trial participants (Table S2 in the Supplementary Appendix).

Of the patients who underwent randomization, 319 did not undergo an index PCI. The proportion of patients who did not undergo an index PCI was higher among participants assigned to hospitals with on-site cardiac surgery than among those assigned to hospitals without on-site surgery. Reasons included referral for surgical or medical therapy and lesion resolution (Table S3 in the Supplementary Appendix). Crossovers between study groups were infrequent but were more frequent among participants randomly assigned to hospitals with on-site cardiac surgery (Fig. 1).

The baseline characteristics of the participants are shown in Table 1. There was a higher incidence of prior PCI in participants randomly assigned to hospitals without cardiac surgery on site. In addition, the rate of emergency catheterization was higher, and the rate of urgent catheterizations lower, among participants assigned to hospitals with on-site cardiac surgery.

The median annual volume of catheterizations per hospital was 150 procedures (interquartile range, 99 to 216). The median annual volume of primary PCIs was 51 procedures (interquartile range, 35 to 74). The participation of 12 hospitals was terminated during the trial because of low volume. Data from these sites were included in the data analysis.

PROCEDURE CHARACTERISTICS

A higher percentage of PCIs were staged among participants assigned to hospitals with on-site cardiac surgery than among those assigned to hospitals without on-site surgery, probably because of the need for transfer (Table 2). As a result, the number of visits to the catheterization laboratory that were needed to complete PCI was higher among participants assigned to hospitals with on-site cardiac surgery. In addition, drug-eluting stents were used more frequently in hospitals with on-site cardiac surgery.

The rate of PCI failure was lower among par-

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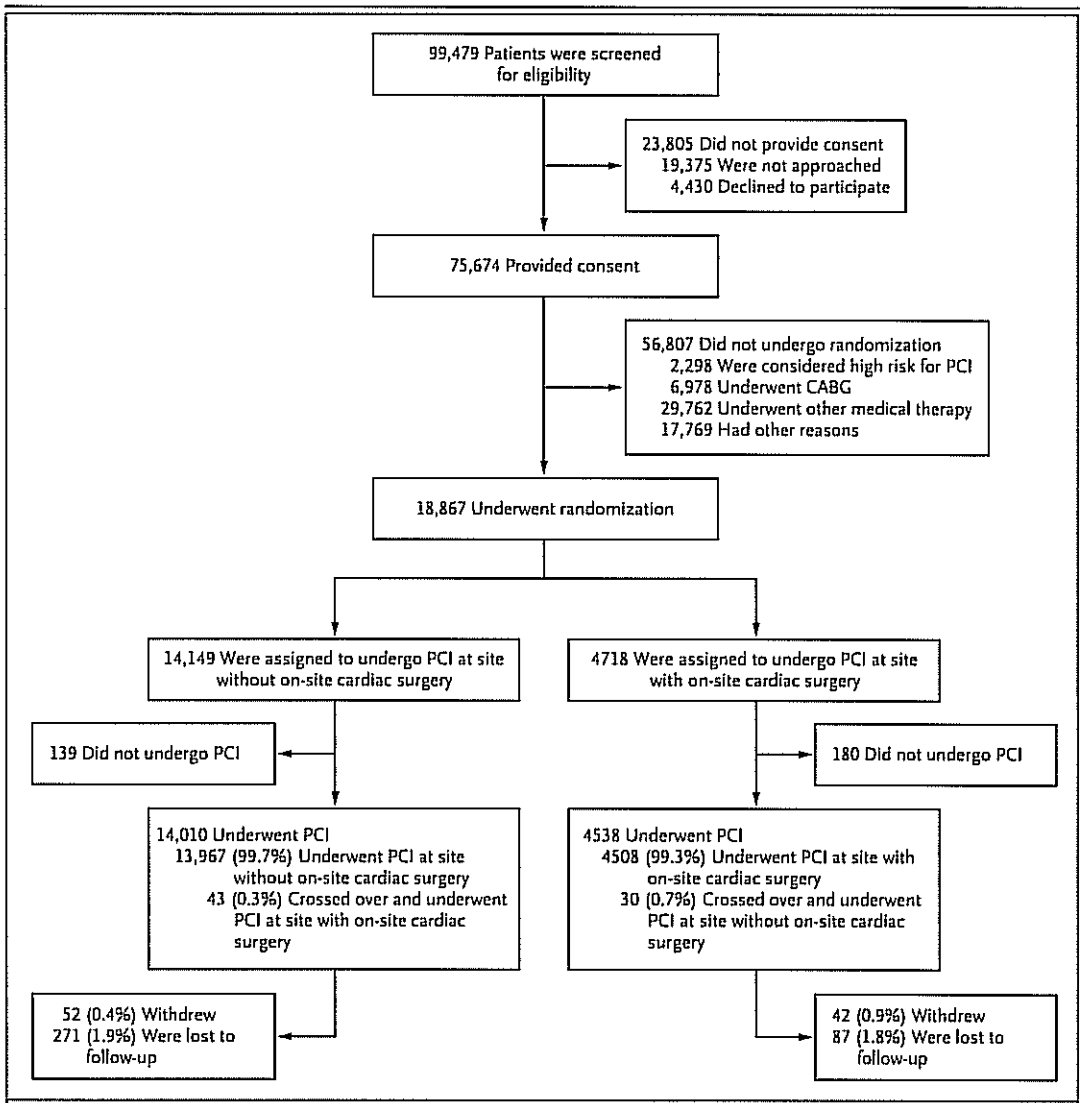

Figure 1. **Enrollment and Randomization of the Study Patients.**
The percentages for the patients who withdrew or were lost to follow-up are based on the patients assigned to undergo percutaneous coronary intervention (PCI). CABG denotes coronary-artery bypass grafting.

ticipants treated at hospitals with on-site cardiac surgery (Table 2). Emergency CABG was associated with high mortality but was rarely performed; it was performed more frequently among participants assigned to hospitals with on-site cardiac surgery. The incidence of unplanned re-catheterization and PCI before discharge was greater at hospitals without on-site cardiac surgery.

OUTCOMES

At 6 weeks after the index PCI, 132 participants assigned to hospitals without on-site cardiac surgery had died and 46 participants assigned to hospitals with on-site cardiac surgery had died. The event rates in the two groups were 0.9% and 1.0%, respectively (difference in event rates, −0.04 percentage points; 95% confidence interval [CI], −0.31 to 0.23; P=0.004 for noninferiority) (Table 3).

At 9 months, there were 1716 major adverse cardiac events in participants at hospitals without on-site cardiac surgery and 529 such events in patients at hospitals with on-site cardiac surgery (12.1% vs. 11.2%; difference in event rates, 0.92 percentage points; 95% CI, 0.04 to 1.80; P=0.05 for noninferiority) (Table 3). There were no significant differences in all-cause mortality or Q-wave

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Table 1. Baseline Characteristics of the Study Patients.*

Characteristic	No On-Site Cardiac Surgery (N=14,149)	On-Site Cardiac Surgery (N=4718)
Age — yr	63.9±11.9	64.0±12.0
Male sex — no. (%)	9046 (63.9)	2970 (63.0)
White race — no. (%)†	11,185 (79.1)	3778 (80.1)
Medical history — no. (%)		
Hypertension	11,950 (84.5)	4024 (85.3)
Hypercholesterolemia	11,567 (81.8)	3865 (81.9)
Smoking (current or former)	8,719 (61.6)	2964 (62.8)
Diabetes	5,485 (38.8)	1868 (39.6)
Family history of CAD	7,730 (54.6)	2623 (55.6)
Heart failure	1,531 (10.8)	518 (11.0)
Prior myocardial infarction	6,011 (42.5)	2030 (43.0)
Prior PCI‡	4,506 (31.8)	1430 (30.3)
Prior CABG	1,852 (13.1)	632 (13.4)
Prior stroke or PVD	2,447 (17.3)	868 (18.4)
Angiographic findings at baseline		
One-vessel CAD — no. (%)	5,097 (36.0)	1645 (34.9)
Two-vessel CAD — no. (%)	5,087 (36.0)	1741 (36.9)
Three-vessel CAD — no. (%)	3,959 (28.0)	1326 (28.1)
Left main CAD — no. (%)	465 (3.3)	178 (3.8)
Graft disease — no. (%)	1,323 (9.4)	456 (9.7)
Left ventricular ejection fraction — %	54.2±10.6	54.3±10.7
Procedure status at time of catheterization — no. (%)§		
Elective	10,350 (73.2)	3414 (72.4)
Urgent¶	3,291 (23.3)	1127 (23.9)
Emergency‡	493 (3.5)	175 (3.7)
Clinical status at time of catheterization — no. (%)‖		
STEMI	390 (2.8)	147 (3.1)
NSTEMI	3,471 (24.5)	1210 (25.7)
Unstable angina	5,196 (36.7)	1665 (35.3)
Stable angina	2,011 (14.2)	636 (13.5)
Atypical chest pain	723 (5.1)	268 (5.7)
Other	2,356 (16.7)	790 (16.8)

* Plus–minus values are means ±SD. CABG denotes coronary-artery bypass grafting, CAD coronary artery disease, NSTEMI non–ST-segment elevation myocardial infarction, PCI percutaneous coronary intervention, PVD peripheral vascular disease, and STEMI ST-segment elevation myocardial infarction.

† Race was self-reported.

‡ P<0.05 for the comparison between groups.

§ For procedure status at time of catheterization, data were missing for 15 patients treated at hospitals without on-site cardiac surgery and 2 patients treated at hospitals with on-site cardiac surgery. The definitions for "urgent" and "emergency" were those used in the American College of Cardiology National Cardiovascular Data Registry module on cardiac catheterization, version 3.02.[10]

¶ P<0.01 for the comparison between groups.

‖ For clinical status at time of catheterization, data were missing for 2 patients in each study group. "Other" includes patients presenting with heart failure, arrhythmia, positive stress tests, syncope, and other non–chest-pain syndromes and patients undergoing cardiovascular risk assessment before a noncardiac surgical procedure.

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Table 2. Characteristics of the Index Procedure.*

Characteristic	No On-Site Cardiac Surgery	On-Site Cardiac Surgery	P Value
PCI staged — no./total no. (%)†	3652/14,010 (26.1)	3084/4538 (68.0)	<0.001
Single-vessel PCI — no./total no. (%)	11,212/14,010 (80.0)	3716/4538 (81.9)	
Multivessel PCI — no./total no. (%)	2937/14,010 (21.0)	1002/4538 (22.1)	
No. of catheterization laboratory visits needed to complete index PCI	1.28	1.73	<0.001
No. of days from randomization to index PCI — median (IQR)	0 (0–3)	1 (0–3)	<0.001
Stent use — no./total no. (%)			0.03
DES only	10,074/14,010 (71.9)	3343/4538 (73.7)	
BMS only	2790/14,010 (19.9)	877/4538 (19.3)	
Both DES and BMS	596/14,010 (4.3)	156/4538 (3.4)	
Balloon only	550/14,010 (3.9)	162/4538 (3.6)	
PCI success — no./total no. (%)			
By patient‡			0.007
Complete success	12,714/14,010 (90.7)	4148/4538 (91.4)	
Partial success	808/14,010 (5.8)	253/4538 (5.6)	
Failure	482/14,010 (3.4)	113/4538 (2.5)	
By lesion§			0.04
Success	19,886/21,292 (93.4)	6499/6907 (94.1)	
Failure	1406/21,292 (6.6)	408/6907 (5.9)	
Emergency procedures			
Emergency PCI — no./total no. (%)	23/14,010 (0.2)	6/4538 (0.1)	
Death associated with emergency PCI — no. of deaths/total no. of emergency PCI procedures (%)	1/23 (4.3)	0	
Emergency CABG — no./total no. (%)	13/14,010 (0.1)	10/4538 (0.2)	0.11
Death associated with emergency CABG — no. of deaths/total no. of emergency CABG procedures (%)	2/13 (15.4)	2/10 (20.0)	

* Data are for all randomly assigned patients who underwent PCI. BMS denotes bare-metal stent, DES drug-eluting stent, and IQR interquartile range.
† Staged PCI indicates that PCI was performed on a different day than the visit to the catheterization laboratory to minimize procedural risk.
‡ Thirty patients (6 in hospitals without on-site cardiac surgery and 24 in hospitals with on-site cardiac surgery) did not have valid postprocedure data available on coronary-artery flow (according to the Thrombolysis in Myocardial Infarction [TIMI] scale, which ranges from 0 to 3, with 0 indicating no flow and 3 normal flow) or percentage of residual stenosis. These 30 patients were excluded from the analysis of PCI success by patient. Complete success was defined as a postprocedure TIMI flow grade of 3 and residual stenosis not exceeding 20% in all treated lesions. Partial success was defined as a postprocedure TIMI flow grade of 3 and residual stenosis not exceeding 20% in at least one (but not all) treated lesions. Failure was defined as no treated lesions with a postprocedure TIMI flow grade of 3 and residual stenosis of more than 20%.
§ Success by lesion was defined as a postprocedure TIMI flow grade of 3 and residual stenosis not exceeding 20%. Failure was defined as a postprocedure TIMI flow grade of less than 3 or residual stenosis of more than 20%.

myocardial infarction between the two groups, but there was a significant difference in the rate of target-vessel revascularization — 6.5% among participants at hospitals without on-site cardiac surgery versus 5.4% among those at hospitals with on-site cardiac surgery (P=0.01).

Several exploratory analyses were conducted (Table 3). If CABG was not considered to qualify as target-vessel revascularization when it was performed as an initial procedure (i.e., for participants who did not undergo the intended index PCI), the rates of major adverse cardiac events at 9 months among participants at hospitals without and those with on-site cardiac surgery were 11.9% and 10.5%, respectively. In per-protocol analyses (excluding participants who crossed over), the death rates at 6 weeks were 0.9% and 0.8%, respectively, and the rates of major adverse cardiac

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Table 3. Trial Outcomes.*

Outcome	No On-Site Cardiac Surgery	On-Site Cardiac Surgery	Difference in Rate (Asymptotic One-Sided 95% CI)	P Value	
				Noninferiority	Superiority
	no./total no. (%)		*percentage points*		
Primary end point (intention-to-treat population)					
Death at 6 wk	132/14,149 (0.9)	46/4718 (1.0)	−0.04 (−0.31 to 0.23)	0.004	
9-mo outcomes					
Death	454/14,149 (3.2)	150/4718 (3.2)			
TVR	915/14,149 (6.5)	255/4718 (5.4)			0.01
Q-wave myocardial infarction	434/14,149 (3.1)	144/4718 (3.1)			
Major adverse cardiac event	1716/14,149 (12.1)	529/4718 (11.2)	0.92 (0.04 to 1.80)	0.05	
Exploratory analyses (intention-to-treat population)					
Major adverse cardiac event, including withdrawal and loss to follow-up	2026/14,149 (14.3)	653/4718 (13.8)	0.48 (−0.48 to 1.44)	0.01	
CABG as initial procedure not included in TVR definition					
TVR	873/14,149 (6.2)	218/4718 (4.6)			<0.001
Major adverse cardiac event	1678/14,149 (11.9)	495/4718 (10.5)	1.37 (0.51 to 2.23)	0.21	
TVR according to stent type					
DES only	484/10,074 (4.8)	120/3343 (3.6)			0.005
BMS only	223/2790 (8.0)	53/877 (6.0)			
Both DES and BMS	39/596 (6.5)	8/156 (5.1)			
Balloon only	138/550 (25.1)	34/162 (21.0)			
Per-protocol analyses					
Death at 6 wk	129/13,967 (0.9)	38/4508 (0.8)	0.08 (−0.18 to 0.34)	0.03	
TVR	860/13,967 (6.2)	202/4508 (4.5)			<0.001
Major adverse cardiac event at 9 mo	1676/13,967 (12.0)	467/4508 (10.4)	1.64 (0.77 to 2.51)	0.42	

* Major adverse cardiac events included death, target-vessel revascularization (TVR), and Q-wave myocardial infarction. BMS denotes bare-metal stent, and DES drug-eluting stent.

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Table 4. Adverse Events.

Event	6 Wk			9 Mo		
	No On-Site Cardiac Surgery (N=14,149)	On-Site Cardiac Surgery (N=4718)	P Value	No On-Site Cardiac Surgery (N=14,149)	On-Site Cardiac Surgery (N=4718)	P Value
	no. (%)			*no. (%)*		
CABG						
All	88 (0.6)	69 (1.5)	<0.001	216 (1.5)	107 (2.3)	<0.001
Emergency	15 (0.1)	10 (0.2)		18 (0.1)	11 (0.2)	
Bleeding	486 (3.4)	150 (3.2)		754 (5.3)	247 (5.2)	
Vascular repair	52 (0.4)	20 (0.4)		151 (1.1)	55 (1.2)	
Stroke	40 (0.3)	8 (0.2)		87 (0.6)	23 (0.5)	
Renal insufficiency	72 (0.5)	20 (0.4)		131 (0.9)	37 (0.8)	
Unplanned catheterization	613 (4.3)	150 (3.2)	<0.001	2102 (14.9)	566 (12.0)	<0.001
Any subsequent revascularization	378 (2.7)	127 (2.7)		1200 (8.5)	329 (7.0)	0.001

events at 9 months were 12.0% and 10.4%, respectively.

CABG was performed more frequently among trial participants at hospitals with on-site cardiac surgery than among participants at hospitals without such access (Table 4). The incidence of unplanned catheterization at 6 weeks and 9 months and the incidence of any subsequent revascularization at 9 months were higher among participants at hospitals without on-site cardiac surgery (Table 4).

DISCUSSION

We compared clinical outcomes between trial participants undergoing PCI at a hospital with on-site access to cardiac surgery and participants undergoing PCI at a hospital without such access. We found that outcomes at hospitals without on-site cardiac surgery were noninferior to those at hospitals with cardiac surgery on site, with respect to all-cause mortality at 6 weeks and major adverse cardiac events at 9 months. There were no significant differences between the two study groups at 9 months with respect to rates of death or Q-wave myocardial infarction, but trial participants treated at hospitals without on-site cardiac surgery more frequently required target-vessel revascularization.

The short-term results from this trial are concordant with the findings in previous registry studies and meta-analyses.[17,18] The longer-term outcomes are similar to those in a small randomized trial of low-risk PCI at two hospitals,[19] which showed equivalent safety at the hospitals with and those without on-site cardiac surgery but more frequent target-vessel revascularization at 6 months among participants treated at the sites without cardiac surgery.

The definition of target-vessel revascularization used in the CPORT-E trial included any revascularization (PCI or CABG) after the index PCI. In addition, for randomly assigned participants who did not undergo an index PCI, any subsequent revascularization of the target vessel, whether by PCI or CABG, was considered a target-vessel revascularization. The inclusion of initial CABG as a target-vessel revascularization is consistent with the intention-to-treat approach, which is based on randomized treatment assignments, regardless of the treatment received. When CABG was not counted as a target-vessel revascularization in these trial participants, hospitals without on-site cardiac surgery were inferior to those with on-site access with respect to the rate of major adverse cardiac events at 9 months (Table 3). The per-protocol analysis also showed a higher rate of major adverse cardiac events in hospitals without on-site cardiac surgery. These differences are small and within the range of noninferiority margins used in recent comparative trials of stent types, from 1.5 percentage points (relative difference,

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19%)[20] to 3.5 percentage points (relative difference, 43%).[21]

In all analyses, the rate of target-vessel revascularization was higher among participants who underwent PCI at a hospital without cardiac surgery on-site, regardless of the definition of target-vessel revascularization and regardless of stent type. The reason for this is not clear from the current study but may reflect a lower initial success rate and a more conservative approach by interventionalists practicing at relatively inexperienced centers that began PCI programs only as part of the CPORT-E trial.

There are a number of important limitations arising from the design and conduct of the CPORT-E trial. Participants were carefully selected and were excluded if they were deemed to be at high risk. It is possible that the population studied is different from the general population requiring PCI, although a comparison of baseline characteristics with those reported in the National Cardiovascular Data Registry[17] suggests that this is not the case (Table S4 in the Supplementary Appendix). For outcomes of PCI at hospitals without on-site cardiac surgery to be similar to those at hospitals with on-site cardiac surgery, it may be necessary for such centers to participate in a formal PCI development program and for interventionalists who perform the procedures to meet the criteria for competency developed by the ACC, AHA, and SCAI.

In summary, the CPORT-E trial compared the clinical outcomes of PCI performed at hospitals with access to on-site cardiac surgery with outcomes of PCI performed at hospitals without such access. Outcomes at hospitals without on-site cardiac surgery were noninferior to those at hospitals with cardiac surgery on site, with respect to all-cause mortality at 6 weeks and major adverse cardiac events at 9 months.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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2012 American College of Cardiology Foundation/ Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update

A Report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents

Developed in Collaboration With the Society of Thoracic Surgeons and Society for Vascular Medicine

Writing Committee Members

Thomas M. Bashore, MD, FACC, FSCAI, Chair*†
Stephen Balter, PHD, FAAPM, FACR, FSIR
Ana Barac, MD, PHD*
John G. Byrne, MD, FACC‡
Jeffrey J. Cavendish, MD, FACC, FSCAI*
Charles E. Chambers, MD, FACC, FSCAI†
James Bernard Hermiller JR, MD, FACC, FSCAI*
Scott Kinlay, MBBS, PHD, FACC, FSCAI§
Joel S. Landzberg, MD, FACC*
Warren K. Laskey, MD, MPH, FACC, FSCAI*
Charles R. McKay, MD, FACC*
Julie M. Miller, MD, FACC*
David J. Moliterno, MD, FACC, FSCAI‖
John W. M. Moore, MD, MPH, FACC, FSCAI*
Sandra M. Oliver-McNeil, DNP, ACNP-BC, AACC*
Jeffrey J. Popma, MD, FACC, FSCAI*
Carl L. Tommaso, MD, FACC, FSCAI†

*American College of Cardiology Foundation Representative; †Society for Cardiovascular Angiography and Interventions Representative; ‡Society of Thoracic Surgeons Representative; §Society for Vascular Medicine Representative; and ‖ACCF Task Force on Clinical Expert Consensus Documents Representative. Authors with no symbol by their names were included to provide additional content expertise apart from organizational representation.

ACCF Task Force Members

Robert A. Harrington, MD, FACC, *Chair*

Eric R. Bates, MD, FACC¶
Deepak L. Bhatt, MD, MPH, FACC
Charles R. Bridges, MD, MPH, FACC¶
Mark J. Eisenberg, MD, MPH, FACC¶
Victor A. Ferrari, MD, FACC
John D. Fisher, MD, FACC
Timothy Gardner, MD, FACC
Federico Gentile, MD, FACC
Michael F. Gilson, MD, FACC
Mark A. Hlatky, MD, FACC¶
Alice K. Jacobs, MD, FACC
Sanjay Kaul, MBBS, FACC
David J. Moliterno, MD, FACC
Debabrata Mukherjee, MD, FACC¶
Robert S. Rosenson, MD, FACC¶
Howard H. Weitz, MD, FACC
Deborah J. Wesley, RN, BSN¶

¶Former Task Force member during this writing effort.

This document was approved by the American College of Cardiology Foundation (ACCF) Board of Trustees and Society for Cardiovascular Angiography and Interventions (SCAI) Board of Directors in February 2012 as well as endorsed by Society of Thoracic Surgeons and Society for Vascular Medicine in February 2012. For the purpose of complete transparency, disclosure information for the ACCF Board of Trustees, the board of the convening organization of this document, is available at http://www.cardiosource.org/ACC/About-ACC/Leadership/Officers-and-Trustees.aspx. ACCF board members with relevant relationships with industry to the document may review and comment on the document but may not vote on approval.

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Appendix 2. Reviewer Relationships With Industry and Other Entities (Relevant)—2012 ACCF/SCAI Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update xxxx

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Preamble

This document has been developed as an expert consensus document by the American College of Cardiology Foundation (ACCF) and the Society for Cardiovascular Angiography and Interventions (SCAI), in collaboration with the Society of Thoracic Surgeons (STS) and Society for Vascular Medicine (SVM). Expert consensus documents are intended to inform practitioners, payers, and other interested parties of the opinion of ACCF and document cosponsors concerning evolving areas of clinical practice and/or technologies that are widely available or new to the practice community. Topics chosen for coverage by this ECD are so designed because the evidence base, the experience with technology, and/or clinical practice are not considered sufficiently well developed to be evaluated by the formal ACCF/American Heart Association (AHA) Practice Guidelines process. Often the topic is the subject of considerable ongoing investigation. Thus, the reader should view the ECD as the best attempt of the ACCF and document cosponsors to inform and guide clinical practice in areas where rigorous evidence may not yet be available or evidence to date is not widely applied to clinical practice. When feasible, ECDs include indications or contraindications. Some topics covered by ECDs will be addressed subsequently by the ACCF/AHA Practice Guidelines Committee.

The ACCF Task Force on Clinical Expert Consensus Documents (TF CECD) makes every effort to avoid any actual or potential conflicts of interest that might arise as a result of an outside relationship or personal interest of a member of the writing panel. Specifically, all members of the writing panel are asked to provide disclosure statements of all such relationships that might be perceived as *relevant* to the writing effort. This information is documented in a table, reviewed by the parent task force before final writing committee selections are made, reviewed by the writing committee in conjunction with each conference call and/or meeting of the group, updated as changes occur throughout the document development process, and ultimately published as an appendix to the document. External peer reviewers of the document are asked to provide this information as well. The disclosure tables for writing committee members and peer reviewers are listed in Appendices 1 and 2, respectively, of this document. Additionally, in the spirit of complete transparency, writing committee members' *comprehensive disclosure information*—including relationships with industry and other entities that do not pertain to this document—is available online. Disclosure information for members of the ACCF TF CECD—as the oversight group for this document development process—is also available online.

The work of the writing committee was supported exclusively by the ACCF without commercial support. Writing committee members volunteered their time to this effort. Meetings and/or conference calls of the writing committee were confidential and attended only by committee members.

Executive Summary

The last expert consensus document on cardiac catheterization laboratory standards was published in 2001 (1). Since then, many changes have occurred as the setting has evolved from being primarily diagnostic based into a therapeutic environment. Technology has changed both the imaging and reporting systems. The lower risk of invasive procedures has seen the expansion of cardiac catheterization laboratories to sites without onsite cardiovascular surgery backup and even to community hospitals where primary percutaneous coronary intervention (PCI) is now being performed. This has increased the importance of quality assurance (QA) and quality improvement (QI) initiatives. At the same time, the laboratory has become a multipurpose suite with both diagnostic procedures to investigate pulmonary hypertension and coronary flow and with therapeutic procedures that now include intervention into the cerebral and peripheral vascular systems as well as in structural heart disease. These new procedures have impacted both the adult and pediatric catheterization laboratories. The approaches now available allow for the treatment of even very complex heart disease and have led to the development of hybrid cardiac catheterization laboratories where a team of physicians (including invasive cardiologists, cardiovascular surgeons, noninvasive cardiologists, and anesthesiologists) is required.

The Cardiac Catheterization Laboratory Environments

Despite a growth in procedural sites and in procedural capabilities in the cardiac catheterization laboratory, the total number of coronary interventional procedures has steadily declined over the last few years.

Cardiac Catheterization at a Hospital With Cardiovascular Surgery

Full-service hospitals should provide, not only cardiovascular surgery, but also cardiovascular anesthesia and consulting services in vascular, nephrology, neurology, and hematology. Advanced imaging and mechanical support services should also be available. Not every hospital with onsite cardiovascular surgery should be offering all services unless the expertise is available to evaluate, treat, and handle any potential complications that occur. Patients requiring highly specialized procedures or pediatric procedures should have

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studies only in facilities with the medical expertise and equipment to perform these procedures at the highest level.

Cardiac Catheterization at a Facility Without Cardiovascular Surgery

Despite prior guidelines that suggest limitations to the expansion of cardiac catheterization without onsite surgical backup, the number of these sites has increased dramatically over the last decade. The Certificate of Need (CON) regulatory programs have had little impact on this expansion. Whether quality and outcomes are similar to hospitals with onsite cardiovascular surgery remains uncertain. The actual number of laboratories without surgical backup is difficult to confirm, but most estimates suggest it is around 25% to 35% of all laboratories in the United States. Because of fixed costs to maintain these facilities, costs and charges per patient at these sites may actually be higher than in facilities with onsite surgery.

The remarkably low risk now associated with *diagnostic cardiac catheterization* suggests that only a few cardiovascular patients cannot safely undergo procedures in these laboratories. The 2001 ACC/SCAI consensus document suggests limiting diagnostic procedures in laboratories without cardiovascular surgical backup to the very lowest-risk patients; the current document lifts almost all these restrictions. Limitations related to age, congestive heart failure (CHF) status, the severity in stress test abnormalities, left ventricular (LV) function, and the presence of valve disease have all been removed. It is still recommended that patients with pulmonary edema due to ischemia, patients with complex congenital heart disease, and pediatric patients still be treated only in full-service facilities.

Certain *therapeutic procedures* should still be done only in facilities with cardiovascular surgical backup. These include therapeutic procedures in adult congenital heart disease and pediatrics. It is generally believed that elective and primary PCI are permissible in sites without cardiovascular surgery, if there is strict adherence to national guidelines. In particular, there must be a documented working relationship with a larger facility with cardiovascular surgical services and an emergency transportation system operative. The document outlines the current guidelines where this is acceptable. The committee also believes that it is the responsibility of any facility performing coronary intervention without cardiovascular surgical backup to document that all national risk stratification and medication guidelines are being followed. In addition, a QA/QI system must be operative and active, and, if an ST-elevation myocardial infarction (STEMI) program is in place, the laboratory should be operational 24 hours a day, 7 days a week. Any national volume guidelines must also be strictly followed.

Quality Assurance Issues in the Cardiac Catheterization Laboratory

The modern cardiac catheterization laboratory is a complex, highly sophisticated medical and radiological facility where patients with both chronic-stable and life-threatening illnesses are evaluated. With the expansion of laboratories and the increase in the complexity of procedures, it is essential to have an active QA/QI system in place regardless of the laboratory setting. The committee strongly encourages all laboratories to participate in national registries, such as the ACC's National Cardiovascular Data Registry (NCDR), to ensure data are systematically collected and available in a predefined format to allow for future analyses. In this manner, all laboratories can benchmark their performance and make appropriate corrections.

Patient Outcomes

The rate of normal or insignificant coronary artery disease angiographically found at cardiac catheterization in any 1 laboratory obviously varies depending on the types of patients studied, but the range is high, varying anywhere from 20% to 39%.

Complications related to the catheterization procedure are very low and should be <1% for diagnostic procedures and <2% for elective PCI. The risk is obviously higher in the setting of an acute myocardial infarction (AMI), but even in that situation, the overall mortality should be <4%. Complication rates >5% must be considered excessive and a cause for concern and programmatic review.

At least 60% of PCI procedures are done ad hoc following lesion discovery on a diagnostic angiogram. Although there is no evidence this practice has an adverse effect on outcomes, ad hoc procedures should be discouraged when the patient would benefit from a multidisciplinary discussion regarding options for therapy or when an interventional procedure at a later time would reduce the risk of contrast nephropathy. In the acute STEMI setting, when multivessel disease is evident, only the culprit lesion should undergo emergency intervention.

Data relating to outcomes in peripheral vascular and cerebrovascular intervention are incomplete. The technology continues to evolve as do the indications. Laboratories historically dedicated to coronary disease have had to transform themselves technically, logistically, and administratively to provide optimal care for this population. Large image detectors are often required and are not optimal for coronary angiography. This area is further complicated by the fact that noncardiologists (i.e., vascular surgeons and interventional radiologists) may also be participating, so guidelines, as well as credentialing issues, may vary among the groups. Because no clear benchmarks yet exist, participation in an ongoing national database for these procedures is particularly important.

Peer Review Continuous QA/QI Programs

Most major QA problems are unrelated to equipment but are due to operational factors. These tend to include inadequate laboratory space, lack of a physician director or advocate, lack of specific operating rules, and a poor feedback mechanism. More than ever, a continuous QA/QI

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program must be considered an essential component of the cardiac catheterization laboratory. It should be dedicated to the lab but not be independent of the other hospital programs. It must be adequately staffed and appropriately funded. The basic components must include a committee with a chair and staff coordinator, a database, and a means of data collection. There should be goals to eliminate outliers, reduce variation, and enhance performance. Feedback mechanisms should be clearly in place. The committee should also be committed to educational opportunities for the staff and incorporating practice standards and guidelines into the laboratory operation. Some composite "scorecard" methods should be included that address cognitive knowledge, procedural skill, clinical judgment, and procedural outcomes. These data need to be collected in a systematic manner and analyzed appropriately. Often a simple comparison of outcomes among physicians in the laboratory is effective in modifying behavior.

To help facilitate organization of a QA/QI process, the current document outlines the major organizational indicators, provides a representative case review form, and outlines the minimum components that should be included in a standard cardiac catheterization form.

Quality indicators should include structural, patient care, system-specific, guideline-driven, and cost-related items. Structural indicators include factors such as training, continuing medical education (CME), procedural volume, awards, presentations, publications, and credentialing. Patient care indicators include issues such as quality of procedures, report generation, timeliness, and appropriateness. System-specific indicators incorporate items such as lab turnover, preprocedural processes, emergency response time, and staff performance. Guideline-driven indicators should focus on infection control, radiation safety, medication and contrast use, procedural indications, and new device usage. Cost-related issues include such things as length of stay, disposables, types and adequacy of supplies, staffing, and use of off-label devices.

In addition to the above, there should be defined outcomes-related indicators collected. These include individual physician complications, service outcomes (e.g., access, door-to-intervention times, and satisfaction surveys), and financial outcomes.

To do this properly requires a serious commitment from the facility administration to ensure that a robust QA/QI program is in place and the program committee is active and aggressive regarding its responsibilities.

Minimum Caseload Volumes

Using minimum case volumes as a surrogate for quality presumes that a high procedural volume equates to a high skill level and that low-volume operators are less skilled. In fact, there is limited statistical power to make judgments in the low-volume instance, and the relationship between procedural volume and outcome remains controversial. This applies to the laboratory facility as well as the physician operator. The particular issue of minimum case volumes is currently being addressed by a forthcoming update to the "ACCF/AHA/SCAI Clinical Competence Statement on Cardiac Interventional Procedures." This document simply outlines the currently available data; the final recommendation awaits the decisions of the competence statement writing committee.

Establishing an appropriate oversight QA/QI process is more important than focusing on minimum volumes. All major complications should be reviewed by the QA committee at least every 6 months, and any individual operator with complication rates above benchmarks for 2 consecutive 6-month intervals should have the issue directly addressed by the QA director and followed up with written consequences. Ideally, some subset of all operators should be randomly reviewed at least annually. All operators should be required to attend regularly cardiac catheterization conferences and obtain a minimum of 12 CME hours per year. Stimulation training may assist in improving skills.

The very low complication rate for diagnostic catheterization makes suggestions for a minimum volume threshold particularly difficult. The prior catheterization standards document suggested 150 cases per year as a minimum, but that committee acknowledged this was arbitrary and had no data to support the recommendation (1). This committee feels that there is no clear minimum volume for diagnostic catheterization that can be supported and prefers to emphasize the QA process to ensure the procedures are of the highest quality.

The annual minimum operator interventional procedural volume of 75 cases per year has become an accepted standard. Numerous publications and editorials have addressed this issue in detail. Although some relationships between operator and/or institutional volumes and outcomes have been described in certain reports, many publications have struggled to confirm these data. Obviously the relationship between volume and outcomes is complex, and many confounding issues are evident. Low-volume operators in high-volume laboratories tend to fare better. Complicating the issue further, however, is the fact that many competent interventional cardiologists do not perform >75 procedures each year. Some cardiologists perform PCI primarily when on-call, and some are at the beginning or the end of careers and are either ramping up or winding down a practice. Some perform procedures at multiple facilities, and the data for such individuals are often incomplete.

The data for primary PCI are particularly difficult to categorize because of the low volumes being performed. This committee believes that it is appropriate for all primary PCIs to be evaluated by the institutional QA committee, regardless of operator volume. Operators wishing to participate in primary PCI should be required to attend these review sessions.

The guidelines for the performance of both elective and primary PCI in a facility without cardiovascular surgical backup are also evolving. Recent prospective studies and meta-analyses of available data both suggest these procedures can be done safely under restrictions. The minimum

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volume issue in this setting will be another focus of the ACCF/AHA/SCAI Writing Committee to Update the 2007 Clinical Competence Statement on Cardiac Interventional Procedures. Because these patients are at highest risk for complications, national guidelines for the proper PCI, particularly in the setting of an AMI, must be strictly followed. The facility must have a robust QA program, clear and documented systems for the urgent transfer of patients to a facility with cardiovascular surgical support, documentation that all medication and indication guidelines are being observed, and 24/7 availability.

Training in Interventional Procedures

The use of minimum volumes and rotation duration for training in interventional cardiology procedures has been established by the ACCF Core Cardiology Training Symposium (COCATS). These are still the established requirements for Level 1, Level 2, and Level 3 training. These are summarized in this report, but the committee recognizes that even here, there is a gradual shift away from minimum numbers and toward a competence standard. The formal training to achieve credentials in peripheral vascular intervention is highlighted for cardiology fellows, and compared with that of interventional radiologists and vascular surgeons; little difference actually exists.

Training in structural heart disease intervention is clearly an area where volume numbers should not supplant evidence for competence by a QA review of outcomes. By definition, most of these procedures require a multidisciplinary approach and should not be attempted by casual operators. It is recommended that both the training and practice activity associated with structural heart disease intervention be concentrated among a limited number of laboratories and operators with a particular interest in these procedures. Often a close working relationship between adult and pediatric operators provides the optimal environment.

Procedural Issues in the Cardiac Catheterization Laboratory

Patient Preparation

A number of procedural issues are addressed. Heightened awareness of protective care from communicable diseases, such as human immunodeficiency virus (HIV) or hepatitis, is important. Each laboratory should have a written protocol for increased sterile technique for highly infectious cases. The protocol should include caps, masks, double gloving, and protective eyewear. Disposal methods and disinfectant techniques are also important.

Patient preparation should include a checklist of items to be reviewed when the patient first arrives at the laboratory. Appropriate consent should include risks, benefits, alternative therapies, and the potential need for ad hoc procedures. All PCI consent forms should outline the potential for emergency surgery. A "time-out" should be a required part of each procedure and should include the name, the procedure, the signed consent, allergies, antibiotic administration, the correct site, confirmation of the pre-wash, the need for any special equipment or imaging, and any pertinent clinical factors (including labs such as the creatinine level). If the radial artery is to be used, the Allen test results should be noted.

The committee reviewed the minimum laboratory data in preparation for cardiac catheterization and found a wide variability in practice patterns. The following recommendations were made: 1) routine laboratory data should include the hemoglobin, platelet count, electrolytes, and creatinine obtained within 2 to 4 weeks of the procedure. These should be repeated if there has been a clinical or medication change within that period or recent contrast exposure; 2) unless there is known liver disease, a hematologic condition of concern, or the ongoing use of warfarin, a protime is not deemed necessary prior to the procedure; 3) for overnight tests, a nothing by mouth (NPO) order is not always in the best interest of the patient; fasting should be no more than 2 hours after clear liquids or 6 hours after a light meal. Hydration should be considered an important component prior to contrast administration; and 4) women of childbearing age should have a urine or serum beta-HCG test within 2 weeks of the procedure. There is little fetal risk during the first 2 weeks of gestation. In addition, the committee could find no data to suggest a concern regarding nitinol device use in patients with nickel allergies.

For patients on warfarin, the drug is usually stopped 3 days prior to the procedure. An acceptable international normalized ratio (INR) of $\leq$1.8 for femoral or $<$2.2 for radial cases is suggested. Vitamin K reversal is discouraged. Patients on aspirin, unfractionated heparin, low-molecular-weight heparin, or glycoprotein IIb/IIIa inhibitors need not have the drugs stopped before catheterization. Dabigatran should be stopped 24 hours prior if the estimated glomerular filtration rate (eGFR) is $>$50 mL/min and 48 hours before if the eGFR is between 30 mL/min to 50 mL/min.

For patients with chronic kidney disease (CKD), there is a risk of contrast nephropathy following the procedure. The highest-risk patients are those with eGFR $<$60 mL/min and diabetes mellitus. It is recommended that patients with CKD have nephrotoxic drugs, such as nonsteroidal anti-inflammatory drugs (NSAIDs), held on the day of the procedure and that adequate hydration with either intravenous (IV) saline or sodium bicarbonate at 1.0 mL/kg/min to 1.5 mL/kg/min for 3 to 12 hours prior and 6 to 12 hours postprocedure should be completed as well. Contrast media should be minimized, and either low-osmolar or iso-osmolar contrast should be used. A contrast volume/creatinine clearance ratio of $>$3.7 has been suggested as a ceiling for contrast use to reduce nephrotoxicity risk. A follow-up creatinine level should be obtained in 48 hours. Acetylcysteine is no longer recommended.

Patients with a strong atopic history or prior contrast allergy should be considered for pre-medication with steroids and/or H1 and H2 blockers. Shellfish allergies are not

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considered important for contrast reactions. Diabetic patients usually have the insulin dose reduced by half the night prior and then held the morning of the procedure. Diabetic patients should have procedures early in the schedule, if possible, to avoid hypoglycemia. Metformin should be held regardless of the creatinine clearance and not restarted until there is postprocedural documentation that the creatinine has returned to baseline. An awareness of the treatment of anaphylactoid reactions to contrast is important. Delayed hypersensitivity rashes should not be confused with reactions to new drugs initiated after the procedure.

Procedural Issues

Radial artery use for access has increased over the last few years. Though the procedure may take slightly longer and radiation exposure is slightly higher, the radial access site has less vascular complications than the femoral approach. In addition, it allows for earlier ambulation and is particularly efficacious in the obese. Medications during the procedure and sterile techniques have not changed over the last decade.

Technical and Hemodynamic Issues

Except for the equipment advances, the actual performance of coronary angiography has changed little over the last decade. Facilities with biplane capabilities are less common now. Biplane coronary angiography may reduce total contrast load in patient with CKD and is important in structural heart intervention. Hemodynamics are less stressed in most laboratories despite accurate hemodynamic measurements being critical in certain disease states (such as constrictive pericarditis). Intracoronary hemodynamics have most recently focused on the use of the pressure wire. The cardiac catheterization procedure can provide information regarding ventricular performance, cardiac output, vascular resistance, and shunt magnitude. The hemodynamics before and after pulmonary vasodilators are also critical to the decision algorithm on therapy for patients with pulmonary hypertension. Vasodilator or inotropic stress testing in patients with low-gradient, low-valve area aortic stenosis, likewise, provides vital information on the best therapeutic option in these patients. Transseptal catheterization has had resurgence with the success of such procedures as balloon mitral valvuloplasty and atrial fibrillation ablation. Entry into the left atrium (LA) provides percutaneous therapeutic options for pulmonary vein stenosis and, for some cases, with mitral regurgitation. Myocardial biopsies are useful in restrictive heart disease and in heart transplant patients. Within the hybrid laboratory environment, LV puncture allows for percutaneous aortic valve replacement via an apical approach. Intracardiac ultrasound and Doppler imaging methods have proven their value in a number of situations, including atrial septal visualization during percutaneous patent foramen ovale (PFO) or atrial septal defect (ASD) closure, left-sided electrophysiological ablation studies, mitral valvuloplasty, and LA appendage occluder deployment.

In addition, there are now therapeutic options to augment cardiac output using placement of an intra-aortic balloon pump or the use of catheters, either connected to a rotary pump or that have a rotary micropump within the catheter itself. The percutaneous application of extracorporeal membrane oxygenation (ECMO) can now be performed in the cardiac catheterization laboratory as well.

The known vagaries of contrast angiography in defining vascular lesion severity and composition has led to the development of a range of intravascular imaging devices, including intravascular ultrasound (IVUS) and other devices that provide plaque imaging with virtual histology and tissue ingrowth assessment using optical coherence technology. Although many are still investigational, they all carry some inherent risk of vessel injury that should be appreciated.

Postprocedural Issues

Vascular Hemostasis

In cases of femoral access where no vascular closure device is being used, if heparin has been used during the procedure, the activated clotting time (ACT) should return to near normal (<180 s) before sheaths are removed and manual compression applied. Common practice is to confine the patient to bed after sheath removal. Bed rest for 1 to 2 hours after either 4- or 5-F sheaths and 2 to 4 hours after 6- to 8-F sheaths is suggested. The radial approach obviates prolonged bed rest. All patients should have the access site auscultated prior to discharge. Should a pseudoaneurysm occur, most can be closed with compression and percutaneous thrombin.

A bleeding risk score for PCI has been developed from the NCDR database. It provides an opportunity to identify those at highest risk for a vascular complication.

The use of vascular occlusion devices has grown rapidly despite evidence their application does not reduce overall vascular complications. An AHA Scientific Statement regarding these devices recommends a femoral arteriogram with identification of sheath site and vascular features be done before their use. The use of any vascular device is considered a Class IIa (Level of Evidence: B) indication.

Medication Use

Little has changed in the use of sedative and pain control medications after the procedure. Hypertension should be aggressively managed with agents such as labetalol, hydralazine, metoprolol, or nicardipine. Vagal reactions can be quite serious, and pre-medication with narcotics prior to sheath removal may help reduce their occurrence. Hypotension after cardiac catheterization is potentially multifactorial and includes diuresis, ischemia, retroperitoneal bleeding, as well as vagal reactions. If a retroperitoneal bleed is suspected, the most effective rapid response is to return to the laboratory for contralateral access and identification of the bleeding site.

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Personnel Issues

Little has changed over the last decade in regard to personnel issues. A cardiac catheterization procedure requires a critical mass of interdisciplinary personnel to allow safe and optimal performance of the procedure. Technical staff should be certified. The staff should be provided opportunities for ongoing continuing education.

Defined physician personnel in the cardiac catheterization include the attending or operating physician (the individual in charge), the teaching attending physician (often supervising cardiology fellows), and secondary operators.

A laboratory director is a prerequisite for all laboratories and should be an experienced (generally >5 years) interventionalist, board-certified, and familiar, if not proficient, with the various procedures and technical equipment being used in the laboratory. In small or new laboratories, a physician director may be just starting his practice. If the director does not have >500 PCI procedures performed, his or her cases should be randomly reviewed by the QA process until that minimum number is achieved and competence established. The laboratory director may or may not be the interventional fellowship director. However, he or she should work closely with the fellowship training program. The director is responsible for monitoring physician and staff behavior and ensuring their competence. The director should be the laboratory's advocate for adequate resources. He or she should collaborate with hospital personnel to ensure safety and compliance with all regulations and possess strong management skills as well.

Cardiovascular trainees may perform all aspects of the procedure as their skill level matures, but they cannot be primary operators and must function under the direct supervision of the attending physician. Physician extenders (nurse practitioners and physician assistants) are primarily used for the pre- and postprocedural evaluations and follow-up, but in monitored situations, they can directly assist the primary operator in the actual procedure.

The number and type of nursing personnel varies widely, but a supervising nurse's role is to manage nonphysician nursing and technical personnel to ensure patient care is optimal and that the staff is properly trained and respected. The committee notes there is currently no formal certification for this position (despite its complexity) and endorses a movement toward such a certification option on a national level.

With the movement away from cine film to digital storage and archival systems, it is important to have access to computer technical support. Because of the increased importance of patient and staff radiation safety, laboratories should have routine access to qualified medical and health physicists. Support is needed beyond meeting the minimum regulatory safety regulations.

All members of the cardiac catheterization team must have Basic Life Support certification in cardiopulmonary resuscitation (CPR) techniques, and the committee strongly urges certification in advanced cardiac life support as well.

The Hybrid Cardiac Catheterization Laboratory

The hybrid cardiac catheterization laboratory/operating room is an integrated procedural suite that combines the tools and equipment available in a cardiac catheterization laboratory with anesthesia and surgical facilities and possesses the sterility of an operating room. It must meet all of the standard features of both an operating room and a cardiac catheterization facility. Procedures suited for a hybrid room include those that require surgical access (i.e., percutaneous valve replacement, thoracic or abdominal stented grafts, and large-bore percutaneous ventricular assist devices), those where conversion to an open surgical procedure may be required (i.e., bailout or apical approach to percutaneous aortic valve replacement, vascular plug deployment in paravalvular prosthetic valve regurgitation, and percutaneous ventricular septal defect closure), hybrid treatments (i.e., combined PCI or other vascular stenting with surgical approaches and epicardial atrial fibrillation ablation), electrophysiology (EP) device implantation or removal, and certain emergency procedures such as ECMO insertion or emergent thoracotomy.

The staff must be comfortable with both the surgical suite and the cardiac catheterization laboratory environment. This is generally done by using a specific team to allow for the necessary training. As the room is neither a standard operating room nor catheterization laboratory, physician training on its use is also a requirement.

The laboratory location can be either in proximity to the operating rooms or to the catheterization suite. It must be located on a clean core or semirestricted corridor where scrubs, hats, and masks are required. Scrub alcoves are a necessity along with a separate control room with wide windows. These rooms are larger than the standard cardiac catheterization laboratory room, though radiation shielding and video equipment are similar. A wide range of lighting is required (dim for viewing images and bright for surgical procedures). The mounting of the x-ray gantry is important so as not to interfere with laminar airflow or the anesthesiologist. The table also differs from the routine laboratory as surgeons need a fully motorized table and tabletop, yet it must be compatible with the production of high-quality x-ray images.

In short, the hybrid laboratory requires considerable planning and a firm understanding of how the room is to be used before its construction. Its dual function provides an opportunity to expand the procedures in the catheterization laboratory. Its stringent requirements demand a cooperative working relationship with a variety of disciplines to be a safe and successful endeavor.

Ethical Concerns

A detailed discussion of ethical issues is beyond the scope of this document. The physician's primary obligation is always

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to the patient and to no one else regardless of financial, regulatory, or social pressures otherwise. Physician responsibilities have increased dramatically with mandates from payers and the government for an ever-increasing amount of documentation. Much of this is time-consuming and creates unnecessary redundancy with little direct impact on the primary obligation. The changing healthcare reimbursement landscape has driven many physicians to align with larger health systems where there may be a further increase in the pressure for increased productivity in the face of declining reimbursement. With the decline in the fee-for-service system and the approaching shift toward reimbursement bundling, the physician must never leverage patient interests to produce a better profit margin.

A few of the major ethical concerns are addressed in this section. They include the inappropriateness of the sharing of fees, fee splitting, and fee fixing. Unnecessary procedures performed, especially those justified as malpractice protection, are improper and not in the patient's interest. Guidelines for appropriate use in many areas are now emerging to address this. Physician self-referral concerns led to the introduction of the Stark laws in 1989, and these regulations are designed to limit procedures being done to simply augment profit. Informed consent continues to get more and more complex, but a clear and understandable description of the procedure, the alternatives, the benefits, and the risks is simply a mainstay of good patient care. Teaching hospitals have a particular obligation to inform the patient of the skill level of all personnel involved. Cardiology has been the leader in developing evidence-based medicine, and clinical research involving patients requires strict adherence to safety guidelines and the protocol being employed. The opportunity for monetary rewards or self-promotion should never override patient safety and respect. Physicians and industry must work together to advance medical knowledge and avoid bias. Physicians should not accept industry gifts. Conflict of interest committees are designed to oversee any potential conflict and are in place to protect both the physician and the institution.

X-Ray Imaging and Radiation Safety

Substantial changes in the x-ray equipment have occurred over the last decade. The movement from cine film to a digital medium has been completed, and the transition from the standard image intensifier to the flat-panel image detector is in progress. Flat-panel detectors enhance image uniformity and brightness and have a much greater dynamic range compared to the standard image intensifier. Radiologists routinely receive formal training in understanding how x-ray images are created, but this learning process is much more informal in cardiology. This section provides an overview of how x-ray images are made and discusses the role of each of the pieces of equipment. The major changes over the last decade include changes in the generator, x-ray tube, image detector, image processing, and image display. The dose-area product (DAP) is a measure of the total radiation exposure and is derived from an ionizing chamber on the output of the x-ray tube. It does not address the amount of radiation to specific organs. The use of the interventional reference point (IRP) is recommended to estimate the amount of skin dose the patient receives.

The biological risk from x-rays is due to disruption to the cellular DNA backbone either by direct or indirect (free-radical) injury. A deterministic injury results in enough individual cellular death to create organ dysfunction. These types of injury are dose-dependent (such as skin burns). A stochastic injury to the DNA results in mutations or cancers, and a single x-ray can be at fault. Although the likelihood of this happening increases with the dose, it is not dose dependent. The effective dose encompasses the stochastic risk and is used to provide a metric of radiation safety. It is the weighted sum of the estimates of dose to each individual organ. The breast, bone marrow, and lungs are among the most sensitive organs in this model. The effective dose correlates with the DAP.

The IRP dose at the isocenter of the gantry (usually the midportion of the patient) is derived by estimating the dose in the midportion of the patient and then dropping back 15 cm (assuming that is where the skin on the patient's back is located). It provides an estimate of the deterministic injury dose.

Recommended guidelines for patient and operator dose limits to reduce deterministic and stochastic injury are provided in the document and reflect current National Council on Radiation Protection and Measurements (NCRP) reports. The NCRP now accepts as a minimum the wearing of a single monitoring device on the thyroid collar; however, the recommended 2-monitor technique provides the best estimate of risk. A pregnant worker must also wear a monitor at waist level under the lead apron. Maximum allowable radiation for medical workers is 50 millisieverts (mSv) per year whole body and a lifetime cumulative dose of 10 mSv × age.

An understanding of x-ray image formation and basic radiation safety principles allows for the understanding of means to limit exposure to both the patient and operator. Exposure to the patient can be reduced by minimizing the framing rate, reducing imaging time, use of retrospectively stored fluoroscopy instead of acquisition, use of pulse fluoroscopy, and limiting use of "high-dose" fluoroscopy, avoiding magnification when possible, using collimation and other filters at the output of the x-ray tube, keeping the image detector close to the patient, and avoiding angulation that increases the source-to-image distance. For the operator, the same rules apply. Plus it is important to remember time, distance, and barriers. The impact of x-rays decreases in proportion to the inverse-square law ($1/d^2$). Lead shielding is effective if use properly.

All cardiac catheterization laboratories manufactured since 2005 are required to provide real-time exposure information, including reference point air kerma. Most fluoroscopes also

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provide DAP readings. A summary of these data should be incorporated in the patient record and part of the QA/QI process.

Special Concerns for the Pediatric Catheterization Laboratory

There are 120 specialized children's hospitals in the United States, and all have cardiac catheterization facilities. All facilities that perform cardiac catheterization on pediatric-aged patients must have the full complement of resources available, including cardiovascular surgery. Pediatric laboratories may be dedicated facilities or shared with an adult program.

Differences in Goals Between the Pediatric Laboratory and the Adult Laboratory

Diagnostic catheterizations in children are essentially always focused on structural heart abnormalities. Hemodynamic measures plus chamber and vessel angiography are much more commonly done than in adult laboratories. Because of the variability in patient size, most data are indexed to body surface area. Often the procedure requires significant sedation or general anesthesia. Due to improvements in noninvasive imaging, three fourths of all pediatric catheterizations are therapeutic and not simply diagnostic. A substantial number of unique procedures are performed in congenital heart disease (such as atrial septostomy) and are not applicable to adults. Therapeutic procedures that might also be performed in certain adult congenital patients include PFO and ASD closure, valvuloplasty, angioplasty, stent implantation in pulmonary and arterial vessels, vascular closure (patent ductus arteriosus, fistulae, anomalous vessels), devise closure of a ventricular septal defect, transcatheter pulmonary or aortic valve replacement, foreign body retrieval, pericardiocentesis, endomyocardial biopsy, and a range of electrophysiological procedures. Hybrid procedures are becoming more important where novel access may be provided (i.e., palliation of the hypoplastic left heart patient with access provided directly through the anterior right ventricle).

Who Should Perform Pediatric Catheterizations?

All pediatric catheterizations should have a director responsible for all aspects of the laboratory operation, similar to the adult laboratory. Attending physicians should be board-certified in pediatrics and at least board eligible in pediatric cardiology. There may be exceptional cases where a competent operator can be granted privileges, but this should not be common practice.

The pediatric age range is from 0 to 18 years. It is recommended that catheterizations in patients within this age range be done by a pediatric cardiologist. Adult congenital heart disease patients may have procedures performed by a pediatric cardiologist or with an adult and pediatric cardiologist together. The only exception is the adult cardiologist with a special interest and expertise in adult congenital heart disease.

Quality Assurance Issues in the Pediatric Cardiac Catheterization Laboratory

Complication rates differ substantially from the adult laboratory and are much higher due to the serious nature for many of the disease processes and the critical hemodynamic state at the times encountered. In 1 registry, adverse events in the pediatric laboratory were found to be 16% overall, with 10% related to diagnostic catheterization and 19% related to interventional procedures. Death occurred in 0.9%. The latest addition of pediatric data to the ACC-NCDR via the IMPACT (Improving Pediatric and Adult Congenital Treatment) registry should provide ongoing monitoring of these procedures. By necessity, informed consent is usually provided by the patient's parents. Similar concerns regarding informed consent in the adult laboratory still apply.

Inpatient Versus Outpatient Settings for Procedures

For most children, an overnight stay following the procedure is medically prudent. This is especially the case with young children where it is difficult for them to remain still after the procedure. Any blood loss may be significant in small children. Often families have traveled long distances, and local medical attention to a problem may not exist. Despite the small size, the sheaths used during pediatric catheterizations are similar to those in adults (5-F to 8-F). Each laboratory should establish a written policy on who might be expected to be discharged immediately following the procedure.

Operator and Laboratory Volumes

Similar to the discussion regarding adult laboratories, the heterogeneity of the patient population and the low volume of procedures make specific minimum volumes problematic. The American Academy of Pediatrics Guidelines suggests the use of specific outcome benchmarks rather than minimum operator or laboratory volumes as a guide to competence. The committee consensus, however, suggests a minimum operator volume of 50 per year and a minimum laboratory volume of >100 per year seems reasonable.

Having a robust QA/QI program in pediatric laboratories is of great importance. There should essentially be no "normal" cardiac catheterization procedures. The same rules outlined for an adult QA/QI program apply to the pediatric laboratory otherwise.

Procedural Differences Compared With the Adult Cardiac Catheterization Laboratory

The need for specific baseline laboratory data greatly differs in the pediatric catheterization laboratory. Many patients do not have noncardiac disease and are not on any medications. There is no standard laboratory data required before the procedure, and no standard pre-medication regiment. Se-

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dation is almost always required to perform the procedure. Vascular access is also individualized depending on whether the patient is a neonate, young or older child, or is of adult size. Most procedures are performed via the femoral artery and vein. Transseptal procedures are common. Newborn procedures are performed generally via the umbilical vein. Venous access can also be accomplished via the internal jugular, subclavian, basilica, and transhepatic approaches. In very young children, balloon aortic valvuloplasty or stenting open the patent ducts may require a carotid artery cut-down. Heparin is variably used during the procedure, whereas vascular occluders are not used in children. As more invasive percutaneous methods are being developed, the potential for catastrophic events increases. There should be access to ECMO in addition to routine resuscitation equipment.

Biplane x-ray capabilities should be standard, though certain procedures can be done with single-plane systems satisfactorily.

Hemodynamics and Angiography

Right and left heart hemodynamics and angiography are routine procedures and require high-resolution equipment to ensure the diagnosis. The framing rates depend on the patient's heart rate and 30 frames per second (fps) is often required to capture all the necessary information. Due to the high heart rates, contrast must be injected at a higher rate (i.e., over 1 to 2 s).

Laboratory Personnel

There is essentially no difference in the types of personnel needed to run an efficient pediatric catheterization laboratory dedicated to the highest standards compared with an adult laboratory.

Radiation Protection and Pregnant Patients

The same principles apply in this age group as with adults. Children are more susceptible than adults to the stochastic effects from ionizing radiation (they live longer and that increases the risk of a cancer developing). A urine or serum beta-HCG level should be obtained within 2 weeks of the procedure in menstruating women. If a pregnant patient must be studied, all of the previously described means to reduce radiation exposure should be followed, and the abdominal and groin area should be shielded from direct x-ray exposure. Scattered radiation still occurs, however.

Summary

The cardiac catheterization laboratory has undergone major changes in the last decade. It is a much more sophisticated environment where a gradual shift in emphasis from a diagnostic laboratory to a therapeutic environment is occurring. As the risk of both diagnostic and interventional procedures has declined, there has been liberalization in the types of patients who may safely have procedures performed in both outpatient settings and in laboratories without cardiovascular surgical backup. The influence of peripheral vascular and structural heart intervention has also required a change in focus for many laboratories and has given rise to the hybrid cardiac catheterization facility. The advances in percutaneous therapies for structural heart disease are just now beginning to impact both the adult and pediatric catheterization laboratory.

Some of the routine practices in many laboratories are being questioned. For instance, the committee no longer suggests a protime be obtained before a procedure, unless an abnormality is anticipated. Overnight NPO orders should be replaced with shorter-term fasting as hydration is important. Acetylcysteine is no longer recommended to reduce contrast nephropathy.

QA is a focus of this report, and its importance is mounting as it becomes harder to justify minimum volume requirements for both the operator and the laboratory. The importance of national databases to provide benchmarks is emphasized.

Radiation safety has also entered into the discussion more prominently as patients and regulators have expressed concern regarding the amount of medical radiation the public receives. Measures of the amount of radiation exposure should be a routine part of the cardiac catheterization report.

The cardiac catheterization laboratory and its functions will continue to evolve and grow over the next decade as newer devices and treatment options emerge. The cardiac catheterization laboratory of today differs significantly from that of a decade ago. It is anticipated that the cardiac catheterization laboratory 10 years from now will undergo a similar evolution.

1. Introduction

The last expert consensus document on cardiac catheterization laboratory standards from the ACCF and SCAI was published in 2001 (1). Although the fundamentals of invasive cardiovascular procedures remain unchanged, many changes have occurred related to the catheterization laboratory and its operational environment. Modifications and evolution have occurred with the imaging equipment technology, the range of diagnostic modalities, the spectrum of pharmacological therapies and mechanical interventions, and the local delivery of cardiovascular health care. Community hospitals without surgical backup have begun performing diagnostic catheterizations on higher-risk patients as well as elective interventional procedures on lower-risk patients, and community programs have been developed that permit onsite primary angioplasty on patients with AMI. At the same time, the cardiac catheterization laboratory has become a multipurpose interventional suite undertaking many therapeutic procedures for the coronary, cerebral, and peripheral vessels, providing corrective intervention for congenital and structural heart disease, sometimes merging with surgical suites into hybrid procedure rooms for valvular and

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complex nonvalvular interventions. This document is designed to update the latest information regarding the catheterization laboratory environment and its operation.

1.1. Document Development Process and Methodology

The development of consensus documents involves multiple healthcare professionals and often 2 or more medical societies. Given the importance of practice guidelines and expert consensus documents, governing principles have been established to ensure the accuracy, balance, and integrity of the content, as well as the composition of committees responsible for these documents. The ACCF has created a methodology manual for expert consensus document writing committees that can be accessed at www.cardiosource.org (2).

1.1.1. Writing Committee Organization

This writing committee was commissioned by the ACCF TF CECD in conjunction with SCAI. Coordination and staff support were provided by the ACCF. Nominations for writing group membership were made to the TF CECD with representatives and liaisons solicited from the TF CECD, SCAI, STS, and SVM. Care was taken to select acknowledged experts in cardiovascular catheterizations and interventions with members from both the academic and private practice sectors and representing a diverse geography. The committee consisted of 16 members: 12 from ACCF, 3 from SCAI, 1 from STS, 1 from SVM, and 1 invited radiation physicist content expert.

1.1.2. Relationships With Industry and Other Entities

As part of the nomination and application process, all writing committee candidates were required to provide an up-to-date disclosure of their relationships with industry and other entities (RWI). Both the ACCF and SCAI believe that including experts on writing committees who have relationships with industry strengthens the writing effort, though a stringent approach to keeping all relationships transparent and appropriately managed is necessary. As such, it was required that the majority (>50%) of writing committee members had no RWI relevant to the entire document. All relevant relationships occurring in the prior 12 months were required to be disclosed (Appendix 1), including the nature and extent of the relationship, as well as the establishment of new industry relationships at any time during the document writing process. Members with relevant RWI were not allowed to draft or vote on document sections where a conflict may have been perceived present.

The writing committee chair was selected by the TF CECD chair, and it was required that this individual have no relevant RWI. The writing committee chair along with support staff created and reviewed a tentative outline of sections for the consensus document. Companies, vendors, and other entities that had products or services related to the catheterization laboratory document were identified and categorized according to which sections of the document a relationship might exist. Writing committee members were then selected and assigned to specific sections. Each section had a primary author who could have no relevant RWI for that section or topic area. Each section also had 1 primary (internal) reviewer from the writing committee.

1.1.3. Consensus Development

The writing committee convened by conference call and e-mail to finalize the document outline, develop the initial draft, revise the draft per committee feedback, and ultimately sign off on the document for external peer review. All participating organizations participated in peer review, resulting in reviewers representing 371 comments. A group of 10 experts, separate from the writing committee, was selected for official review: 3 were nominated by ACCF, 3 by SCAI, 2 by STS, and 2 by SVM. In addition, 21 content reviewers from 3 ACCF Councils provided comments. There were no restrictions regarding the reviewers' RWI, though all reviewers were required to provide full disclosure regarding relevant relationships. This information was made available to the writing committee and is included in Appendix 2.

Comments were reviewed and addressed by the writing committee. A member of the ACCF TF CECD served as lead reviewer to ensure that all comments were addressed adequately. Both the writing committee and TF CECD approved the final document to be sent for board review. The ACCF Board of Trustees and SCAI Board of Directors reviewed the document, including all peer review comments and writing committee responses, and approved the document in February 2012.

The STS and SVM endorsed the document in February 2012. This document is considered current until the TF CECD revises or withdraws it from publication.

1.1.4. Document Methodology

The writing committee for this expert consensus document on cardiac catheterization laboratory standards began by reviewing the 2001 "ACC/SCAI Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards" (1). At the same time, the group conducted a brief review of the literature and clinical practice evolution relative to the catheterization laboratory environment. With this insight, it was agreed that there was enough important information to warrant a new consensus document. A formal review of the literature was performed and clinical data were reviewed considering a range of cardiovascular topics including, but not limited to, the following: hospitals and clinical environments with and without surgical back-up for complex diagnostic and interventional procedures; QA, proficiencies, and patient safety; procedural and postprocedural management issues including unique patient groups; new pharmacological and mechanical therapies; laboratory designs, imaging equipment, and technologies.

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1.2. Purpose of This Document

The workplace and function of the cardiac catheterization laboratory has steadily evolved over the last 70 years. Although numerous historic events have occurred during this time, and the developmental phases of the catheterization laboratory are not strictly delineated, 4 broadly defined intervals can be considered. In the earliest phase, roughly from 1940 to 1960, procedures were primarily focused on hemodynamic assessments and structural heart disease. With the development of radiographic techniques and subsequently surgical revascularization, anatomy-focused diagnostic studies became the mainstay of laboratory activity in the interval from 1960 to 1980. The advent of PCI and multiple percutaneous revascularization devices were the hallmarks requiring changes in the catheterization laboratory in the era from 1980 to 2000. Most recently, interventions on peripheral and cerebrovascular disease, structural cardiac abnormalities, and percutaneous valve therapies are influencing the needs and resources of the catheterization laboratory.

2. The Cardiac Catheterization Laboratory Environments

2.1. The Current Landscape

Over the 10 years since the publication of the "ACC/SCAI Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards" (1), much has changed in the cardiac catheterization laboratory. The importance of invasive hemodynamic assessment has been supplanted by major improvements in noninvasive imaging technologies. With this change, there has been an unfortunate loss in the capability of many laboratories to provide complex hemodynamic information, even when it might be of value clinically. The focus has now shifted primarily to coronary anatomy assessment, where sophisticated tools now allow for low-risk coronary interventions that were completely unavailable just a decade ago. Improved techniques have also reduced the overall risk for cardiac catheterization and transformed diagnostic catheterization into an outpatient procedure. Similar advances in interventional methods have nearly eliminated the need for immediate surgical standby for low-risk procedures, and a substantial amount of interventional procedures are now being performed in settings without an in-house coronary surgical team even available—something the prior consensus document condemned.

Of the 5,099 hospitals in the United States, the 2007 National Healthcare Cost and Utilization Project statistics note that a remarkable number of hospitals, a total of 4,345 (85.2% of all), now provide cardiac catheterization services, and 1,061 (20.8%) provide cardiac surgical services (3). As reported in the 2009 Update on Heart Disease and Stroke statistics from the AHA (4), the total number of inpatient cardiac catheterizations, however, actually declined slightly from 1996 to 2006, despite the incidence of inpatient PCI rates increasing from 264 to 267 per 100,000 population. During the same period, the incidence of coronary artery bypass grafting (CABG) declined from 121 to 94 per 100,000 patients (5). It is clearly a very dynamic time in the cardiac catheterization laboratory.

2.2. General Complications From Cardiac Catheterization Procedures

With the increase in the widespread use of cardiac catheterization, there has been a general decline in the risk of the procedure. Complication rates from diagnostic catheterization are quite low. As suggested by the "ACCF/AHA/SCAI Clinical Competence Statement on Cardiac Interventional Procedures" in 2007 (6), complications can generally be divided into 3 major categories: coronary vascular injury, other vascular events, and systemic nonvascular events. Major adverse cardiac and cerebrovascular events (MACCE) include death, stroke, myocardial infarction (MI), and ischemia requiring emergency CABG. MACCE for diagnostic procedures occurs in <0.1% of diagnostic procedures (6). Additional complications include vascular access site complications, contrast nephropathy, excessive bleeding, and other miscellaneous complications such as arrhythmias, hypotension, coronary perforation, and cardiac tamponade. The specific definitions of cardiac catheterization complications have been standardized to a great extent and outlined by the ACC-NCDR (7).

In a single-center review of diagnostic cardiac catheterization for 7,412 patients over a 10-year period (8), only 23 (0.3%) had major complications, and there were no deaths related to the diagnostic procedure. Complications were least common after procedures done by more experienced physicians, when smaller catheter sizes were used and when only left heart (and not left and right heart) procedures were performed. Obese patients had more vascular complications. Data from the ACC-NCDR database regarding PCI for both elective procedures and for acute coronary syndromes (ACS) are shown in Table 1 (9). These data reveal a trend toward fewer complications from PCI and a low risk-adjusted in-hospital mortality of 2.0% for ACS patients who had undergone PCI and 0.5% for elective PCI patients.

In 2009, the Mayo Clinic published 25-year trend data regarding their experience with 24,410 PCI procedures (10) (Fig. 1). The authors analyzed the first 10 years (1979 to 1989), the period from 1990 to 1996, the period from 1996 to 2003, and then finally the period from 2003 to 2004. They found that despite an older and sicker population with more comorbid conditions, the success rate from PCI had improved from initially 78% to 94%, hospital mortality had fallen from 3.0% to 1.8%, and the need for emergency CABG had dropped from 5% to 0.4%. In their latest assessment, major adverse complications following PCI occurred in only 4.0% of in-hospital patients.

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Table 1. Complication Rates for PCI Reported From the ACC-NCDR Database

Variable	Percutaneous Coronary Intervention			
	ACS		Non-ACS	
	Q1 to Q2 (2005) (n=92,534)	Q1 to Q2 (2009) (n=144,989)	Q1 to Q2 (2005) (n=50,532)	Q1 to Q2 (2009) (n=79,892)
Lesion information, %				
Previously treated	7.5	7.3	8.2	7.5
Bypass graft lesion	7.7	6.4	6.9	5.9
High-risk (Type C) lesion	43.3	46.9	33.7	38.7
Lesion length >25 mm	20.4	21.3	17.9	18.5
Bifurcation lesion	11.4	12.3	11.2	12.1
Procedural information, %				
Radial access	1.2	2.0	1.6	2.3
Multivessel PCI	13.9	12.9	15.5	15.3
Stents used during PCI				
DES	83.6	65.5	85.7	73.0
BMS	9.6	27.3	7.6	20.4
Angioplasty only	6.8	7.2	6.7	6.6
Procedural complications and results, %				
Dissection	2.4	2.1	2.2	2.0
Acute closure	0.7	0.7	0.5	0.5
Perforation	0.3	0.3	0.3	0.3
Procedural success	93.0	94.3	94.0	94.8
Vascular complications, %				
Access site occlusion	0.07	0.03	0.03	0.02
Peripheral embolization	0.08	0.04	0.02	0.02
Access vessel dissection	0.20	0.17	0.24	0.19
Pseudoaneurysm	0.42	0.46	0.38	0.84
Arteriovenous fistula	0.07	0.05	0.27	0.27
Bleeding complications, %				
Access site bleeding	1.20	0.78	0.67	0.49
Retroperitoneal bleeding	0.33	0.42	0.25	0.17
Gastrointestinal bleeding	0.54	0.67	0.27	0.15
Genitourinary bleeding	0.20	0.13	0.07	0.05
Other bleeding	0.60	0.97	0.27	0.27
In-hospital outcomes, %				
Transfusion after PCI	5.1	4.7	2.6	2.3
Stroke	0.3	0.3	0.1	0.1
Emergency bypass	0.4	0.4	0.2	0.2

Note: all outcomes are self-reported with only a small portion validated. Modified with permission from Roe et al. (9). Source of new data: ACC-NCDR Cath PCI Registry.
ACS = acute coronary syndrome (includes unstable angina); BMS = bare-metal stent; DES = drug-eluting stent; Non-ACS = those without any acute ischemic criteria; PCI = percutaneous coronary intervention.

2.3. The Cardiac Catheterization Laboratory at a Hospital With Cardiovascular Surgical Capability

Table 2 outlines the optimal onsite support services that allow for cardiac catheterization to be performed safely in any patient with heart disease. A hospital with all of these services is considered a "full-service" facility. Although cardiac surgical capability is the defining service, the other important support services listed are critical for optimal patient care and management. The catheterization laboratory in this setting is fully equipped for the most complex studies. Although direct surgical intervention is infrequently needed during percutaneous interventional procedures, the associated depth of expertise within the facility (technology, equipment, personnel, and specialized physicians such as anesthesiologists, perfusionists, and surgeons) have experience with the most complex cases and greater experience with emergent and critically ill patients. Often associated higher volumes translate into improved patient care and outcomes for high-risk patients. Therefore, although surgical service may not be directly required, the associated local expertise is available should the need arise. Essentially all laboratories that have full support services are located in a hospital setting. There may be special situations where a mobile laboratory is temporarily attached to or in an adjacent facility beside the hospital. In this latter setting, the situation should be considered similar to the inpatient laboratory with full support services in the hospital.

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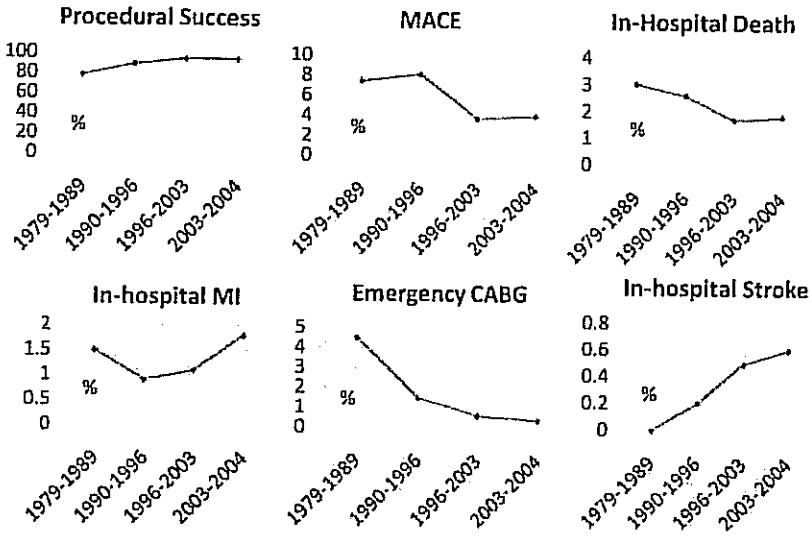

Figure 1. Trends in In-Hospital Outcomes Following PCI: The Mayo Clinic Experience

Modified with permission from Singh et al. (61). In-hospital MI = Q-wave MI; MACE = major adverse cardiovascular events.

2.3.1. Patients Eligible for Invasive Cardiovascular Procedures at a Hospital With Full Support Services (Including Cardiovascular Surgery)

In this environment, all patients and all procedures can, in general, be safely undertaken, provided the operators are sufficiently experienced and competent in the procedures being performed. Even though a hospital may have the appropriate support services as outlined above, some patients should still be referred to an even more highly specialized center if the technical expertise and experience required (e.g., transseptal puncture, valvuloplasty, assessment of complex congenital disease, and percutaneous ASD occlusion) are not available. To this end, there is a growing number of centers focused on structural heart disease. This is particularly true for the pediatric patient population. The laboratory setting appropriate for the pediatric population is outlined in Section 10.7 of this document.

Table 2. Optimal (Recommended) Onsite Support Services for Invasive Cardiac Procedures

Cardiovascular surgery
Cardiovascular anesthesia
Intensive care unit
Vascular services
Nephrology consultative services and dialysis
Neurology consultative services
Hematologic consultative and blood bank services
Advanced imaging services (echocardiography/Doppler, MRI, CT)
Mechanical circulatory support services
Endovascular surgery/interventions
If a pediatric catheterization laboratory, similar services for pediatric-aged patients

CT = computed tomography; MRI = magnetic resonance imaging.

2.4. The Cardiac Catheterization Laboratory at a Hospital Without Cardiovascular Surgical Capability

With the increase in the number of cardiovascular laboratories over the last couple decades, the performance of both diagnostic and interventional coronary procedures is now becoming more commonplace in settings without cardiovascular surgery, despite guideline recommendations limiting PCI in these settings. Perhaps surprisingly to many, evidence exists that having a strict CON regulatory program is only modestly associated with lower rates of cardiac catheterization. In fact, in 1 review, only minimally reduced rates of equivocally or weakly indicated procedures for AMI were found in CON states, whereas the presence of a CON requirement had no effect on strongly indicated procedure rates (11).

The actual number of laboratories without onsite surgical backup providing either elective or primary PCI is difficult to confirm. Data from the ACC-NCDR database suggests that about one third of the laboratories performing cardiac catheterization do not have cardiovascular surgery backup, with at least elective PCI being performed without surgical backup in around one fourth (ACC-NCDR database information).

These data are similar to other databases. For instance, from July 2000 through December 2006, according to the National Registry of Myocardial Infarction (NRMI), 35.1% of participating hospitals providing primary PCI reportedly did not have onsite surgery. Of note, only a little more than half (53.6%) were in rural settings (12), suggesting the possibility of multiple primary PCI sites in an urban environment.

There are limited data on comparative costs, but 1 report suggests that the costs and charges of elective PCI at a hospital without cardiovascular surgery might be considerably more than those at a full-service hospital ($3,024 more in costs and $6,084 more in charges) (13). Based on the available information, therefore, anywhere from about one fourth to one third of

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the currently operating cardiac catheterization laboratories do not have onsite cardiovascular surgery. This is quite a large number considering that most national organizational guidelines have discouraged the practice over the last decade.

Some insight into which patient groups might benefit from undergoing PCI can be gained by considering risk factors for periprocedural death. The latest data from the New York State Cardiac Advisory Committee (2005 to 2007) is of interest and summarized in Table 3. It seems appropriate to be cognizant of the patients at greatest risk for developing an adverse outcome when considering whether PCI can be safely done in low-volume settings or in those institutions without cardiovascular surgical programs.

Table 3. Multivariate Risk Factors for Deaths Within 30 Days Following PCI, 2005–2007

Risk Factor	Prevalence	Odds Ratio
Non-emergent PCI risk factors		
Demographic		
Body surface area squared		3.0
Ventricular function		
LVEF 40% to 49%	13.3%	1.9
LVEF 30% to 39%	6.1%	2.8
LVEF 20% to 29%	3.2%	2.1
LVEF <20%	0.8%	3.9
Preprocedural MI		
MI; 1 to 7 days prior	12.9%	3.4
MI; 8 to 14 days prior	1.3%	3.4
Comorbidities		
Cerebrovascular disease	8.0%	2.0
CHF, current	5.4%	2.6
COPD	6.4%	2.6
Malignant ventricular arrhythmias	0.4%	4.1
Peripheral vascular disease	7.3%	1.8
Renal failure, creatinine 1.6 to 2.5 (mg/dL)	5.9%	1.9
Renal failure, creatinine >2.5 (mg/dL)	1.4%	2.4
Renal failure, dialysis	2.1%	4.2
Vessels diseased		
Three-vessel disease	13.7%	1.8
Left main disease	3.9%	1.9
Emergency PCI risk factors		
Demographic		
Female gender	27.1%	1.8
Hemodynamic state		
Unstable	4.1%	4.4
Ventricular function		
LVEF 20% to 29%	6.2%	2.2
LVEF <20%	1.2%	3.7
Comorbidities		
CHF, current	5.1%	2.3
Malignant ventricular arrhythmias	1.6%	3.3
Renal failure, creatinine 1.1 to 1.5 (mg/dL)	38.2%	1.7
Renal failure, creatinine 1.6 to 2.0 (mg/dL)	4.7%	3.2
Renal failure, creatinine >2.0 (mg/dL)	1.8%	6.0
Renal failure, requiring dialysis	0.7%	7.0
Severity of CAD (1-, 2-, or 3-vessel disease): no severity with odds ratio >1.5		

Only those with odds ratio of >1.5 listed. Modified with permission from King et al. (58).
CAD = coronary artery disease; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; LVEF = left ventricular ejection fraction; MI = myocardial infarction; PCI = percutaneous coronary intervention.

Diagnostic cardiac catheterization is increasingly being performed in facilities without onsite surgical backup. These facilities include hospital settings (often rural), freestanding laboratories, and mobile cardiac catheterization units (either parked at a hospital or occasionally at a cardiovascular clinic). With diagnostic cardiac catheterization now principally an outpatient procedure, these types of laboratories have become more accepted and widespread. To ensure these sites are properly monitored, and that contingencies are in place for urgent transfer if a complication occurs that may require surgical intervention, SCAI has proposed a list of requirements for offsite surgical backup of PCI procedures (14). Before performing elective procedures, the cardiothoracic surgeon must be available and the receiving hospital must be capable of accepting patients before the procedure is initiated. These requirements are outlined in Table 4 and have been modified by this committee. Although primarily designed for programmatic backup of interventional procedures, similar requirements should be in place even for diagnostic procedures in a setting without onsite cardiovascular surgery. The focus of these requirements is to ensure that a written and monitored program is in place before any invasive cardiovascular procedures are considered acceptable in a facility without onsite cardiovascular surgery.

2.4.1. Patients Acceptable for Diagnostic Cardiac Catheterization at a Facility Without Cardiovascular Surgical Capability

Given the low risk of complications outlined above and the favorable reports regarding both safety and the quality, the committee feels that the prior relatively stringent restrictions regarding eligibility for undergoing diagnostic cardiac catheterization suggested in the 2001 cardiac catheterization standards document may now be relaxed. The highest-risk patients are still better served clinically in a laboratory with onsite cardiovascular surgical backup. For the most part, however, the vast majority of stable patients can safely undergo diagnostic cardiac catheterization in this setting. Table 5 outlines the current recommendations regarding the specific types of patients who should be excluded from laboratories without cardiovascular surgical backup and contrasts them with the previous document (1). The committee feels these newer recommendations better reflect the reality of the clinical care currently being provided in the cardiology community. The data to support this change are based on available literature for identifying the high-risk patient and a general consensus of the committee.

2.4.2. Patients Acceptable for Elective Coronary Intervention in a Facility Without Cardiovascular Surgical Capability

There are now multiple reports that the performance of elective PCI in hospitals without onsite cardiovascular surgery has acceptable outcomes and risk, if proper patient

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Table 4. Minimum Requirements for the Performance of Invasive Cardiovascular Procedures in a Setting Without Onsite Cardiovascular Surgical Services

1. A working relationship between the interventional cardiologists and cardiothoracic surgeons at the receiving hospital must be established.
2. The cardiothoracic surgeon must have privileges at the referring facility to allow review of treatment options.
3. Surgical backup must be available for urgent cases at all hours and for elective cases at mutually agreed times.
4. Ideally, face-to-face meetings between cardiothoracic surgeons and cardiologists involved should occur on a regular basis.
5. Before performing elective procedures, the cardiothoracic surgeon must be available and the receiving hospital must be capable of accepting the patient before the diagnostic or PCI procedure is started.
6. The interventional cardiologist must review with the surgeon the immediate needs and status of the patient should an urgent transfer be required.
7. The interventionalist should be familiar with and have available appropriate life support devices, such as an intra-aortic balloon pump.
8. The interventionalist should be qualified to deal with emergencies such as pericardial tamponade (pericardiocentesis) and embolization, should either event occur.
9. Hospital administrations from both facilities must endorse a transfer agreement.
10. Both the referring and the receiving hospital must have a rigorous and detailed protocol for rapid transfer of patients, including a listing of the proper personnel.
11. A transport provider must be available to begin transfer within 20 minutes of a request and must have appropriate life-sustaining equipment.
12. The transferring physician should obtain surgical consent prior to transfer.
13. The initial diagnostic and PCI consent should inform the patient that the procedure is being done without onsite surgical backup.

Modified with permission from Dehmer et al. (14).
PCI = percutaneous coronary intervention.

selection, procedural precautions, and backup preparations are in place. Data from the ACC-NCDR reveal an increase in the number of such facilities from 8.7% to 16% during the period from 2004 to 2005 (15), despite national guidelines to the contrary. As suggested by the NRMI database, the number may be as high as 25% to 35% in 2010.

Table 5. General Exclusion Criteria for Invasive Cardiac Procedures in a Setting Without Cardiothoracic Surgery

Exclusions: Catheterization Laboratory Without Cardiothoracic Surgical Backup	
2001 Document	**Current Document**
Diagnostic procedures	
Age >75 years	No age limitation
NYHA functional class 3 or 4	No limitation
Pulmonary edema due to ischemia	Pulmonary edema due to ischemia
Markedly abnormal stress test with high likelihood of LM or 3-vessel disease	No stress test result limitation
Known LM coronary disease	No coronary anatomic restriction
Severe valvular dysfunction with reduced LV function	No valvular or LV function limit unless severe (Class 4) symptoms
Patients at risk for vascular complications	Permissible only if vascular services are available
Complex congenital heart disease	Complex congenital heart disease
Acute or intermediate coronary syndromes	ACS except where PCI procedures are approved
All pediatric procedures	All pediatric procedures
Therapeutic procedures	
Diagnostic or therapeutic pericardiocentesis	Pericardiocentesis allowed if operator competent
All therapeutic procedures in adult congenital	All therapeutic procedures in adult congenital
All pediatric therapeutic procedures	All pediatric therapeutic procedures
Elective PCI	Elective PCI permissible under specified guidelines (55)
Primary PCI (not available at time)	Primary PCI permissible under specified guidelines (55)

The current recommendations are compared to the prior consensus document (1).
ACS = acute coronary syndrome; LM = left main; LV = left ventricular; NYHA = New York Heart Association; PCI = percutaneous coronary intervention.

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This issue remains controversial. This may especially be the case when other active PCI programs are located within the same geographic area. It behooves the cardiology community to foster these programs only when such programs improve access to a higher level of cardiovascular care than would otherwise be available. This has become a particular hot button issue since the publication of certain politically provocative articles such as COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) (16), which suggests PCI did not improve the rates of death or MI in patients with stable angina, or SYNTAX (Synergy Between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery) (17), which asserts that PCI with drug-eluting stents is inferior to CABG for left main and multivessel disease. There is a declining volume of PCI despite the improvement in outcomes from stent technology and consistent with a better appreciation of which procedures provide optimal benefit to patients. These types of studies suggest maturation of the technology so that further expansion may be limited despite concerns regarding a need for more procedures in an aging population. To this end, some have called for a moratorium on allowing any further expansion of PCI services, especially to low-volume facilities without cardiovascular surgical backup (18).

If the financial and marketing incentives are ignored, however, when patients are appropriately selected, most published studies regarding the risks of elective PCI at facilities without onsite cardiovascular surgical backup have shown the procedure to be relatively safe. The Swedish Coronary Angiography and Angioplasty Registry (19) of 34,383 patients found no difference in outcomes of elective PCI between hospitals with or without surgical backup. Similarly community sites in the United States (10,13,20–22), Germany (23), Japan (24), the Netherlands (25), the United Kingdom (26), and Australia (27) all confirm there is little or no difference in the outcomes among patients undergoing elective PCI in hospitals with or without onsite surgery. A similar finding was suggested by an analysis of 4 controlled trials (28–31) involving 6,817 patients (32). A meta-analysis of nonprimary PCI (elective and urgent; n=914,288) also found no difference in outcomes in PCI performed at sites with onsite cardiovascular surgery compared with those without (33).

The issue is further complicated due to the fact the published literature to date is limited by its methodology (registries, cohort studies, self-reported, and unmonitored data) and lack of long-term follow up. In addition, the exceeding low event rate in the elective setting makes it difficult to demonstrate differences in smaller studies (type II error). Finally, there is simply a lack of large, randomized studies with independent monitoring of events in this arena.

In 2007, SCAI addressed the issue and concluded that although they were unable to support the widespread use of PCI without onsite surgery, they acknowledged that many of these programs are now in existence and suggests that criteria be met in order to ensure patient safety. They proposed that certain patient characteristics and lesion characteristics should be considered "high risk," and these features should be taken into account before deciding whether a patient is a candidate for PCI in this setting. It is the consensus of this committee that high-risk patients or those with high-risk lesions should not undergo elective PCI in a facility without onsite surgery (Table 6).

In the 2007 "ACCF/AHA/SCAI Update of the Clinical Competence Statement on Cardiac Interventional Procedures" (6), similar patient and lesion characteristics were found to be associated with higher short-term mortality after PCI and would thus be considered high risk. That statement also included the following groups as high risk: the advanced in age, females, and those with ACS, a peripheral vascular disease, or impaired renal function (especially in diabetic patients with regard to contrast nephropathy). High-risk target-lesion anatomic features included the modified 1990 classification scheme proposed by the ACC/AHA Clinical Task Force on Clinical Privileges in Cardiology (34). In that scheme, lesions were classified as Type A, Type B1, Type B2, or Type C. Type C lesions were considered the highest risk and had an angioplasty success rate of 61%, in those days, and a complication rate of 21%. The characteristics of a high-risk Type C lesion included

Table 6. Elective PCI Patient and Lesion Characteristics That Identify High-Risk Patients Who May Be Unsuitable for PCI in a Facility Without Cardiothoracic Surgical Backup

High-risk patient
1. Decompensated CHF (Killip Class 3 to 4)
2. Recent (<8 weeks) cerebrovascular accident
3. Known clotting disorder
4. Left ventricular ejection fraction ≤30%
5. Chronic kidney disease (creatinine >2.0 mg/dL or creatinine clearance <60 mL/min)
6. Serious ongoing ventricular arrhythmias
High-risk lesion
1. Left main stenosis ≥50% or 3-vessel disease (>70% proximal or mid lesions) unprotected by prior bypass surgery
2. Target lesion that jeopardizes an extensive amount of myocardium. Jeopardy scoring systems, such as SYNTAX, may be useful in defining the extent.
3. Diffuse disease (>20 mm length)
4. Greater than moderate lesion calcification
5. Extremely angulated segment or excessive proximal or in-lesion tortuosity
6. Inability to protect side branches
7. Older SVG grafts with friable lesion
8. Thrombus in vessel or at lesion site
9. Vessel characteristics that, in the operator's judgment, would impede stent deployment
10. Chronic total occlusions
11. Anticipated probable need for rotational or other atherectomy device, cutting balloon, or laser

Modified with permission from Dehmer et al. (14) and high-risk features from the New York State Percutaneous PCI Registry 2006–2007 (58).

CHF = congestive heart failure; PCI = percutaneous coronary intervention; SVG = saphenous vein grafts; SYNTAX = Synergy Between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery.

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chronic total occlusion, a high grade (80% to 99% diameter stenosis), stenosis bend of >60 degrees, and excessive tortuosity. The data from these resources suggest that high-risk patients and target lesions can be defined prior to the performance of an elective PCI procedure and that it is appropriate to avoid these patients when there is no onsite cardiovascular surgery available.

In 2011, the initial results from the randomized Atlantic Cardiovascular Patient Outcomes Research Team (Atlantic C-Port-E) trial was reported (35). Only those sites with >200 PCIs per year and performing 24/7 PCIs were eligible for enrollment. Individual operators were required to meet the standard of >75 PCI cases per year. Sixty sites participated, and 13,981 patients were enrolled at sites without cardiovascular surgery whereas 4,515 patients were enrolled at sites with surgery. The authors concluded that PCI success was >90% in both situations, but this was lower in hospitals without onsite surgery (a success rate difference of 1.1% on per-patient basis and 0.7% on lesion basis). In addition, slightly more unplanned catheterization and PCI procedures occurred in patients undergoing PCI at a nonsurgical site. Emergency CABG was rare, but it was slightly higher in sites without surgery (0.2% versus 0.1%). Overall mortality and catheterization complications were similar between the 2 groups. Their conclusion was that PCI was safe within the bounds established by the trial.

Finally, further support for the safety of PCI in facilities without cardiovascular surgery comes from the ACC-NCDR data registry (36). These data revealed that centers without onsite cardiovascular surgery were predominantly in nonurban areas, had lower PCI volumes, treated a higher percentage of patients who presented with subsets of MI, and had better reperfusion times in primary PCI than centers with onsite facilities. There was also no difference in procedure success, morbidity, emergency cardiac surgery rates, or mortality (regardless if elective PCI or primary PCI). Although the data are observational, voluntarily submitted, and included from only 60 sites without cardiovascular surgery, it does suggest the current usage of these facilities may be safe and emphasizes the importance of reporting outcomes to a national data registry.

2.4.3. Patients Acceptable for PCI in ACS in a Facility Without Cardiovascular Surgical Capability

Primary PCI has now been shown to be more effective than fibrinolytic therapy in obtaining coronary reperfusion in patients with STEMI (37). Based on GRACE (Global Registry of Acute Coronary Events) data from 1999 to 2005, the use of primary PCI increased worldwide from 16% to 53%, whereas fibrinolytic therapy decreased from 50% to 28% (38). The improvement in patient outcomes as a result of this shift has led to a growing interest in offering primary PCI to as many patients as possible. Due mostly to access issues, however, only about 33% of patients with STEMI in the United States receive primary PCI, whereas 56% still receive fibrinolytics, and the remainder receives neither (39). This has provided the impetus to consider regionalization of STEMI care in the United States and a relook at the potential advantage of primary PCI particularly at rural hospitals without onsite cardiovascular surgery (40).

A standard treatment protocol using rapid interhospital transfer of STEMI patients between 6 referral centers and 2 STEMI accepting hospitals (41) revealed that 87.7% of patients received primary PCI. Door 1-to-departure time averaged 46 minutes, and Door 1-to-balloon time at the accepting hospital averaged 117 minutes. The authors suggested that, in a coordinated healthcare system, primary PCI can be centralized.

An NRMI report compared 58,821 STEMI patients from 214 hospitals with onsite cardiovascular surgery to 52 hospitals without. The authors found no difference in mortality among patients undergoing primary PCI at the different sites. They did report, however, that the overall STEMI mortality was higher, and the patients were less likely to receive guideline-recommended medications at the hospitals without surgical backup (42). In an NRMI database follow-up report (42) involving 100,071 patients from 2004 to 2006, the in-hospital mortality was found to be lower at hospitals with cardiovascular surgical support compared with those without (5.0% versus 8.8%). Hospitals with surgical services had higher use of guideline-recommended medical therapies, which may have contributed to better outcomes.

Support for the concept of performing primary PCI at the local facility also comes from a small randomized trial (43) and 2 registries (44,45) with favorable outcomes, though a study from Michigan also suggests that expanding a primary PCI program to hospitals without onsite cardiovascular surgery only improves access to a modest degree (46). A recent meta-analysis of primary PCI for STEMI of 124,074 patients demonstrated no increase in in-hospital mortality or emergency bypass at centers without onsite surgery compared with those that had cardiovascular surgery available (33). Despite the mixed data, there remains much enthusiasm from rural and hospitals without cardiovascular surgery to offer this service. Some of this is driven by the importance of providing timely access to early reperfusion strategies for STEMI patients in the local community. It is also driven by fear of loss of profitable cardiac patients and the concern that without the service, the hospital will be perceived as less than a full-service facility.

Some of these programs are also only providing primary PCI during working hours and not during off-hours. A review from the NRMI database has pointed out that there is a 70% less likelihood of patients with STEMI undergoing primary PCI if the presentation is off-hours (12). Since no clinical characteristics explain the reason a smaller percentage of these patients undergo primary PCI, the conclusion is that the procedure is just not available when the patient arrives in the emergency department. In fact, the authors note that 47% of the hospitals in the study perform <10 primary PCIs per year, suggesting that the volume of such

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procedures may be too low to provide optimal care when primary PCI is only performed during normal daytime laboratory hours and not 24/7.

The 2009 Focused Update of the ACC/AHA Guidelines for the Management of Patients With STEMI also focused on the strategy to be followed, depending on whether the patient initially presents to a PCI-capable facility or to a non–PCI-capable facility (47). It does not specifically address whether the hospital has onsite cardiovascular surgery. A consensus document from the SCAI notes that there is no justification for providing elective PCI procedures without onsite surgery and without providing primary PCI 24 hours a day (14). AHA has also endorsed the principle that a facility providing primary PCI care should be operating around the clock (48). There are few data in this regard, but in 1 small study, the results of primary PCI done during off-hours appears similar to those done during regular working hours (49).

The ACC/AHA guidelines for the management of acute STEMI patients focus on the development of a community-wide system. Table 7 outlines their current recommendations for triage and transfer of STEMI patients for PCI. Included in the table are definitions for the "high-risk" STEMI patient. Although it is tempting to recommend that patients with these high-risk features be excluded from primary PCI at a hospital without cardiovascular surgery services, there are no data to confidently support that recommendation. In addition, coronary anatomic features are only discovered after angiography has been performed, so it is difficult to include such features as contraindications for intervention.

In an attempt to gather data on the wisdom of the use of primary PCI in the community at large, several ongoing programs have been undertaken including regionalization of care across the United States (50): the AHA's Mission: Lifeline program (48), the Reperfusion of Acute Myocardial Infarction in Carolina Emergency Departments (RACE) (51), and the ACCF's D2B Alliance (www.d2balliance.org). These programs are all working to develop community-based approaches to providing the optimal reperfusion strategy in STEMI patients, and they are tracking the results. Regionalization and improvements regarding in-field diagnosis, transfer and triage improve access times (door to balloon [D2B], emergency medical serivces to balloon [E2B], and/or S2B [symptoms to balloon]) and can optimize the use of primary PCI while avoiding duplication of local services. Given that fibrinolytic therapies are still in use in about 25% of U.S. hospitals, and even at PCI-capable hospitals (12), the choice of a reperfusion strategy is complex.

In many geographic situations, the ability to provide primary PCI at a hospital without surgical backup is suggested as a necessary step if other systematic approaches are unable to minimize the time from symptom onset to reperfusion. Evidence from the TRANSFER-AMI (Trial of Routine Angioplasty and Stenting After Fibrinolysis to Enhance Reperfusion in Acute Myocardial Infarction) study and CARESS (Combined Abciximab Reteplase Stent Study in Acute Myocardial Infarction) studies suggest a pharmacoinvasive approach with immediate transfer to a PCI center improves outcome (52–54). If the pharmacoinvasive approach is verified, this semielective approach to PCI at a tertiary hospital may reduce the concern over needing to offer primary PCI services in the local community or all local hospitals.

The Atlantic Cardiovascular Patient Outcomes Research Team (C-Port) trial randomized 451 AMI patients at

Table 7. Recommendations From the 2009 Joint STEMI/PCI Focused Update on the Appropriate Performance of Primary PCI in Settings Without Onsite Cardiovascular Surgery

Class I: Each community should develop a STEMI system of care that follows standards at least as strong as those developed for the American Heart Association's national initiative, *Mission: Lifeline*, to include the following:

- Ongoing multidisciplinary team meetings that include emergency medical services, non–PCI-capable hospitals/STEMI referral centers, and PCI-capable hospitals/STEMI receiving hospitals to evaluate outcomes and quality improvement data;
- A process for prehospital identification and activation;
- Destination protocols for STEMI receiving centers; and
- Transfer protocols for patients who arrive at STEMI referral centers who are primary PCI candidates, are ineligible for fibrinolytic drugs, and/or in cardiogenic shock. *(Level of Evidence: C)*

Class IIa: It is reasonable for "high-risk" patients who receive fibrinolytic therapy as primary reperfusion therapy at a non–PCI-capable facility to be transferred as soon as possible to a PCI-capable facility where PCI can be performed either when needed or as a pharmacoinvasive strategy.

Consideration should be given to initiating a preparatory antithrombotic (antiplatelet plus anticoagulant) regimen before and during patient transfer to the catheterization laboratory. *(Level of Evidence: B)*

Class IIb: Patients not at high risk under the same conditions as listed in Class IIa recommendation. *(Level of Evidence: C)*

High risk is defined in CARESS-in-AMI (59) as STEMI patient with ≥1 high-risk features. High-risk features include extensive ST-segment elevation, new-onset LBBB, previous MI, Killip Class >2, LV ejection fraction ≤35% for inferior MI; any anterior MI with ≥2 mm ST-segment elevation in ≥2 ECG leads.

High risk is defined in TRANSFER-AMI (60) as STEMI patient with ≥2 mm ST-segment elevation in 2 anterior leads or ≥1 mm ST-segment elevation in inferior MI along with at least 1 of the following: systolic BP <100 mm Hg, heart rate >100 bpm, Killip Class 2 to 3, ≥2 mm ST-segment depression in anterior leads, or ≥1 mm ST elevation in right-sided V_4 lead, indicative of RV involvement.

Reprinted from Kushner et al. (47).

BP = blood pressure, BPM = beats per minute; CARESS = Combined Abciximab Reteplase Stent Study in Acute Myocardial Infarction; ECG = electrocardiogram; LBBB = left bundle-branch block; LV = left ventricular; MI = myocardial infarction; ST = the ST segment of the ECG; STEMI, ST- elevation myocardial infarction; PCI = percutaneous coronary intervention; RV = right ventricular; TRANSFER = Trial of Routine Angioplasty and Stenting After Fibrinolysis to Enhance Reperfusion in Acute Myocardial Infarction.

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hospitals without onsite cardiovascular surgery, and at 6 months, found better composite outcome (driven primarily by a reduction in reinfarction), in the primary PCI group compared with the fibrinolytic cohort with no significant difference in mortality (43). The newest PCI guidelines have reflected the more recent data since the last Catheterization Standards document and have elevated the use of elective PCI from a Class III indication to a Class IIb (55). Primary PCI in facilities without onsite cardiovascular surgery is considered a Class IIa instead of Class IIb indication in the latest revision of these guidelines.

Recommendation: Because of the current lack of definitive data in this area, this committee recommends that all facilities that perform primary PCI in a setting without cardiovascular surgical backup comply with all current guidelines on the establishment of such a program (as outlined in this section and in the accompanying tables). It is critical the facility documents that all medication and risk stratification guidelines are being followed as well, and that the facility has availability for STEMI patients 24 hours per day, 7 days per week. The committee cannot recommend any PCI programs without cardiovascular surgical backup that only provide primary PCI coverage during daytime and weekday hours.

To further ensure quality oversight, the facility should also be part of a defined registry to monitor outcomes and track all complications on a regular basis. D2B should be tracked closely, with goal D2B times of <90 minutes in >75% of cases. Regionalized systems of care may provide a more efficient system of diagnosis and triage and transfer, and they may or may not justify the current trend of establishing primary PCI capability at hospitals without surgical backup (56).

Finally, pharmacoinvasive strategies (54,57), if confirmed in other experiences, may provide superior, or at least comparable, outcomes to primary PCI at low-volume centers, and this should be evaluated further to determine whether increased centralization of services may result in improved outcomes.

3. Quality Assurance Issues in the Cardiac Catheterization Laboratory

The modern cardiac catheterization laboratory is an amalgamation of complex, highly sophisticated medical and radiological instrumentation used in the diagnosis and management of patients with both chronic stable disease and acute life-threatening illnesses. In any complex, procedure-oriented area, it is essential to have a QA program that incorporates QI to provide ongoing feedback within an established infrastructure for change. The Cardiac Catheterization Laboratory QA/QI committee should be considered a separate entity specific to the cardiac catheterization laboratory. Interactions with other medical staff and/or hospital QA/QI committees are critical, with personnel often assigned to work in multiple QA/QI committees and to share similar concerns, projects, and expertise.

The following discussion summarizes the key components of a QA/QI program for the diagnostic and interventional cardiac catheterization laboratory. These components are as follows: 1) clinical proficiency; 2) equipment maintenance and management; and 3) peer review. A fourth component, radiation safety, is discussed separately in this document. Table 8 outlines clinical proficiency based on cognitive skills, procedural conduct, and clinical judgment.

Table 8. Assessment of Proficiency in Coronary Intervention

Type	Component	Mode of Assessment
Individual	Cognitive	• Formal training program
		• Present requirement by ABIM: 3-year fellowship in ACGME-accredited program
		• Board certification: requirement for added qualification in interventional cardiology: 12 months in ACGME-accredited program and pass grade on ABIM examination ("Board") for interventional cardiology
	Procedural	• Risk-adjusted outcomes
		• Individual data benchmarked against the ACC-NCDR or similar database
		• Peer recognition
	Judgment	• Appropriateness
Laboratory	Procedural outcomes	• Risk-adjusted outcomes
		• Comparison with similar institutions
		• Laboratory data benchmarked against national databases (e.g., ACC-NCDR database)
	Activity	• A minimum of 200 to 400 interventions per year
		• Director with career performance of enough PCI cases to be a competent independent operator (ideally >500 interventions). Must be board certified in interventional cardiology
		• QA staffing to monitor appropriate use, complications, and outcomes
	Support	• Experienced support staff to handle emergencies
		• Regularly scheduled mortality and morbidity conferences and a review of all major complications
		• Facilities and equipment for high-resolution fluoroscopy and digital video processing

ABIM = American Board of Internal Medicine; ACC = American College of Cardiology; ACGME = Accreditation Council of Graduate Medical Education; NCDR = National Cardiovascular Data Registry; PCI = percutaneous coronary intervention; QA = quality assurance.

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3.1. Patient Outcomes in the Diagnostic Catheterization Laboratory

3.1.1. Rate of "Normal Catheterizations"

The frequency of normal hemodynamic and angiographic findings at diagnostic catheterization is a function of the pretest likelihood of disease and the physician's clinical acumen. For purposes of definition, "normal" coronaries are defined pragmatically as those without a "significant" diameter reduction (<50%) on visual inspection. Since the publication of the 2001 Expert Consensus Document on Catheterization Laboratory Standards, there has been scant information reported on this topic in populations of patients undergoing diagnostic coronary angiography. New data from SCAI indicate that the frequency of normal angiograms is 20% to 27%, which appeared to vary little over a reporting period of several years (62,63). Notably, in a report from the ACC-NCDR, the proportion of patients undergoing elective diagnostic catheterization who were found to have minimal obstructive disease (<20% stenosis) was remarkably high at 39.2% (64).

It is recognized that many studies include patients with "insignificant disease," which is defined as <50% coronary diameter narrowing by visual estimate. Clearly, ACS occurs in patients without "significant" antecedent luminal narrowing on angiography. In addition, certain clinical syndromes may relate to coronary endothelial or microvascular dysfunction. Some laboratories may also have a high prevalence of patients studied for noncoronary issues, such as pulmonary hypertension, cardiomyopathy, valvular heart disease, or adult congenital heart disease. Ultimately, the rate of normal studies in any facility may more properly be viewed as a system performance metric as the outcome of any given angiographic study reflects pretest likelihood, complex decision pathways, local practice, and patient preference (65).

3.1.2. Specific Complication Rates Following Diagnostic Catheterization

There is extensive, albeit dated, literature on the major complications of diagnostic cardiac catheterization (62,63,66). Fortunately, the (composite) rate of MACCE is "acceptably" low at <1% to 2%. As expected, the likelihood of major complications increases significantly with the severity of the underlying cardiac and noncardiac disease (67). Patients with both valvular and coronary artery disease are slightly more likely to sustain a complication than patients with isolated coronary artery disease (68). Although complications encountered in patients with valvular or myocardial disease are more likely to reflect the patient's underlying clinical status, specific complication rates for transseptal catheterization (69) and endomyocardial biopsy (70) have been reported and fall within the previously referenced range. Because of patient selection, the likelihood of major complications during outpatient studies is less than that found during inpatient examinations (67), although the constantly changing definition of "outpatient" may blur this distinction. Current estimates from the NCDR continue to support the validity of the above-cited estimates for MACCE.

3.1.2.1. ACCESS SITE COMPLICATIONS

Although not considered a "major complication" of diagnostic procedures, access site complications remain an important contributor to patient morbidity (71). It must be acknowledged that over the past decade, dynamic changes have occurred in the choice of access site for procedures, the caliber of diagnostic catheters, anticoagulation and antithrombotic protocols, and the means of achieving access site hemostasis (72,73). Progressive changes in the practice of invasive cardiology, in addition to advances in technology and technical competence, have led to significant reductions in access site complications for patients undergoing invasive diagnostic and therapeutic procedures (72).

3.1.2.2. CEREBROVASCULAR COMPLICATIONS

Reported rates of clinically evident periprocedural cerebrovascular complications were generally <1 per 1,000 patients undergoing diagnostic cardiac catheterization and angiography (62). More recently, reports of subclinical manifestations of cerebrovascular events during and immediately following retrograde aortic valve catheterization in the setting of evaluation for aortic valve stenosis have appeared (74). Although admonitions against this practice have appeared in the literature (75), the true rate of clinical "stroke" in this setting is still unknown. However, in view of the increasing interest in catheter-based aortic valve repair/replacement techniques, this salient complication will remain an important focus of attention. Cerebrovascular complications in the setting of PCI will be discussed below.

3.1.3. Diagnostic Accuracy and Adequacy

An important, although generally ignored area, is that of the completeness and accuracy of diagnostic catheterization procedures. Incomplete procedures (aborted or technically inadequate procedures) that fail to obtain the critical information for diagnostic purposes and erroneous interpretation of the acquired information are markers of quality no less important than outcome data. Failure to selectively engage native coronary arteries or coronary bypass grafts often results in insufficient opacification of the lumen to accurately assess coronary anatomy or stenosis presence and/or severity. Inability to recognize the presence of anomalous coronary arteries contributes to this problem. The implications of inadequate or incomplete studies are significant and range from the need to repeat procedures to the performance of unnecessary and more invasive procedures. Inadequate opacification of the ventricle due to hand injections is inappropriate. In the coronary interventional era, the need for high-quality diagnostic angiography is great, as life-altering decisions are generally made on the basis of this information. This includes failure to opacify vessels fully due to inappropriate injection, incorrect catheter sizing, or failure to obtain adequate views that best characterize the

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lesion. Inadequate attention to the details of accurate hemodynamic recordings in patients with valvular heart disease and the failure to accurately demonstrate coronary anatomy must be viewed as critical measures of outcome. For all the above reasons, it is reasonable to expect a rate of either inadequate or incomplete procedures to be <1%.

3.2. Patient Outcomes After Coronary Interventional Procedures

3.2.1. Major Adverse Cardiac or Cerebrovascular Events

Although patient outcomes are often considered the most important indicators of proficiency and competence in interventional cardiology (76), they are arguably the most difficult to accurately quantify. Moreover, the importance of risk adjustment for even crude event frequencies cannot be overstated (77). Therefore, it is essential that careful and complete preprocedural and intraprocedural information is accurately and reliably collected, sorted, and analyzed. Given that operator and institutional outcomes depend on many demographic, clinical, anatomic, and administrative variables, an adequate information system within the laboratory is mandatory, and the emphasis on both individual and institutional outcomes is appropriate (78–80). This is particularly so when attempting to risk-adjust outcomes for low-volume operators (81). The ability to estimate the likelihood of a significant complication (82,83), choose devices, and conduct procedures appropriately (84), promptly recognize and treat ischemic and other complications (85), and ultimately select (or refuse) cases appropriately are the hallmarks of an experienced, competent operator.

It is the responsibility of the director of the cardiac catheterization laboratory to establish a method of QA to track major events, (e.g., death and serious hemodynamic and/or arrhythmic events). Ongoing peer review of randomly selected cases from all operators is highly desirable and strongly encouraged. It should include the assessment of angiographic quality, technique, and thresholds being used for intervention. In addition, periodic review of less severe complications (e.g., hematoma or other vascular entry site injury) should be part of any ongoing QI program. Admittedly, some outcomes may be hard to standardize (e.g., periprocedural MI), but there is little ambiguity when outcomes for PCI are either consistently superior (e.g., <2% major complication rate) or consistently suboptimal (e.g., >5% major complication rate). At present, with overall in-hospital mortality averaging 1% and rates of emergent CABG averaging <1%, a composite major complication rate of <3% to 4% (95% confidence interval: 1.9% to 4.1%) for non-emergent PCI is to be expected (Tables 1 and 8, Fig. 1).

Since the 2001 "ACC/SCAI Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards" (1), much information has been added to the literature on PCI outcomes and complication rates in increasingly high-risk populations (e.g., advanced age, patients with CKD or ACS). Table 9 provides specific complication rates following PCI from large-scale clinical trials and "real-world" registries; Table 1 outlines data from a voluntary registry, the ACC-NCDR database. Each series includes patients undergoing PCI for a variety of indications under widely varying clinical conditions. The definitions of *elective*, *urgent*, and *emergent* vary among studies. Complication rates (especially bleeding and access site complications) in the GP IIb/IIIa inhibitor era vary, not only according to the definition applied, but in the rigor with which these outcomes are ascertained. For this reason, in-hospital complication rates in nonclinical trial, "real-world" settings remain a challenge in interpretation, given the unverified (nonadjudicated) and likely biased nature of such reporting. These results, however, can provide approximate boundaries for expected complication rates ("performance benchmarks") in "all-comers" undergoing PCI. The use of 30-day event rates to more completely assess PCI outcomes (86,87) and, by inference, benchmark operator performance (88) has also been proposed.

Table 9. In-Hospital or Short-Term MACCE Following Elective PCI in the "Stent" Era

Study Population	Year	Reference	Death (%)	MI (%)	In-Hospital CABG (%)	Neurologic (%)	Major Vascular (%)	Significant Bleeding (%)
ACC-NCDR (registry)	2002	Anderson et al. (130)	1.4	0.4	1.9	...	...	...
SIRIUS (RCT)	2003	Moses et al. (131)	0.09	1.9	0	...	...	...
RESEARCH (registry)*	2004	Lemos et al. (132)	1.6	0.8	1.0	...	...	...
SYNERGY (RCT)	2004	SYNERGY (133)	0.47	5.7	0.3	0.9	...	2.06§/2.46‖
ACUITY (RCT)*	2006	Stone et al. (134)	1.4	5.0	...	<0.1	0.5	5.5
NHLBI DR (registry)†	2007	Yatskar et al. (71)	...	...	...	...	1.8	...
NHLBI DR (registry)	2009	Venkitachalam et al. (93)	0.2	2.0	0.3	...	6.0	...
ACC-NCDR (registry)	2009	Aggarwal et al. (135)	...	...	...	0.22	...	...
ACC-NCDR (registry)‡	2009	Mehta et al. (136)	...	...	...	...	...	2.4
EVENT (registry)	2009	Novack et al. (137)	0.1	6.5	...	...	...	...

*30 days; †access site bleeding requiring transfusion; ‡transfusion requiring; §non-CABG bleeding, TIMI risk score; ‖non-CABG bleeding, GUSTO risk score.

... = not reported; ACC = American College of Cardiology; CABG = coronary artery bypass grafting; GUSTO = Global Utilization of Streptokinase and tissue Plasminogen Activator for Occluded Coronary Arteries; MACCE = major adverse cardiac or cerebrovascular events; MI = myocardial infarction; NCDR = National Cardiovascular Data Registry; NHLBI = National Heart Lung and Blood Institute; PCI = percutaneous coronary intervention; RCT = randomized controlled trial; TIMI = Thrombolysis In Myocardial Infarction.

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Mortality, the least frequent but the most dire adverse outcome within the composite MACCE outcomes following PCI, has been the subject of intense interest since the early days of PCI (89). Efforts to predict its occurrence have been limited by its infrequency, resulting in studies of low statistical power and poor predictive ability. Accordingly, composite outcome variables, all of which included death, have been constructed and allow for improved precision in the estimate of an overall frequency of major complications following PCI (82,90,91). However, there are numerous limitations to the use of such composite variable constructs, particularly when inferences regarding an element (e.g., mortality) may be misinterpreted (92). As in-hospital mortality rates following PCI have declined in parallel with the many positive advances in interventional cardiology (93), larger sample sizes are necessary to estimate its frequency and to meaningfully predict its occurrence. The most robust estimate of the overall risk of in-hospital mortality, culled from large-scale, nonclinical trial registries published after 2001, ranges from 0.7% to 1.8% (94–96). These same studies are also in general agreement regarding the risk factors predictive of in-hospital mortality: age, gender, CKD, left ventricular ejection fraction (LVEF), antecedent MI, shock, prevalent heart failure, and peripheral vascular disease. Anatomic features (i.e., left main disease), procedural indication (i.e., urgent versus emergent), and intraprocedural variables (i.e., the number of lesions attempted and total occlusion attempted) are less agreed upon as predictors of mortality in these models.

3.2.1.1. PCI IN THE SETTING OF ST-ELEVATION MYOCARDIAL INFARCTION

Table 10 summarizes outcomes from the latest published literature on PCI for STEMI—decidedly the highest-risk group of patients undergoing PCI. Event rates are unadjusted, and rates of access site and bleeding complications reflect a complex mix of systemic anticoagulation, systemic lytic activity, adjunctive use of platelet antagonists, and varying definitions and rigor of ascertainment. Nevertheless, some themes are evident across these diverse studies (e.g., the relative constancy of the risks of in-hospital death, stroke, and significant bleeding).

3.2.2. Ad Hoc PCI Issues

The performance of a coronary interventional procedure at the same laboratory visit as the diagnostic procedure is a strategy referred to as "ad hoc" PCI (97). If this is to be used, then it is important the discussion occurs with the interventionalist prior to entering the catheterization laboratory room. Ad hoc PCI should be discouraged in cases where the patient would benefit from a multidisciplinary discussion. Patients presenting with a STEMI or ACS, where the culprit vessel is readily identifiable, generally require an interventional procedure in conjunction with the diagnostic procedure for expeditious patient care and to reduce recurrent in-hospital ischemic events. However, when "routine" diagnostic procedures are immediately followed by "routine" coronary intervention, the considerations are more complex from a risk–benefit perspective. Considerations for when ad hoc procedures are encouraged include patient and physician convenience, the potential for a decrease in vascular access complications, a desire to avoid higher contrast load in patients with chronic kidney disease, and cost reduction.

Using the ACC-NCDR database, Krone et al. (98) published the outcomes of 68,528 patients undergoing PCI with the diagnosis of stable angina from 2001 to 2003, 60% of whom underwent ad hoc PCI. A multivariate analysis was performed to determine whether the performance of an ad hoc PCI had an independent association with procedure success or an adverse event. Patients categorized as high risk and those with significant renal disease were less likely to undergo PCI at the time of the diagnostic procedure. There was no difference in mortality, renal failure, or vascular complications when ad hoc patients were compared with patients undergoing staged procedures at a separate setting from the diagnostic case, so there appears to be no evidence that patient outcomes are affected.

When tracking outcomes for ad hoc versus separate setting PCI, important issues for the assessment of quality must be addressed. Complications encountered during the diagnostic catheterization and angiography (e.g., coronary dissection or abrupt occlusion) may be treated with prompt intervention but should not be considered ad hoc interventions. This leads to coding issues, as does the success of the

Table 10. In-Hospital or 30-Day MACCE Following PCI for STEMI in the "Stent" Era

Study Population	Year	Reference	Death (%)	(Recurrent) MI (%)	Neurological (%)	Significant Bleeding (%)
CADILLAC*	2002	Stone et al. (138)	2.7	0.8	0.2	2.5
NHLBI-DR (registry)	2007	Abbott et al. (139)	4.0	1.7	0.4	3.3
HORIZONS-AMI (RCT)	2008	Stone et al. (140)	2.58	1.75	0.5	6.6
NRMI (registry)	2009	Pride et al. (42)	3.56	1.0	0.5	7.19
GRACE (registry)	2009	Steg et al. (141)	3.7†/2.1‡	2.0/2.5	0.6/0.5	3.2/2.1
Medicare (database)	2010	Chen et al. (142)	10.3	...	...	...

*Outcomes at 30 days for the stent-plus abciximab arm; †PCI with bare-metal stent; ‡PCI with drug-eluting stent.
... = not reported; MACCE = major adverse cardiac or cerebrovascular events; MI = myocardial infarction; NHLBI = National Heart Lung and Blood Institute; NRMI = The National Registry for Myocardial Infarction; PCI = percutaneous coronary intervention; STEMI = ST-elevation myocardial infarction; RCT = randomized controlled trial.

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intervention mitigating the inciting event. Although the composite procedure was "successful," how is the original complication recorded? Complications encountered during the interventional portion of the procedure should be attributed to the interventional procedure and not to the antecedent diagnostic study. Given the increasing use of the ad hoc approach, it will be important to continually and carefully define the indications, clinical outcomes, and overall cost effectiveness of this practice pattern (99).

3.3. Peripheral Vascular Intervention

The development of vascular medicine as a specialized discipline, which overlaps "traditional" medical, cardiological, radiological, and surgical disciplines, has led to the expansion of the types of angiographic procedures performed in cardiac catheterization laboratories. Laboratories historically dedicated to coronary angiography and cardiac diseases have had to transform themselves technically, logistically, and administratively in order to provide optimal care for a patient with cardiac and vascular disease. Large image intensifiers for vascular rooms are not optimal for coronary angiography. Performance criteria for training and credentialing in vascular medicine have been adopted by key stakeholders (100), and guidelines for maintenance of competence and technical proficiency have also been developed (101). Although minimum caseload volumes have been suggested, there currently is insufficient literature regarding performance metrics and outcomes analogous to coronary intervention (e.g., procedure-specific complication rates, patient-specific complication rates, and target organ or vascular bed versus overall clinical outcomes). From a catheterization laboratory standards standpoint, comparative outcome data are presently absent but are much needed in order to establish performance benchmarks and appropriate use criteria. The issue is further complicated by the fact that noncardiologists (e.g., vascular surgeons or interventional radiologists) are now participating in some of these studies, and guidelines regarding training and ongoing credentialing for these groups often differ from those of the invasive cardiologist. Laboratory participation in a centralized data repository is currently being developed by the NCDR. Data from resources as these will help define the ongoing changes in how the traditional cardiac catheterization laboratory is being used.

3.4. Peer Review Continuous QA/QI Program

A continuous QA/QI program is an essential component to the cardiac catheterization laboratory and must be in place for all laboratories. This should be a dedicated program to address the specific issues of the catheterization laboratory, but it need not be independent from other hospital QI programs. The peer review component for this process is designed to promote clinical proficiency under the broad rubric of system-level performance analyses, which should connote a more constructive (rather than punitive) context (102).

The core components of the Continuous Quality Improvement (CQI) program are data collection, feedback, and intervention (103). Table 11 outlines the essential components of the process. The CQI committee should be adequately staffed and resourced by the facility. It should be chaired by the medical director of the cardiac catheterization laboratory because he/she should be the individual primarily responsible for quality within the facility. The administrative co-chair should be a required staff position for this committee with specific job description assignments to QA/QI. Additional membership should include invasive/interventional physicians with nonpartisan representation from all physician groups. Finally, noninvasive cardiologists, noncardiology physicians, and support personnel from hospital administration may or may not be included, based on what the committee chairman deems appropriate for committee effectiveness. Though individual physician performance is being reviewed, the results of the entire process apply to the performance of the laboratory as a whole.

The peer review component of the QA program includes the challenge of assessing clinical proficiency of the operators in the cardiac catheterization laboratory and should not be limited to a simple "scorecard" analysis (102). Issues of cognitive knowledge, procedural skill, clinical judgment, and procedural outcomes are best assessed by a composite of a series of variables that reflect the overall quality of care (6). This information must be collected in a systematic manner and analyzed appropriately. Finally, an approach must be developed for quality improvement that involves not only a process for change but also a measure for feedback on the effectiveness of the solutions as well as educational opportunities for all involved (103).

Table 11. Basic Components of the Continuous Quality Improvement Program for the Cardiac Catheterization Laboratory

Committee with chairman and staff coordinator
Database and data collection
Data analysis, interpretation, and feedback
QA/QI implementation
Goals outlined to eliminate outliers, reduce variation, and enhance performance
Tools available to accomplish data collection and analysis
Feedback mechanisms in place
Educational provisions for staff and operators
Incorporation of practice standardization/guidelines
Professional interaction and expectation
Incentives for high-quality metrics
Adequate financial support for QI personnel
Administrative oversight and action plans
Thresholds for intervention
Appropriate use assessment

QA = quality assurance; QI = quality improvement.

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3.4.1. Overview of the Peer Review Process: Quality Indicators, Data Collection and Analysis, and QA/QI Interventions

A review of cardiac catheterization laboratory settings has outlined certain practical lessons learned by the Laboratory Survey Committee of the SCAI (104). This committee noted that the major QA problems were not usually related to equipment but rather to inadequate laboratory space, lack of a physician medical director, lack of specific operating rules for the laboratory space, and lack of a functioning QA program (104). Not only must a QA program provide procedural complication information, but the committee emphasized that a feedback mechanism to modify behavior must be in place.

A QA program is only as effective as the commitment of all involved in the process of healthcare delivery, with the most conspicuous components being the assessment of procedural outcomes and individual operator proficiency (6). It is the responsibility of each individual operator to actively participate in the QA process along with other team members as well as actively participate in both CME and maintenance of competence activities on a regular basis. Each interventionalist should be aware of his/her own volume, complications, and outcomes. These data should be used to direct personal improvement. However, a procedure must be in place to assure this information is both accurate and complete. Utilizing "indicators" to help quantify the quality of the physician's performance may be beneficial. The indicators for organizational purposes include structural, process, and outcomes (105).

Structural indicators are those often considered by the hospital credentials committee and include staff credentialing/re-credentialing. This committee must assess medical training, licensure, board certification, procedure volume, and CME. Additionally, the committee/hospital may require, or consider appropriate, specific training courses/CME for a given procedure, society membership/offices held, awards/honors, and publications/presentations. Establishing a transparent standard for a given facility limits confrontation when physicians are either inadequately trained or fail to maintain required qualifications. The committee must be empowered to withdraw credentials when individuals fail to meet written minimum standards.

Process indicators refer to patient management regarding evaluation and treatment. Table 12 lists examples of procedural or process indicators. Since these are less objective and potentially amenable to observer bias as opposed to "hard" clinical outcomes, they are more difficult to measure and validate. These indicators are, however, helpful in working through the entire process from protocols and staffing to the rapidity of room turnover and patient length of stay. By tracking these indicators, analysis of outcomes issues an assessment of cost containment can be addressed within the QA process (106).

PCI appropriate use indicators are also important. The latest suggestions from the ACCF/SCAI/STS/AATS/AHA/ASNC/HFSA/SCCT should be valuable in ensuring that only appropriate patients are undergoing interventional procedures, and these guidelines can be used to help monitor appropriate use activity (107).

Table 12. Examples of Patient Management/ Process Indicators

Direct patient care–related indicators
Quality of angiographic studies
Radiation utilization (e.g., dose per procedure)
Report generation/quality of interpretation
Appropriateness
System-specific indicators
Patient transport/lab turnover/bed availability
Preprocedure assessment process and adequacy
Emergency response time
Cardiovascular surgery/anesthesia/respiratory care/perfusion performance
Guidelines-driven indicators
Infection control
Patient radiation dose (use of all available dose indicators, not only fluoroscopy time)
Treatment protocols (radiographic contrast issues, drugs usage)
Procedure indications
New device use
Cost-related indicators
Length of stay pre-/post-procedure
Disposables needed
Quality and adequacy of supplies
Number and qualification of personnel/staffing

Modified with permission from Heupler et al. (102).

Outcome indicators are outlined in Table 13. These are now often publicly available, and they are the most recognizable. Risk adjustment is the essential component to outcomes reporting and, therefore, dictates the need for detailed databases (7). Benchmarking individual physician and laboratory performance against national standards (e.g., the ACC-NCDR database) is an important component to this process (108). Though risk adjustment is essential to this process, awareness of the potential public health hazards with public reporting of inadequately risk-adjusted outcomes is of great concern (109). Although individual physician and hospital scorecards provide information on performance, they are not sufficient when used alone. Outcome data should not be used to punish an outlying practitioner but rather to search for causes that can be remedied and processes that can be improved (102,103).

Effective data collection requires a data repository and dedicated personnel for data acquisition. Information technology systems for the cardiac catheterization laboratory and the hospital should be integrated to allow for information transfer regarding patient demographics, catheterization data, and hospital laboratory data, thereby decreasing personnel data entry time. Hospital administration must be actively involved in this process to provide the needed staff support. Though identification of the most appropriate data collection instrument is still not standardized, an under-

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Table 13. Outcomes-Related Indicators

I. Physical outcomes
Individual physician MACCE
Death
Stroke/nerve injury
MI
Respiratory arrest
Perforation of vessel of heart with sequelae
Nerve injury
Radiation injuries
Emergent cardiovascular surgery
Access site complications
Access site complications requiring surgery
Rate-based outcomes (outcomes related to volume)
Diagnostic cardiac catheterization completion rates
PCI success rates
Normal cardiac catheterization rates
II. Service outcomes
Access to facility information
Door-to-balloon times
Satisfaction surveys
III. Financial outcomes
Procedural costs (as laboratory and as individual physician)
Risk management/litigation costs

Modified with permission from Heupler et al. (102).
MACCE = major adverse cardiac and cerebrovascular events; MI = myocardial infarction.

standing of entire catheterization laboratory process is essential for accurate and complete data acquisition with data entry verified for accuracy.

Data analysis requires a review of specific adverse events, as well as risk-adjusted event rates, for the facility/operator. Specific adverse events should be identified, and an individual case review should be performed. A potential list of case examples that should be reviewed might include those listed under clinical outcomes in Table 13 (102). Table 14 represents an example of an adverse event case report form. Such case reports should be completed by a "neutral" observer whenever possible to avoid confrontation. Results should be reviewed and discussed as indicated at regularly scheduled CQI meetings. In the case of possible litigation, the cardiac catheterization laboratory CQI process should work with the hospital risk management department and not be driven by the latter.

Interventions to improve performance should be the goal of the peer review process. The CQI process should focus on improving the performance of the "low-end physician" and not the elimination of this person, unless the performance is repeatedly below minimum standards and the individual is recalcitrant to positive suggestions. Once performance variance has been identified, programs should be established to correct these variances and address specifics issues to improve the total laboratory performance (102). Continuing employment of physicians not performing appropriately, despite efforts from the CQI process, should be the responsibility of hospital oversight committees, group practices, or departmental leadership.

The tools available for the CQI process are many. Establishing practice protocols and order sets helps standardize practice and reduce variation in individual performance. Appropriately used in a nonpunitive forum, scorecard benchmark performance can provide feedback that may allow outliers to see where potential areas of improvement are required. Identifying the need for an intervention is a clear component of this process. Counseling may be required with confidential but swift correction of unprofessionalism. Education, either with in-lab proctoring or external CME, can allow for any potential knowledge gap to be narrowed. Laboratory surveys provide feedback for both individuals as well as overall laboratory process performance. Working with hospital administration to consider incentives to improve performance and enhance educational opportunities may prove beneficial. Finally, administrative policy for intervention must be established to address the potentially "uncorrectable" outlier. SCAI has provided an outline of the components of an ideal quality control and inspection program and a Quality Improvement Toolkit (QIT) that is now available on their Web site (http://www.scai/QIT). Subspecialty "boards" in adult interventional cardiology are properly focused on proficiency, both cognitive and technical (6). For coronary interventional procedures, proficiency is most easily related to procedural volume, although proficiency and volume are only loosely associated. Some quantitative evidence now exists for selected volumetric cut points for interventional procedures (55) though controversy remains and enforcement is basically nonexistent, except at the credentialing committee level at each facility. The recent PCI guidelines acknowledge the controversial relationship between quality and volume. Risk-adjusted outcomes remain preferable to institutional and individual operator volumes as a quality measure (55). This issue is currently being addressed by the ACCF/AHA/SCAI Writing Committee to Update the 2007 Clinical Competence Statement on Cardiac Interventional Procedures. The situation is even less clear with respect to diagnostic catheterization. Given the absence of similar quantitative data for diagnostic procedures, as well as the significantly decreased associated morbidity and mortality associated with diagnostic catheterization, operator proficiency may be better assessed in a larger overall context. Rates of normal studies, peer review of the diagnostic quality of studies, rates of referral for intervention, and perhaps development of criteria for the appropriateness of these studies have all been suggested as methods of incorporating physician practice into the QI process for diagnostic procedures. The quality and the timeliness of catheterization reports should also be part of the QI process. A preliminary report should be immediately available and a final report completed within 24 hours. However, processes for credentialing and the assessment of proficiency must be developed in accordance with both local governance policies, as well as professionally developed

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Table 14. Data Quality Event Review Form (Representative Data Collection Form)

Patient Data

Patient Name:_____ Age:_____ ID#:_____

Procedure:_____ Physician:_____ Date:_____

Reason for Review:

Potential for Patient Safety:_____; Sentinel Event:_____

Mortality: In Lab_____; In Hospital_____ 30 Day_____

Morbidity: Neuro:_____; Vascular:_____; Coronary:_____;

Arrhythmia:_____; Renal:_____; Radiation:_____

Other:_____

Case Summary:

_____

_____

Risk Group: Average/Low High Salvage

Clinical _____ _____ _____

Cath _____ _____ _____

Process Review:

Appropriate Uncertain Inappropriate

Indication :_____

Technique :_____

Management :_____

Related to: Disease:_____; Provider:_____; System:_____;

Preventable:_____; Not Preventable:_____; Comments:_____

Recommendation by

Reviewer:_____

_____

Reviewer:_____

Recommendation by

Committee:_____

_____

_____

Patient Safety/Risk Management Review: Y N; Hospital/Department Review: Y N;

Corrective Action: Y N; Education_____; Proctor_____; Other:_____

Date:_____ Signature:_____

_____

standards. In particular, the granting of privileges by healthcare systems should fall within the legal purview of these institutions. It is hoped that these systems use criteria similar to those outlined in this document in association with the major cardiovascular societies to support the decision to credential physicians and monitor system performance.

Over a 10-year period, improvements in instrumentation, imaging, data recording, and procedural outcomes have proceeded rapidly. Consequently, continuing education for practitioners beyond the standard level of training programs has become the norm for the acquisition of many of these advanced skills. Training programs themselves are also changing from the traditional 1-year program in interventional cardiology to 2-year programs in some institutions. Subspecialty certification "boards" in interventional cardiology reflects this burgeoning knowledge base (6,110). All of this translates into the need to provide continuing education to all members of the team. The implementation of new technology requires a critical evaluation of both the experience in the literature as well as the experience within individual institutions. An organized didactic program coupled with cautious early clinical experience is an ideal mechanism for the introduction of new therapies. These types of programs, in conjunction with attendance at regional or national scientific meetings devoted to the unbiased presentation of new data, provide a solid infrastructure for credentialing purposes. Attention to this aspect of laboratory QI is critical to maintaining expertise.

3.4.2. Noncardiologists Performing Cardiac Catheterization

An independent operator in the cardiac catheterization laboratory must be proficient, not only in the technical aspects of the invasive procedure, but also in the cognitive aspects, including preprocedural evaluation, indications, cardiac physiology and pathophysiology, emergency cardiac care, radiation safety, and interpretation and clinical application of the cardiac catheterization data. ACCF has developed recommendations for training in diagnostic cardiac catheterization, as well as specific technical skills, including both education and case volume (111). Cardiology fellowship training requires completion of a 3-year program in order for the operator to be considered competent to perform diagnostic angiography and an

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additional year of dedicated training for coronary interventions (76).

The spectrum of participation in cardiac catheterization is broad and includes physician-supervised assistance by nonphysicians, independent nonphysician performance, and noncardiologist performance of cardiac catheterization. Nonphysicians serving in an assistant role during the catheterization with a cardiologist present are standard practices in most training and teaching programs and not the issue here. There is limited literature regarding safety/outcomes of nonphysicians independently performing cardiac catheterization. This topic was reviewed by SCAI in a statement regarding nonphysicians performing cardiac catheterization as independent operators (112). No relevant data are currently available establishing either the safety or the healthcare manpower requirement for nonphysicians performing as independent operators in the cardiac catheterization laboratory, and this practice is not appropriate. Some exceptions to this policy include right-heart catheterization procedures performed by competent operators from intensive care units or electrophysiologists utilizing the cardiac catheterization facility.

Medical and surgical subspecialties create training requirements to establish and maintain patient safety and quality of care (76,100,111). Hospital privileges for specific procedures are based upon training requirements. It is an ethical obligation to honestly disclose relevant information to the patient (e.g., the training credentials of the primary operator for any procedure, including cardiac catheter procedures). Beneficence is the ethical obligation to act in the patient's best interest (112). Patients, the public, and the government are rightly seeking greater assurance that physicians hold the interests of their patients above their own. Diagnostic cardiac catheterization and percutaneous coronary intervention should be performed by trained cardiologists, or comparably trained noncardiology physicians, who have been trained specifically for this procedure (110,111). It is not appropriate for noncardiologists to perform percutaneous coronary interventions.

3.4.3. National Database Use

In assessing quality, adverse outcomes are often equated to a lack of quality which, in turn, is related to performance. However, it is obvious that adverse events will occur, even in the best hands and at the best centers (113). The frequency of these events is, in large part, related to the condition of the patient and experience of the operator and center. Volume alone may not be the best barometer of quality (114).

The SCAI Registry was developed to offer individual centers an opportunity to assess their results relative to the national reporting network of catheterization laboratories on a voluntary basis. This registry tracked both diagnostic and interventional procedures and was the standard for assessing quality in the 1980s and 1990s, though the information was not risk adjusted and the number of variables was limited. This database is no longer being supported. With the termination of this database, no effort, to date, has been attempted to track and risk adjust diagnostic adverse outcomes on a national basis. State Health Departments require low-volume diagnostic laboratories to complete a data form on all patients. However, comparative national data for diagnostic catheterization have not been available since the 1990s.

ACC-NCDR is a voluntary national registry that currently receives data from approximately 1,300 participating hospitals. The purpose of this registry is to provide risk-adjusted outcomes to individual institutions and their physicians. Such risk-adjusted outcomes are considered the most appropriate measure of quality (108). The data collection processes as well as the details regarding the dataset have been described in detail (7). Each data element is predefined, linked to ACCF/AHA PCI Guidelines, and available at www.cardiosource.org. Data at each participating facility are entered locally into ACC-NCDR–certified software. Compatibility with individual laboratory reporting systems and ACC-NCDR, or any regional/national database such as the Northern New England Cardiovascular Disease Study Group or the New York State Department of Health Database, is essential to allow for complete data entry and minimize duplication. Many local QA programs are based on these data, and the sites themselves are responsible for auditing the data for completeness and accuracy. In addition, the ACC-NCDR has a limited national audit system of approximately 5% of the data. This registry has developed and validated a number risk adjustment models for specific adverse outcomes (7,108,113,115). An example of the output from the ACC-NCDR Cath PCI dashboard is shown in Figure 2.

This writing committee strongly encourages all laboratories to participate in a national or regional registry to benchmark their results and provide an ongoing system for tracking complications. Benchmark data are important, and because the validity of these data are dependent on a high number of participating laboratories, this committee strongly recommends that all cardiac catheterization laboratories actively participate in such a data registry.

3.4.4. Catheterization Laboratory Reporting Requirements

The catheterization report should be individualized to a particular institution depending upon the recommendations of the medical director and participating physicians, the administrative and informational infrastructure of the institution, and the requests of the referring physicians. Table 15 presents standard information required in such a report (116). A complete procedural report, finalized within 24 hours of a procedure and inclusive of content in Table 15, is a requisite and standard of care. Furthermore, structured reporting using standardized data elements captured as discrete data is highly preferred to verbose (i.e., handwritten or dictated) reporting. An initiative to define best practice workflows for data acquisition, processing, and reporting is

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Figure 2. Example of the NCDR CathPCI Executive Summary Quality Dashboard

NCDR = National Cardiovascular Data Registry; PCI = percutaneous coronary intervention.

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underway to develop a standardized, structured report format for diagnostic and therapeutic cardiac catheterization procedures. Prior to this, institutional preference for the use of a vendor-based versus a "home-grown" standardized reporting system should be viewed in the context of ensuring compatibility with a national database for complete data entry while minimizing duplicated effort. Appropriate immediate post procedure chart documentation is required for inpatient procedures if the completed catheterization report is not immediately available. Notification of findings to the patient, family, and referring physician/primary care physician should be expected standard practice.

Table 15. Minimum Components of the Standard Catheterization Report

1. Indications for the procedure
   a. Patient demographics
   b. Pertinent patient history including risk factors
   c. Specific indication for each component of the procedure (e.g., right-heart and renal angiography)
2. Procedure information
   a. Primary operator and additional staff present
   b. Procedures performed
   c. Access site information
   d. Equipment utilized
3. Procedure documentation
   a. Medications, including dose and duration of antiplatelet therapies
   b. Radiographic contrast used and dose
   c. Fluoroscopic time
   d. Radiation dose (mGy and Gy × cm^2)
4. Diagnostic findings
   a. Coronary anatomy (diagram optional but ideal)
   b. Ventricular functional assessment (EF, LVEDP)
   c. Other hemodynamic information (HR, BP)
   d. Other angiography
      I. Aortography (thoracic, abdominal)
      II. Renal angiography
   e. Relevant hemodynamics
      I. Right and left heart
      II. Response to medications or maneuvers
      III. Oxygen saturations
      IV. Cardiac output-result and method
      V. Valvular assessment (gradients; valve areas when appropriate; estimation of regurgitation severity; summary of mild, moderate, and severe disease assessment)
5. Interventional procedure(s)
   a. Separate listing for each procedure including site and procedure performed
6. Documentation of equipment and medications in catheterization laboratory results (i.e., ACTs)
7. Complications encountered in lab
8. Conclusion (a diagram provides visual information and is much preferred over textual alone reporting)
   a. Summary of appropriate of findings
      I. Coronary anatomy
      II. Ventricular function
      III. Hemodynamics
      IV. Valvular pathology
      V. Interventional procedures
   b. Recommendations or patient disposition (optional) based upon physician and laboratory preference

It is suggested that a preliminary report of the findings be made available immediately and the complete report made available within 24 hours. A catheterization report should focus on the coronary tree diagram as the preliminary report. Procedural details can be reserved for a second and more complete report.

ACT = activated clotting time; BP = blood pressure; EF = ejection fraction; HR = hemodynamic response; LVEDP = left ventricular end-diastolic pressure.

3.4.4.1. STORAGE OF INFORMATION (LENGTH AND TYPE)

There are several essential components to an information storage system for the cardiac catheterization laboratory, regarding both written word and recorded images. Important considerations for an individual institution are price, performance, capacity, and function. In choosing a system, users must first be considered so as to select a system that is operator- and institution-friendly. Linking the catheterization laboratory reporting system with the hospital information system improves information availability and patient care. In-laboratory and postprocedural complications and hospital outcomes should be tracked and reported regularly by the CQI committee. If possible, 1-month and intermediate-term outcomes and readmissions should also be monitored. Staff efficiency is improved when demographics are entered once into a system that "talks" throughout the hospital and/or health system. Additionally, inventory and billing can be linked to this system. This seamless interface between report generation and the information management system, not only provides an accessible report for patient care, but also enhances inventory maintenance and verifies billing (117).

As with all information systems, compliance with the 1996 Health Insurance Portability and Accountability Act (HIPAA) must be assured. Though physician access for patient care is important, all patient information interactions must be verified as HIPAA compliant, whether that be accessing lab values or signing reports (118).

Information storage strategies may take several forms. Varying redundant array of independent disks (RAID) schemes provide different levels of data access performance and system failure protection (119). The RAID schemes divide and replicate data among multiple hard drives, writing identical data as well as splitting data on more than 1 disk. Error correction is accomplished through redundancy, allowing read/write problems to be detected and corrected. This technology is particularly useful when large files (i.e., cine images) require storage.

The more advanced the data storage system, the more data replication mechanisms and storage servers are likely to be available. Long-term archiving provides for expanded storage, data protection, or both, when the primary space capacity is reached. Disaster recovery is essential to any storage system to prevent permanent data loss. Having a disaster recovery system in a nondirect access format prevents a computer virus, for example, from infecting and erasing data. Data duplication via a mirror image server, often at a remote facility, may be

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done in real time allowing for near instantaneous data replacement (120).

The Integrating Health Care Enterprise (IHE) was originally developed with support of the Radiological Society of North America and the Health Information and Management Society. In 2003, a cardiology domain was initiated by the ACCF, American Society of Echocardiography, American Society of Nuclear Cardiology, SCAI, and European Society of Cardiology to focus on integration of information within the cardiology department. IHE does not create standards but rather provides integration profiles from existing standards for specific clinical needs. Multiple profiles can be developed creating a cardiac catheterization laboratory workflow integrating ordering, scheduling, image acquisition, storage, and viewing (121). This can be integrated with echocardiography, electrocardiogram, and stress testing to display reports as well incorporate workflow through procedure/postobservational areas.

The transition from cine film to digital acquisition and storage in the catheterization laboratory was made possible with the creation of the Digital Image Communication in Medicine (DICOM) Standard (122,123). The DICOM Standard is a set of rules that allow medical images to be exchanged among all medical imaging devices. In the digitally enabled catheterization laboratory, digital images are stored for short-term archival on the proprietary digital storage unit of the specific imaging equipment or network servers with only limited storage capacity for immediate access.

Cine image storage in the digital imaging era is challenged by the pure volume of data (124). Various compression ratios have been employed in order to optimize storage capacity requirements, but the latter in anything greater than a 4:1 compression ratio frequently resulted in nondiagnostic images. Therefore, to preserve image quality, only lossless compression is currently used. A diagnostic cardiac catheterization with 5 to 10 cine runs of 6 to 7 seconds at a frame rate of 30 fps contains approximately 2,000 images. With minimum specifications of a 512 × 512 matrix and a pixel depth of 1 to 1.5 bytes, a standard diagnostic study results in 500 to 750 MB at 30 fps. At 15 fps, this is approximately 350 MB/case. In a facility that performs 5,000 cases per year for 7 years, this requires a storage capacity of 10.5 terabytes. This calculation does not consider the improvement in spatial resolution with a matrix size of 1,012 × 1,012 to 2.5 to 3.0 LP/mm (line pairs/mm). The latter is the preferred imaging technology to properly visualize stents in the right coronary artery in the right anterior oblique projection (125).

Long-term archival technology of these massive files has similarly progressed over time from stacked magnetic disks, to digital archival tapes, to large optical disks ("jukebox"), to current generation RAID 5 subsystems (119). Speed for recovery from long-term archival has dramatically improved. A picture archiving and communication system (PACS) is integral to hospital image storage and access. The inclusion of cardiac catheterization laboratory studies into the traditional radiology PACS system was generally precluded due to the file size requirements. Modern PACS may now comfortably accommodate catheterization laboratory images (120).

Duration of storage has been based more upon tradition than written policy. The "standard" cine film storage was 7 years. Currently, in the digital era, storage duration is based upon storage capabilities. However, the potential usefulness of adult cine storage >7 years is in question, although pediatric image storage may well require lifetime access to appreciate anatomy prior to interventions. The reality is that most laboratories provide image storage for only 7 years, even in the pediatric cardiac catheterization environment. The progressively low cost of digital image storage is making these minimum storage guidelines rather obsolete, as indefinite storage is now readily available.

3.4.5. Equipment Maintenance and Management

Equipment maintenance and management remain crucial issues from a catheterization laboratory QA/QI standpoint and specific guidelines are, therefore, provided. Each aspect of the radiographic system should be able to meet these performance expectations (126). The same is true for the physiological recorders and other specific devices used in the laboratories.

The modern diagnostic and interventional catheterization laboratory uses many sophisticated radiological, electronic, and computer-based systems, each of which requires a program of rigorous maintenance and troubleshooting. The x-ray imaging system, a crucial component of every laboratory, must be carefully assessed at frequent intervals to detect early signs of deterioration in performance. Unfortunately, this aspect of quality control is the first to be sacrificed in an era of cost constraints.

A program of periodic assessment of system performance and image quality has been recommended by SCAI (127). Additional programs, which address issues specific to digital imaging systems, are under evaluation (127). A representative outline of the performance characteristics needed to assess radiographic cardiac imaging systems is presented in Table 16.

Note that at present, the only federally mandated parameter for fluoroscopic systems is the maximum "table-top" exposure rate (see Section 9). The concept of minimum image performance standards must await universal acceptance of a suitable test instrument for cardiac fluoroscopy. Currently, there is considerable heterogeneity across laboratories in selective measurements of image quality (123,128). Such heterogeneity precludes specific recommendations with respect to what is considered "acceptable" performance. Current-generation imaging systems must be capable, at minimum, of providing images of sufficient diagnostic quality to enable decision making with respect to intervention and provide sufficient spatial and contrast resolution for the conduct of contemporary coronary intervention.

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Table 16. Performance Characteristics of Radiographic Imaging Systems

Category	Example
System measure	Image quality
	Dynamic range
	Modulation transfer function
Component measures (not inclusive)	Fluoroscopy and cine spatial resolution
	Fluoroscopy field of view size accuracy
	Collimator tracking and alignment
	Low contrast resolution
	Record fluoroscopic mode and automatic exposure control under standard conditions and at maximum output
	Calibration of integrated radiation dose meters

Interventional procedures occur in environments of high information density. In the past, physiological recorders were used only for the acquisition and recording of analog signals. They are now required to serve as front ends for the increasingly complex gathering of data. These recorders have essentially been transformed into desktop personal computers capable of acquiring, storing, and transmitting data to other sites. Given the critical importance of these data for numerous administrative purposes (billing, QA, report generation), flawless transmission without data loss must take place at all times (117). Backup systems and low-cost storage media are essential (125).

The need for patient safety-related precautions is paramount (129). The operational efficiency of infrequently-used equipment (e.g., defibrillators and external pacemakers) must be assessed routinely, and the appropriate logs must be kept. Electrical isolation and grounding systems must be regularly assessed (122). The number of ancillary devices used in coronary intervention (Doppler and pressure-tipped sensor wires and ultrasound catheters) now requires that electrical safety precautions that were adequate in the past need to be revisited at periodic intervals (122).

3.5. Minimum Caseload Volumes

The cardiac catheterization laboratory previously referenced was primarily an arena for the diagnosis and treatment of coronary artery disease. However, in the last decade, there has been not only an expansion of the anatomic indications for PCIs, but also an expansion of percutaneous interventions to most other vascular beds, as well as the development of a new branch of interventional cardiology involving the treatment of numerous forms of structural heart disease.

Determining who should perform procedures based on volume remains controversial and difficult to adjudicate. The goal is to have successful procedures done on appropriate patients. There are clinical, angiographic, operator, and institutional characteristics that have been shown to influence procedural success. Operator characteristics include cognitive skills, technical skills, experience (including the latest total cases and lifetime total cases), and training (including fellowship, cardiology and interventional board certification, and CME).

Utilizing minimum case volumes for credentialing focuses on only 1 of many factors that may play a role. Case volumes are often used as a surrogate for quality on the presumption that a high volume enhances the operator skills. It is presumed that skill maintenance is also greater for both the operator and the institution if procedural volumes are high. The documented relationships between activity level and outcome are statistical associations, but they may be of limited clinical significance. The heterogeneity within hospital volume groups found by Epstein et al. (143) suggests that activity level is an incomplete surrogate for quality. High-volume operators and institutions are not necessarily of high quality, and low-volume operators and institutions are not by definition poor-quality operators. There is limited statistical power to judge the outcome results of low volume operators. Establishing appropriate oversight and QA programs is more important than volume measures alone. All major complications in any laboratory should be reviewed by the QA committee at least every 6 months, and individual operator complication rates exceeding national benchmarks for 2 contiguous 6-month periods should be reviewed by the QA director (76). Ideally an ongoing subset of cases performed by all operators should be reviewed yearly. To help facilitate the knowledge transfer that is important in continuous quality improvement, participation in catheterization laboratory conferences and a minimum of 12 hours of CME per year should be a required component for operators in the cardiac catheterization laboratory.

Simulation training offers an additional method of improving cognitive and technical skills that is increasingly being used to increase clinical competencies, including endovascular procedures (144). Simulation training is a tool that may be used for maintenance of certification in the Interventional Cardiology Board prerequisite and may be particularly useful for low-volume operators and for low-volume procedures. Simulation training of rarely performed and/or complex procedures and new protocols may be of value.

3.5.1. Operator Volumes

3.5.1.1. OPERATORS PERFORMING DIAGNOSTIC PROCEDURES

Because of the low risk of diagnostic cardiac catheterization, it is difficult to arrive at any consensus as to what would constitute a minimum caseload. There are no data supporting the prior recommendation of at least 150 diagnostic cases per year (1). Previously, this has been simply convention. The minimum laboratory diagnostic caseload may vary widely depending on arbitrary requirements such as the presence of the CON process or state department of health regulations. It falls upon the director of the laboratory to ensure that all cardiac catheterization studies are appropriately indicated, performed, and interpreted (76). A maximum number of procedures that an operator should be

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performing is also controversial, an area where there are essentially no data. This emphasizes the dependence on the QA process to monitor physician and laboratory behavior appropriately.

3.5.1.2. OPERATORS PERFORMING INTERVENTIONAL CORONARY PROCEDURES

An annual interventional caseload of 75 procedures per year has been used for a considerable time as a standard for ensuring quality. Numerous analyses have addressed the relationship between individual operator caseload and procedural complications. Many of these studies have found an inverse relationship between volume and outcome (78,145,146) whereas others have found no relationship (147–149). Hospital volume affects the operator volume–outcome relationship (150,151). Malenka et al. (152) suggested that differences between high- and low-volume operators are minimized at a high-volume hospital. Moscucci et al. (153) examined the operator volume issue in the stent era and found no relationship between operator volume and in-hospital mortality, though the relationship between volume and any MACCE as measured by major cardiovascular event rates (death, CABG, cardiovascular accident or transient ischemic attack, MI, and repeat in-hospital PCI) was demonstrable. Although there does appear to be a statistical relationship between annual operator volume and MACCE rates, analysis of a linear plot examining these 2 variables reveals a scattergram, though the trend toward higher complication rates at lower volumes is observable (Fig. 3). In this figure, the majority of operators with procedural volumes <75 cases per year perform with excellent outcomes, whereas there are clearly operators >75 cases per year that have higher MACCE rates than expected. The value of using an annual threshold of 75 cases per year is limited when considering each individual operator.

In a report from the Cardiac Advisory Committee of New York State (58), the case volume range was dramatic, ranging from a very small number of cases (presumably only done when the physician was on call) over a 3-year period all the way up to a maximum of 3,722. No comment is made regarding any possible relationship between volumes and adverse outcomes. The report provides individual volumes for the 3-year period from 2004 through 2006, but the data are presented for each laboratory. Those that perform procedures at multiple laboratories are also noted. With those caveats, obviously creating the potential for substantial error, if it is assumed that 225 cases per 3 years should be the minimum for each operator during the 3-year period, then up to 57.9% of the listed physicians in the New York State Report (Table 3 of their report) did not meet the minimum criteria. In Table 4 of the report, 17.5% of operators performing procedures at multiple hospitals did not perform 225 procedures over the 3-year period. Even if these numbers are inaccurate by a wide margin, it does point out that there are many competent operators who do not perform the minimum of 75 PCI procedures per year.

SCAI has noted that the AHA report on the number of PCIs has been revised downward by about half, due to double counting. In the AHA Heart Disease and Stroke Update published in December 2010, the number of inpatient PCIs in 2007 is actually about 0.6 million rather than the 1.3 million in their publication (154).

As outlined earlier, performance of all interventionalists regardless of the volume of procedures performed should be assessed by a standing QA committee. There should be in place a review process to provide evidence to the appropriate oversight committee (usually the credentials committee in association with the director of the cardiac catheterization laboratory) that operators with <75 PCI procedures per year are having a random subset of their cases (at least 15%) critically reviewed each year. This should be in addition to the guidelines for the QA process for all operators as outlined earlier. The QA committee is encouraged to require within their bylaws that each operator obtain some level of PCI education every 2 years. This additional education should be mandatory for the lowest (<75 PCI per year) volume operators.

Volume requirements are of a magnitude of importance, as well as controversy, that a document specifically addressing clinical competence for cardiac interventional proce-

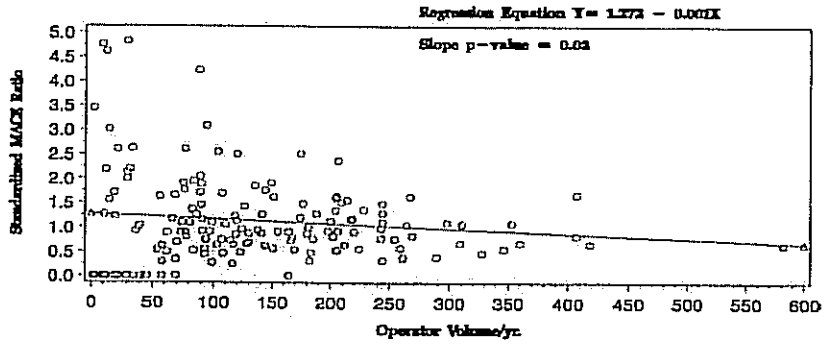

Figure 3. Linear Plot of Standardized MACE Ratios (Observed/Predicted Rates) Versus Annual Operator Volume

There remains only a general, but statistically important relationship with higher major adverse cardiovascular events (MACE) in operators doing fewer procedures. Reprinted from Moscucci et al. (153).

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dures was developed in 1998, updated in 2007, and the issue is currently being revised. The results of that writing committee are embargoed at the time of this document's publication. The "2011 ACCF/AHA/SCAI Guideline on Percutaneous Coronary Intervention" also include the same volume requirements as herein stated, and it favors the observational evidence of a volume–outcome relationship in PCI at both the institutional and operator level (155). However, the guideline also acknowledges that the volume–outcome relationship is complicated and may be inconsistent across low-volume institutions or operators and that new data in primary PCI suggest that operator experience may modify the volume–outcome relationship at the institutional level (156,157). The ACCF/AHA/SCAI Writing Committee to Update the 2007 Clinical Competence Statement on Cardiac Interventional Procedures will review current data and environmental trends and recommend how we can best assess competence for both individual operators and institutions for PCI in the current era.

3.5.1.3. PRIMARY PCI OPERATORS

PCI for AMI (primary angioplasty) is the application of PCI to, as a group, the sickest patient population undergoing PCI. Additionally, the constraints of D2B time of <90 minutes confer additional pressures on the operator and system. Current recommendations suggest that primary PCI be performed only by higher-volume operators experienced in both elective PCI and primary PCI for STEMI. The current guidelines recommend the operator perform >75 elective PCI procedures per year and about 1 primary PCI per month (11 per year) (6,158). The reality is that this requirement is not being followed in many institutions, would likely eliminate a large number of primary PCI operators, and is likely to prevent many institutions from providing 24/7 interventional calls due to a limited number of qualifying physicians. The data concerning volume–outcome relationship for primary PCI are particularly difficult to categorize because of the relatively small volume of STEMI patients per operator per year.

Vakili and Brown (159), analyzing primary PCI procedures for STEMI, could find no relationship between physician total PCI volume and mortality. The authors also reported an association between an operator's primary PCI activity level and the outcome of primary PCI for STEMI that was independent of the operator's experience in elective PCI (160). Hannan et al. (150) analyzed the New York State angioplasty registry data, found an increased in-hospital mortality at institutions with lower volumes of primary PCI, whereas Politi et al. (161) showed no relationship between operator volume and mortality or MACCE at a high-volume PCI institution. Other studies have also shown no relationship between institutional volume of primary PCI and in-hospital mortality. It is therefore recommended that all primary PCI procedures be subject to review by a designated QA committee, regardless of the operator volume. Operators who wish to perform primary PCI must participate in these reviews if they wish to continue to perform primary PCI. Each facility's QA process must determine whether the results are acceptable for both the institution and the operators involved.

3.5.1.3.1. PCI OPERATORS IN THE FACILITY WITHOUT CARDIOVASCULAR SURGICAL SUPPORT. Data from the ACC-NCDR, the largest and most comprehensive assessment of PCI centers with and without onsite cardiovascular surgery, reveal that there are more patients presenting to lower-volume centers without cardiovascular surgery with ACS than to full-service facilities (36). In comparison to sites with onsite cardiovascular surgical back-up, sites without onsite cardiovascular surgery have similar rates of procedural success, morbidity, need for emergency surgery, and risk-adjusted mortality for all patients. Centers without onsite cardiovascular surgery have significantly shorter reperfusion times (2.1 ± 5.1 versus 2.6 ± 8.4 h). Seventy-nine percent of these sites without cardiovascular surgery provide both elective and primary PCI. Eighty-one percent of interventional operators work at both offsite and onsite surgery facilities; only 17% operate exclusively at offsite centers. No differences have been reported in outcomes (36).

Compared with full-service PCI centers, offsite PCI programs are predominantly located in nonurban areas, have lower annual PCI volume, treat a higher percentage of patients who present with subsets of AMI, and have better door-to-reperfusion for primary PCI. These same sites have, for the most part, similar observed procedural success rates, morbidity, emergency cardiac surgery rates, and mortality in cases that required emergency surgery as full-service facilities. The risk-adjusted mortality rates in offsite PCI facilities are comparable to those of PCI centers that had cardiac surgery onsite, regardless of whether PCI is performed as primary therapy for STEMI or in a nonprimary setting. These issues have been previously addressed in this document (see Section 2.4.3.).

An SCAI expert consensus document (14) emphasizes that though offsite surgical backup can be performed with acceptable outcomes and risks, the development of such programs should be based on the health needs of a local area, not on desires for personal or institutional financial gain, prestige, market share, or other similar motives. They recommend that operators performing PCI without onsite surgery should perform ≥100 total PCIs per year, including ≥18 primary PCIs per year. They also recommend that initial operators at a facility without onsite cardiovascular surgical backup should not begin performing PCI in such facilities until they have a lifetime experience of >500 PCIs as primary operator after completing fellowship. Operators in such facilities must demonstrate complication rates and outcomes equivalent or superior to national benchmarks and must evaluate their outcomes against established benchmarks.

There are obviously many operators performing primary PCI in facilities without cardiovascular surgical backup who do not meet these stringent guidelines, and these sugges-

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tions have not been enforceable. The role of PCI without onsite cardiovascular surgical backup continues to evolve as a strategy for the delivery of care in patients with MI. Systems of care within a community should generally direct STEMI patients to facilities that are able to achieve a D2B time of <90 minutes and have a laboratory available on a 24 hours a day, 7 days a week basis. As pointed out earlier, the committee cannot recommend elective PCI programs without cardiovascular surgical backup that only provide primary PCI coverage during daytime and weekday hours.

It is the consensus of this committee that operators able to achieve successful primary PCI within the established guidelines may perform these procedures if there is a medically obvious advantage to the patient and the community. The decision must not be based on financial or prestige gain to the disadvantage of patient care. It should only be made available where there are written and enforceable guidelines from a full-service facility willing to accept patients should complications arise. Partnership with an experienced tertiary care hospital with a PCI program supported by cardiovascular surgery is mandatory. The organization of a primary PCI program and the patients eligible for primary PCI procedures in sites without onsite cardiovascular surgery have been discussed earlier and the highlights are outlined in Tables 2, 3, 4, 5, 6, and 7.

3.5.2. Institutional Minimum Caseloads

3.5.2.1. DIAGNOSTIC CATHETERIZATION INSTITUTIONAL VOLUME

The minimum diagnostic caseload for the entire laboratory facility varies widely from state to state, often depending on the presence of the CON process or other frequently arbitrary requirements. It falls upon the director of the laboratory to ensure that all studies in the cardiac catheterization laboratory are of the highest quality. In general, high-volume laboratories have consistently been shown to have fewer complications than low-volume facilities, although quality cannot be presumed by analysis of the total laboratory volume alone. Minimum laboratory diagnostic volumes are generally about 600 cases per year for financial viability, and that figure is often used as a cutoff minimum value with no strong data to support that it is the minimum number for highest quality. In some states, a minimum volume of 200 diagnostic cases per year has been found acceptable. All of these minimum volume numbers appear arbitrary to the writing committee, and there is concern that very low-volume laboratories may be poorly equipped or poorly maintained because of cost constraints. Just as in PCI programs, facilities performing only diagnostic cardiac catheterization must have an ongoing QA program that functions to ensure that the procedures being done are appropriate and that there are no quality issues with the procedure, the reporting system, or the decision making based on the procedural results.

3.5.2.2. INTERVENTIONAL CORONARY CATHETERIZATION INSTITUTIONAL VOLUME

In many states, the State Board of Health or the CON process will stipulate a minimum institutional PCI volume. McGrath et al. (145) examined institutional volume and outcome relationships. They noted an increased 30-day mortality rate of 4.29% for low-volume PCI programs performing <80 Medicare-reimbursed procedures per year versus high-volume programs that performed >160 Medicare procedures per year (3.15%). It should be noted that higher-volume facilities generally have the capacity to provide more extensive supplies and specialized equipment for PCI procedures, an immeasurable advantage in complex interventions and during unanticipated in-lab complications.

Kimmel et al. (78) using data from SCAI, found an inverse relationship between the number of PCI procedures a hospital performed and the rate of major complications. These results were risk stratified and independent of the patient-risk profile. There were significantly fewer complications in institutions that performed at least 400 PCIs yearly.

Jollis et al. (146) similarly found that low-volume hospitals were associated with higher rates of emergency coronary artery bypass surgery and death after PCI. Improved outcomes were identified at a threshold of 75 Medicare PCIs per physician and 200 Medicare PCIs per hospital. Using a 50% ratio of Medicare patients, the threshold value was estimated to be 150 to 200 PCIs per cardiologist and 400 to 600 PCIs per institution.

Epstein et al. (143), using an administrative dataset, analyzed risk-adjusted mortality in 362,748 admissions to 1,000 U.S. hospitals between 1997 and 2000, during which a PCI was performed. They found a consistent trend of decreasing risk-adjusted mortality with increasing hospital volume. The differences among groups were small, though. There was considerable heterogeneity within groups, suggesting that hospital volume was not the sole determinant of outcome. There are other studies that support the relationship of complication rate to institutional procedural volume (80,162,163). However, some investigators have pointed out that despite data that low procedure volume is poorly related to outcomes (164), many of these studies are small in number and underpowered (165). The National Health Service in the United Kingdom recently published the MACCE for each U.K. facility with data from 2007 and 2008 (Fig. 4) and found no linear relationship between MACCE and institutional volume (166), though improved outcomes were suggested when the institutional volume was >400 cases per year. These data form the basis for the recommendations of the Joint Working Group of PCI of the British Cardiovascular Society (167).

Based on data accumulated in the current stent era, a general volume–outcome relationship appears to exist. For example, Brown and coworkers (168) evaluated the out-

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comes of PCI at all hospitals in California in 1997. Mortality and emergency CABG rates for PCI in which a stent was used was 1.5% and 1.2%, respectively, in hospitals performing <400 procedures per year compared with 1.1% and 0.8% in hospitals performing >400 procedures per year (110). Taken as a whole, an institution should be considered low volume if <400 PCI procedures are performed each year. The 2011 ACCF/AHA/SCAI guidelines consider a low laboratory volume of PCIs to be from 200 to 400 per year (158).

For both institutional and individual volume assessments, ongoing 2-year volumes should be measured then averaged to arrive at annual statistics. It is recommended that lower-volume institutions (<400 per year) must hold conferences with a more experienced partnering institution, with all staff expected to attend on a regular basis. Weekly cardiac catheterization laboratory conferences should be a mandatory aspect of the quality control and inspection program. It is also recommended that any institution that falls >2 standard deviations outside the risk-adjusted national benchmarks in mortality or emergency same-stay CABG during 2 of 3 contiguous 6-month periods have an external audit looking for opportunities to improve quality of care. The appropriateness of continuing to perform PCI procedures in an institution with low volume and unsatisfactory outcomes should be directly addressed from a medical standpoint and not from a financial or marketing standpoint.

3.5.3. Training

The cardiac catheterization laboratory represents a platform for training in invasive cardiovascular procedures. The goal of training programs is to teach the cognitive knowledge as well as the technical skills used in invasive cardiology. This includes indications and contraindications for the procedures, pre- and postprocedure care, management of complications, and the analysis and interpretation of hemodynamic and angiographic data. The trainee's professional goals determine the knowledge and skill set to be acquired during their time in the catheterization laboratory (169). The ACCF COCATS requirements differentiate among 3 levels of training based on distinct career goals (169). Level 1 training is designed for noninvasive cardiologists, whose invasive activities will be confined to critical care unit procedures. The goal of their catheterization laboratory experience is to learn the indications for procedures as well as how to interpret the data obtained in the laboratory. Level 2 training is for invasive cardiologists who will practice diagnostic, but not interventional, cardiac catheterization. Level 3 training is for interventional cardiologists who plan to perform both diagnostic and interventional cardiac catheterization (169).

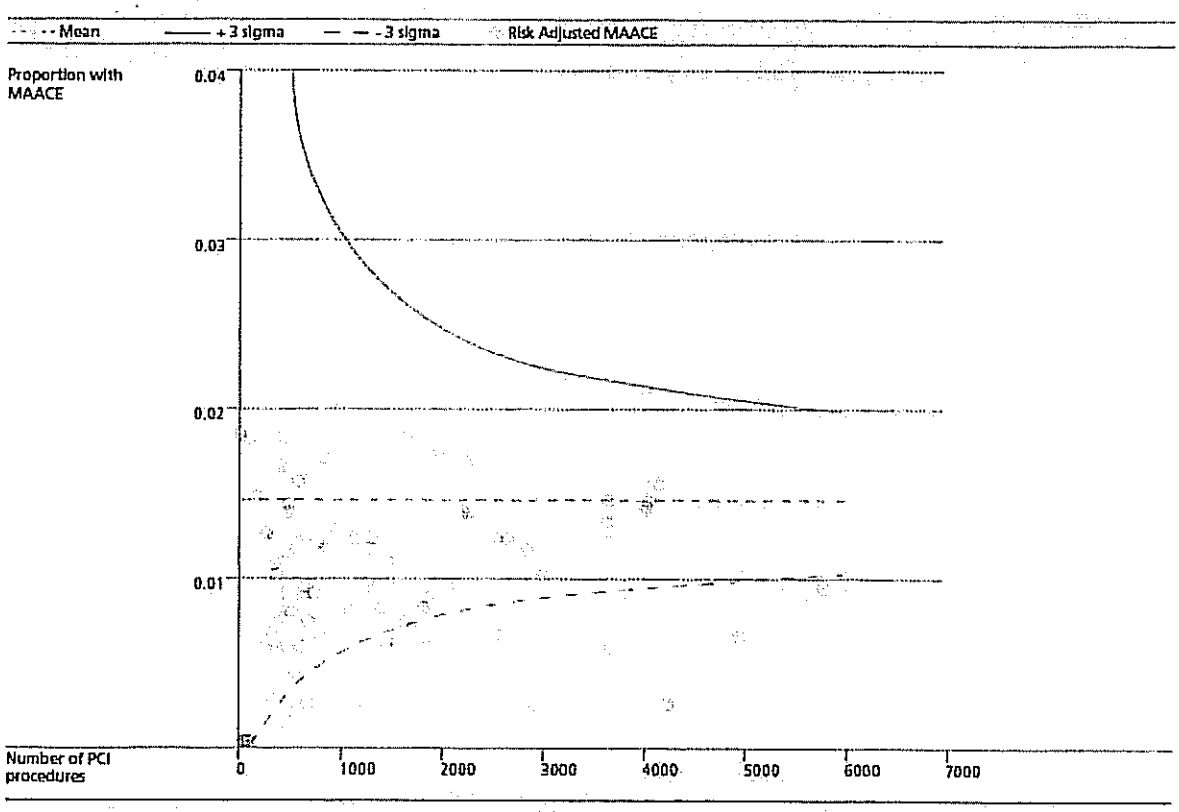

Figure 4. Relationship Between MACCE and Institutional Volume

No clear relationship is observable in this assessment of data from a national audit of PCI procedures in the United Kingdom (2007 and 2008). Reprinted from NHS Information Centre for Health and Social Care (166). MACCE = major adverse cardiac and cardiovascular events.

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Table 17. Summary of Training Requirements in Diagnostic and Interventional Cardiac Catheterization

Area	Level of Training	Minimum Number of Procedures	Cumulative Duration of Training (Months)
Diagnostic catheterization	1	100	4
	2	200 (300 total)	8
Interventional catheterization	3	250	20

Modified from Jacobs et al. (169).

3.5.3.1. DIAGNOSTIC CARDIAC CATHETERIZATION AND PCI

A minimum of 4 months experience with at least 100 diagnostic catheterizations is required for Level 1 training, with 8 months experience and at least 200 additional cardiac catheterizations required for Level 2 (Table 17).

In contrast to diagnostic cardiac catheterization, training in PCI requires enrollment in an additional fellowship year in interventional cardiology in an Accreditation Council for Graduate Medical Education (ACGME)-accredited program (169). The trainee should participate in a minimum of 250 coronary interventional procedures during this year. In addition, the trainee should be proficient with the use of associated PCI procedures, such as IVUS and fractional flow reserve. Newer procedures, such as optical coherence tomography, may also find a role, and adequate training in such procedures should be anticipated. Completion of such a program leads to eligibility to sit for the American Board of Internal Medicine interventional cardiology examination. The goal should be that board certification is accomplished for everyone completing an accredited training program who wishes to actively participate in a coronary interventional practice. During fellowship training, all diagnostic and interventional cases should be performed under the direct supervision of a faculty member. Details of the cognitive knowledge and technical skills required for all 3 levels are outlined in the ACCF COCATS 3 training statement. Participation in cardiac catheterization conferences and exposure to cardiac catheterization research must be part of the training of all cardiology fellows.

3.5.3.2. PERIPHERAL VASCULAR PROCEDURES

At present, catheter-based peripheral vascular interventions are performed by subspecialists with diverse formal training including interventional radiology, interventional cardiology, and vascular surgery. Although guidelines of each subspecialty society include endovascular procedures within their training curricula, there is a lack of uniformity regarding the amount of patient exposure required and the precise mechanisms for evaluation of the experience (101,170).

Specific knowledge required for safe and effective performance of peripheral interventions includes the pathophysiology, clinical manifestations, as well as the evaluation and treatment of diseases for a variety of vascular territories. The training requires knowledge of peripheral arterial disease, renal artery stenosis, extracranial cerebrovascular disease, vascular aneurysms and arterial dissections, mesenteric ischemia, and both arterial and venous thromboembolism (101). The ACCF COCATS 3 training statement suggests that for vascular medicine and peripheral catheter-based intervention, training be a minimum of 12 months for both Level 2 (vascular medicine specialist) and Level 3 (peripheral vascular intervention) competence (100). Level 3 peripheral vascular training may be undertaken concurrently with advanced training for coronary interventions, but it must include a minimum of 100 diagnostic peripheral angiograms and 50 noncardiac peripheral vascular interventional cases evenly distributed among the different vascular beds (100).

The fellowship training requirements for performing peripheral vascular interventions are detailed in Table 18. Simulation training has been shown to improve performance of carotid angiography (171). Lower-volume established operators may also benefit from including simulation training as part of their CME.

The ACCF/ACP/SCAI/SVM/SVS Writing Committee on Clinical Competence on Peripheral Vascular Disease suggests that in order to achieve a balanced experience required for competence, the trainee's experience should include no fewer than 20 diagnostic and 10 interventional

Table 18. Formal Training to Achieve Competence in Peripheral Vascular Catheter-Based Interventions

Training requirements for cardiovascular physicians
• Duration of training*—12 months
• Diagnostic coronary angiograms†—300 cases (200 as the supervised primary operator)
• Diagnostic peripheral angiograms—100 cases (50 as supervised primary operator)
• Peripheral interventional cases†—50 cases (25 as supervised primary operator)
Training requirements for interventional radiologists
• Duration of training‡—12 months
• Diagnostic peripheral angiograms—100 cases (50 as supervised primary operator)
• Peripheral interventional cases†—50 cases (25 as supervised primary operator)
Training requirements for vascular surgeons
• Duration of training—12 months§
• Diagnostic peripheral angiograms‖—100 cases (50 as supervised primary operator)
• Peripheral interventional cases¶—50 cases (25 as supervised primary operator)
• Aortic aneurysm endografts—10 cases (5 as supervised primary operator)

This table is consistent with current Residency Review Committee requirements. *After completing 24 months of core cardiovascular training and 8 months of cardiac catheterization. †Coronary catheterization procedures should be completed prior to interventional training. ‡After completing general radiology training. §In addition to 12 months of core vascular surgery training. ‖In addition to experience gained during open surgical procedures. ¶The case mix should be evenly distributed among the different vascular beds. Supervised cases of thrombus management for limb ischemia and venous thrombosis, utilizing percutaneous thrombolysis or thrombectomy, should be included.

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individually supervised cases in each of the major vascular territories, including aortoiliac and brachiocephalic, abdominal visceral, renal, and infrainguinal (101). The 12-month training period is in addition to the 24 months required for clinical core cardiology training and at least 8 months acquiring experience in diagnostic cardiac catheterization in an ACGME-accredited fellowship program. It is recommended that the trainee perform a minimum of 300 diagnostic coronary procedures, including 200 procedures with supervised primary responsibility prior to beginning interventional training. The trainee should also participate in a minimum of 100 diagnostic peripheral angiograms and 50 noncardiac peripheral vascular interventional cases during the interventional training period. At least 50 of the diagnostic angiograms and 25 of the interventional cases should be as supervised primary operator. The case mix should be evenly distributed among the different vascular beds. Supervised cases of thrombus management for limb ischemia and venous thrombosis that utilizes percutaneous thrombolysis or thrombectomy should be included.

3.5.3.3. STRUCTURAL HEART DISEASE

The inherent problems in setting threshold volumes in structural intervention is that the procedures—as compared to coronary artery interventions—are more diverse, of higher complexity, of lower frequency, and often require a multidisciplinary approach. Many of these procedures require multiple imaging modalities during the procedure (fluoroscopy and echocardiographic imaging). In addition, most of these procedures are in evolution in terms of indications, procedural issues, devices, and outcomes (172). The current guidelines on congenital heart disease do not offer volume guidelines (173). SCAI is actively addressing this issue and has recently published initial guidelines regarding training (174) as well as a survey of physicians to gain a better understanding of how best to establish competence (175).

Percutaneous noncoronary cardiac interventions for structural heart disease, including ASD and PFO closure, alcohol septal ablation therapy, and valvuloplasty represent growing and important components of the field of interventional cardiology. In addition, newer methods are being investigated for percutaneously approaching closure of other congenital vascular defects and connections as well as repairing or replacing cardiac valvular abnormalities. Although it is recommended that trainees in interventional cardiology programs get exposure to these procedures (169,176), at present, there are few official guidelines for training in each of these interventions. Guidelines for alcohol ablation for hypertrophic cardiomyopathy suggest a minimum of 20 procedures is required for proficiency. The "ACCF/AHA/SCAI 2007 Update of the Clinical Competence Statement on Cardiac Interventional Procedures" provides a review of the additional knowledge skills and training that are necessary for gaining competence in structural heart interventions (6). Due to the small number of these procedures performed, and the specialized knowledge and skills required, it is recommended that both training and practice activity be concentrated among a limited number of operators to allow for adequate expertise to be obtained (169).

For PFO and ASD closure or for the use of alcohol septal ablation in the treatment of the outflow tract gradient in hypertrophic cardiomyopathy, a minimum of 10 procedures each during training is recommended for trainees whose goal is to perform these procedures independently. Alcohol septal ablation should be offered only in those institutions that can employ a multidisciplinary program for pre- and postprocedural evaluation, careful case selection, and assessment of clinical outcomes. If available, partnership with a pediatric interventionalist should be considered when performing septal closure with the available percutaneous devices. In almost all situations the proper performance of interventions in structural heart disease requires a multidisciplinary team of cardiologists, cardiothoracic surgeons, vascular specialists, noninvasive imaging specialists, and radiologists.

Percutaneous aortic and mitral valvuloplasties are among the most complex and challenging interventional procedures. The importance of an operator learning curve has been well described for both of these interventions (177–179). Therefore, it has been recommended that 5 to 10 cases be performed with an experienced colleague, before performing balloon valvuloplasty independently (6). The significance of a learning curve is even more applicable for novel techniques such as percutaneous mitral valve repair, the closure of prosthetic paravalvular regurgitation, or transcatheter valve replacement. At the time of this document, most of these latter procedures remain primarily within clinical trials (177). In order for laboratories to become competent in the performance of structural heart procedures, the supervising or performing operator should be fully credentialed by the local facility in the procedure. Initially, this may require offsite training, simulation training, a visiting proctor, or a combination of these approaches. These procedures should only be done in a full-service hospital facility (Table 2). The operator responsible for the performance of the procedure in the catheterization laboratory should educate and supervise the staff in acquiring the necessary skills for the particular procedure. Since these are essentially always lower-volume procedures, there should be a small number of dedicated staff members and operators trained to perform structural heart procedures. For adult cardiologists performing these studies, a close working relationship with pediatric invasive cardiologists is also critical to ensure optimal performance in addressing percutaneous approaches to adults with congenital heart disease.

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4. Procedural Issues in the Cardiac Catheterization Laboratory

4.1. Safety in Patients With Communicable Diseases

Screening for blood-borne pathogens is not routinely performed before referral to the cardiac catheterization laboratory. Therefore, it should be assumed that every patient has the potential to transmit an infectious agent. This reinforces the need to apply Universal Precautions in the cardiac catheterization laboratory. However, some patients referred for cardiac catheterization laboratory will be known to carry the HIV or the hepatitis virus (180). Heightened protective care should be taken in any case in which a communicable disease such as hepatitis or HIV positivity is present. Every cardiac catheterization laboratory should have an approved additional sterile technique protocol for known highly infectious cases. This protocol should include the use of surgical caps and masks as well as eye protection. Double gloving has been shown to reduce the chances of a puncture and to better clean an inadvertent needle that has punctured the gloves. In a study by Gerberding et al. (181), 17.5% of gloves developed a perforation during surgery. Wearing 2 pairs of gloves reduced the chances of a puncture hole in the inner glove by 60%. Though this practice has not proven to prevent transmission of hepatitis or HIV, it seems prudent to use this technique when the operator is working with high-risk patients. In case of blood-borne pathogen exposure to personnel, the catheterization laboratory should have in place ready access to hospital occupational health resources to rapidly address the risk of exposure to the staff along with the appropriate treatment, if indicated. For example, timely assessment and treatment of HIV-exposed personnel can reduce the risk of HIV-seroconversion. In addition to the usual surgical gown, disposable shoe covers for the cardiologist and all technicians and nurses in the room should be considered. Protective eyewear should be worn by all in-room personnel to prevent accidental blood exposure to the operator's eyes. The careful disposal of all needles, catheters, sheaths, tubing, and other instruments, as well as fluids that come in contact with the infected patient, is obviously important. Disposal of protective gear and all contaminated equipment at the end of the procedure as well as proper disinfection for nondisposable equipment is also important, especially for blood-borne pathogens that are communicable by contact (e.g., methicillin-resistant *Staphylococcus aureus*).

Vaccination for hepatitis B virus should be strongly considered, if not mandatory, for all operators and other personnel who work in the cardiac catheterization laboratory (182).

4.2. Patient Preparation

Many laboratories use a checklist to ensure that all relevant data are available prior to a procedure. Although this can be individualized, the checklist should at least include the patient name and hospital number, birth date, the procedure being planned, the status of the consent form signing, the core physical exam features, the indications for the procedure, the American Society of Anesthesiologists classification, the planned site of entry, medications and any allergies, pertinent laboratory findings (including creatinine clearance), and proposed contrast media limit.

Prior to any procedure, appropriate informed consent must be obtained. Discussing the risks and benefits of the procedure, as well as the alternatives to the procedure, must be done. Each facility must have an approved consent form that includes risks of the procedure in terms the patient can understand. For most coronary procedures, the potential need for ad hoc PCI should be included along with the adherent additional risks reviewed. All elective PCI procedures must mention the possible need for surgical intervention. The written informed consent may be obtained by trained secondary operators or physician extenders, but the major concerns should be reiterated when the primary operator discusses the procedure with the patient. Risks of PCI should be explained at the same time as the diagnostic catheterization risks, if the case has the possibility of requiring PCI immediately following the diagnostic procedure.

Educating each patient about the procedure and explaining in detail what they should expect allays patients' anxiety and ensures patients are fully informed. Additional procedures that the patient has not consented to must not be performed unless a life-threatening emergency develops. Written informed consent should be obtained in all elective cases, and ideally in emergency cases. However, in cases that are emergent, it is recognized that written informed consent may not be feasible. In these cases, local standards for documentation of necessity should apply, and documentation should be clearly written in the patient's record.

Prior to the start of the procedure, calling a time-out assures that the appropriate procedure is being performed on the correct patient. This is now a Joint Commission on Accreditation of Healthcare Organizations requirement. The time-out period must occur before the patient is sedated at the start of the procedure. The time-out participants include the attending physician, any trainees or other participating secondary operators, and the procedural staff. The patient should participate if awake to confirm the information. A member of the procedural staff or the attending physician should initiate the time-out period. The elements of the time-out must include, but are not limited to the following: 1) correct patient name; 2) correct procedure being performed; 3) consent signed; 4) confirmation of any allergies; 5) any antibiotic administration; 6) correct site and side is being used; 7) confirmation of pre-wash performed, if indicated, and/or double prep, if necessary; and 8) availability of any special equipment and/or imaging studies that will be used during the procedure.

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4.2.1. Minimum Laboratory Data in Preparation for the Procedure

Within 2 to 4 weeks prior to any cardiac catheterization procedure, a hemoglobin, platelet count, electrolyte panel, and creatinine should be obtained on all patients. If the patient arrives and has had any significant clinical change or recent contrast exposure since the laboratory tests were obtained, the studies should be repeated on the day of the procedure and prior to the catheterization.

Unless the patient has a known liver disease or a hematologic condition that might affect hemostasis or is on antithrombin therapy, the consensus of the committee is that the routine acquisition of a protime/INR procedure is optional and no longer necessary before the cardiac catheterization in most cases.

In addition, the committee feels that the patient's need for overnight NPO is not always in the best interest of patient hemodynamics, and only a minimum NPO period of 3 hours is sufficient, unless conscious sedation will clearly be required. If conscious sedation is required, the NPO period is suggested to be at least 4 hours. The American Society of Anesthesiologists last published NPO guidelines in 1999, at which time they suggested 2 hours of fasting after clear liquids and 6 hours after a light meal (183). Adequate hydration remains an overlooked but is an important preparatory feature.

Women of child-bearing age should have a urine beta-HCG level or a serum beta-HCG checked within 2 weeks prior to the procedure to exclude pregnancy. During the initial 2 weeks of gestation, the embryo has little risk from ionizing radiation unless a large dose is received (>100 mGy). At that exposure, there is a higher likelihood of fetal death or failure of the blastocyst to implant. The uterus provides considerable protection. Since only a few cells make up the embryo during that period, embryo cells that survive are progenitors of many other cells and exhibit no ill effects from the radiation exposure (206a). The data thus appear to justify the 2-week margin before any woman of child-bearing age receives ionizing radiation.

The presence of a nickel allergy has also been a concern for patients in whom a nickel-containing device may be implanted. It is estimated that about 15% of the population has a skin nickel allergy (184). Nitinol is a nickel/titanium alloy used in self-expanding devices. One report suggests nickel allergy may result in an increase in migraine headaches after ASD or PFO closure with large occluder devices made from nitinol (185). Another report suggested the use of the Helex device rather than the Amplatzer to prevent any nickel allergic reactions (186). The Helex device minimizes the nitinol exposure as its circumferential support is enclosed in an ePTFE membrane. Coronary stents are made of stainless steel, which is biologically inert but may contain as much as 5% nickel. Although there are anecdotal data regarding early stent closure in nickel-allergic patients, there are no data to support routine skin testing for nickel allergy before the use of either occluder devices, or of coronary or vascular stents at the present time.

4.2.2. Patients Receiving Antiplatelet and Antithrombin Agents

Aspirin is not stopped or held prior to cardiac catheterization, and if patients have not been taking aspirin, it should be started prior to the procedure. Many patients are loaded with or started on thienopyridines prior to cardiac catheterization if there is a high likelihood of PCI and low likelihood of CABG. Ticlopidine is generally no longer used (except in the rare clopidogrel-allergic patient), and newer antiplatelet agents are becoming increasingly available and may be substituted when medically indicated.

Patients taking warfarin should be instructed to stop taking it at least 3 days prior to the catheterization, and their INR should be checked prior to the procedure. An acceptable INR to perform femoral artery cardiac catheterization procedure is <1.8.; an INR of <2.2 is acceptable for radial access. These thresholds are rather arbitrary and based on scant data. Of note, a new study of fully anticoagulated patients undergoing PCI from either the radial or femoral access site suggests a major advantage to the use of radial access regarding periprocedural bleeding (187). Overuse of parenteral vitamin K may make it difficult to re-establish an antithrombin effect following the procedure, therefore allowing the patient's INR to drift downward after stopping the medication is preferred. In high-risk groups, especially those with mechanical heart valves, a bridging protocol is generally followed (188).

Patients receiving heparin, low-molecular-weight heparin, or glycoprotein IIb/IIIa inhibitors undergo cardiac catheterization safely with only a minimum increase of bleeding risk, particularly in the setting of an ACS. A longer time to hemostasis may be required postprocedure, and the combination of aspirin, heparin, and other antiplatelet agents increases the risk of bleeding. Newer non-heparin anticoagulants may require a change in practice regarding the timing of performing cardiac catheterizations and subsequent angioplasty procedures. Following activated clotting times (ACTs) for patients on IV heparin has been the standard for years. With newer low-molecular-weight heparins, factor Xa inhibitors, and direct thrombin inhibitors (e.g., bivalirudin [Angiomax]), ACTs are often not appropriate. Knowledge of the time when the last dose of the low-molecular-weight heparin or factor Xa inhibitor will dictate further anticoagulant therapy during PCI procedures, risk of bleeding, and the timing of sheath removal. The half-life of bivalirudin is short, 25 minutes in patients with normal renal function.

Dabigatran etexilate (188a) is a small nonpeptide molecule that reversibly inhibits both free and clot-bound thrombin (factor IIa) and has been approved for stroke prevention in patients with atrial fibrillation. At the time of this writing, it is being actively investigated for other indica-

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tions. It has a predicable pharmacokinetic profile that allows for a routine dosing regimen without need for routine coagulation monitoring. Peak effect occurs in 2 to 4 hours after administration. Its estimated half-life is 15 hours with normal renal function. Testing for its effect provides a qualitative and not quantitative measure. It does not alter the INR. The activated partial thromboplastin time (aPTT), although not sensitive to the effects, can provide negative predictive value; an aPTT <30 seconds suggests no effect, whereas the median peak aPTT level is about 2 times control. The thrombin time for direct thrombin inhibition is sensitive, though it is still most useful to exclude an anticoagulant effect as other anticoagulant agents can affect its value. The ecarin clotting time has a linear relationship with dabigatran levels, but at present, it is not widely available. Drug levels are affected by renal function. Based on the pharmacokinetics, in patients with normal renal function (eGFR >50 mL/min), discontinuation of 2 doses results in a decrease in the plasma level to about 25% of baseline, and discontinuation of 4 doses will decrease the level to about 5% to 10%. Some reversal of the effects can be achieved by the use of recombinant activated factor VII and prothrombin complex concentrates. It can also be removed with dialysis. About 60% is removed after 2 to 3 hours of dialysis. From a practical standpoint, the drug should be stopped 24 hours (2 doses) prior to cardiac catheterization if the eGFR is >50 mL/min and for 48 hours if the eGFR is 30 mL/min to 50 mL/min. The drug should not be used in patients with eGFR <30 mL/min. The anticoagulant effect in patients with such chronic kidney disease (eGFR <30 mL/min) may persist for 2 to 5 days (189).

Rivaroxaban, a factor Xa inhibitor that is structurally similar to the antibiotic linezolid, has now been approved by the Food and Drug Administration (FDA) as a once-a-day alternative to warfarin. Apixaban, a factor IIa inhibitor similar to dabigatran, is likely to be available soon. A review summarizes their potential advantages and uses (190).

4.2.3. Chronic Kidney Disease/Renal Insufficiency

Though there is some controversy regarding the classification of patients with CKD, groups can be divided by glomerular filtration rate (GFR) into 5 categories (based on the Modification in Diet in Renal Disease [MDRD] GFR calculation method). The stages are outlined in Table 19.

Table 19. Progressive Stages in Renal Dysfunction Utilizing the GFR via the MDRD Method

Stage	Severity	GFR (mL/min/1.73 m²)
I	Slight	<90
II	Mild	60 to 89
III	Moderate	30 to 59
IV	Severe	15 to 29
V	Severe and established	<15

Reprinted with permission from Levey et al. (191).
GFR = glomerular filtration rate; and MDRD = Modification of Diet in Renal Disease.

The occurrence of contrast-induced nephropathy (CIN) correlates directly with the severity of chronic kidney disease, contrast volume, and the combination of chronic kidney disease and diabetes mellitus. CIN carries a poor prognosis, particularly if patients become dialysis dependent; however, the occurrence of CIN varies widely depending on the definition used (192). Two definitions (an incremental increase in creatinine >0.5 mg/dL and >25% rise in serum creatinine) are now accepted as a measure of CIN occurrence (193). A multitude of studies have been performed using different iodinated contrast agents, gadolinium, and various modalities to try and prevent contrast nephropathy.

4.2.3.1. ATTEMPTS TO REDUCE THE RISK OF CONTRAST NEPHROPATHY

The cause of nephropathy following radiographic contrast is unknown. There are data that suggest both renal vasoconstriction and direct (possibly free-radical injury) play a role. Some reduction of contrast nephropathy can be accomplished by minimizing contrast volume (194). Iso-osmolar or low-osmolar contrast agents are preferred. One report suggests the volume threshold can be estimated by using the ratio of contrast volume to creatinine clearance. Nephrotoxicity is more likely when the contrast volume/creatinine clearance ratio exceeds 3.7:1 (195).

Biplane coronary angiography should be utilized to reduce the contrast load if the equipment is available. Avoiding unnecessary "test" or "puff" injections, eliminating ventriculography and aortography, and taking the least number of angiograms can limit contrast volume. Careful fluoroscopy setup to reduce panning and use of a higher frame rate may also reduce the volume of each contrast injection per image acquisition. Performing ad hoc interventions and combined coronary and peripheral procedures should be carefully reviewed. There should be a low threshold to have the patient return for a repeat procedure to avoid large volumes of contrast during a single procedure. A discussion of maximum contrast limits should be part of the initial "time-out" before the procedure. N-acetylcysteine has been extensively studied, but the latest randomized data from the Acetylcysteine for Contrast-Induced Nephropathy trial evaluated the effectiveness using large doses of acetylcysteine in 2,308 patients before and after the use of contrast media, and the authors found no evidence for prevention of CIN (196). Its use is no longer recommended. Vitamin C has also been used with some favorable effect to reduce free-radical injury, as has sodium bicarbonate. None have been consistently useful, though, and none proven in any large randomized trial. Fenoldapam and theophylline, agents used to reduce the vasoconstrictive component, have not been found effective (192), and the use of gadolinium is not recommended for coronary angiography but has been used in renal and peripheral angiography (197).

Prehydration and posthydration with normal saline or sodium bicarbonate has been the gold standard for reducing the incidence of contrast nephropathy and the only modality

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that has consistently been shown to be of some value. This is generally easy to accomplish in an inpatient setting; however, it is more difficult in an outpatient setting. The use of sodium bicarbonate infusion 1 hour prior to and 6 hours after angiography has been shown to decrease contrast nephropathy in some studies and might have an advantage compared to normal saline hydration, though the advantage is very modest (198).

Continuous veno-venous hemofiltration and hemodialysis have been tested and the benefits remain unclear. It may be considered in the very high-risk patients (199). There are also data suggesting an advantage with the use of statins (200) and the use of iso-osmolar contrast (201). However, the latest data do not suggest an advantage of iso-osmolar contrast over low-osmolar agents (202). Guidelines to reduce contrast nephrotoxicity have been developed by SCAI (203) and the Contrast Nephropathy Working Group that met in 2006 (204). At this juncture, the only recommendations the writing committee suggests are outlined in Table 20. These are consistent with the "2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention" as well (158).

4.2.4. Other Contrast Media Reactions

Identifying patients at risk for a reaction to iodinated contrast remains a cornerstone of the preprocedure history. Besides the nephrotoxicity issues noted above, contrast media reactions include 1) acute hypersensitivity (anaphylactoid reactions—non-IgE mediated); 2) delayed hypersensitivity (IgE mediated and often resulting in rash or fever up to 48 hours after the procedure); 3) acute hemodynamic or electrophysiological consequences during the procedure (now less common with low-osmolar and iso-osmolar contrast); 4) possible hypercoagulation (e.g., stressing the importance of minimizing the contrast media–blood interface in syringes); and 5) hyperthyroidism (the only real side effect due to the iodine in the contrast media—seen usually in elderly patients with history of thyroid nodules).

A previous anaphylactoid reaction and a history of atopic conditions such as asthma are the most significant risk factors for acute hypersensitivity reactions (205). It should be recognized that contrast reactions can be idiosyncratic so that a history of any past reaction (regardless of subsequent reactions) should be treated. Patients with other food or medication allergies, those of an advanced age, and women are at higher risk. It has never been shown that patients with a history of shellfish allergy have a higher risk of a reaction to radiocontrast media and, in fact, the allergen is actually in the tropomysin protein and appears unrelated to iodine. Pre-medication is recommended for those with a strong atopic history and for patients with a known prior allergy to contrast. It appears that anaphylactoid reactions are much more common when contrast is administered in the venous rather than the arterial circulation, so these types of potentially life-threatening reactions are much more common with computed tomography (CT) angiography or IV pyelography use than during cardiac angiography. Premedication regimens with H2 blockers and steroids are recommended for the highest-risk atopic patients, particularly those with known prior reaction. Current options include giving 50 mg oral prednisone 13 hours, 7 hours, and 1 hour prior to the procedure or 200 mg IV hydrocortisone 2 hours before the cardiac catheterization with or without H2 blockers (205). Anaphylaxis results in profound vasodilation, bronchospasm, and circulatory collapse. Treatment not only includes epinephrine but requires circulatory support with large doses of IV fluids and other inotropic agents.

The importance of recognizing delayed hypersensitivity due to contrast is important to avoid stopping appropriate medications, such as clopidogrel, on the assumption the transient fever and rash may be due to a new medication started after the procedure rather than simply due to the contrast media.

Table 20. Suggested Protocol to Reduce the Incidence of Contrast-Associated Nephropathy Following Cardiac Catheterization

1. Identify risks
   a. Highest risk—eGFR <60 mL/min/1.73 m²
   b. Diabetes
2. Manage medications
   a. Hold nephrotoxic drugs (e.g., NSAIDS)
3. Manage intravascular volume
   a. Hydrate with either normal saline or sodium bicarbonate (either acceptable)
   b. Hydrate with 1.0 to 1.5 mL/kg/min for 3 to 12 hours before and 6 to 12 hours post
4. Radiographic contrast
   a. Minimize contrast volume
   b. Use either low-osmolar or iso-osmolar contrast
5. Follow-up data: obtain 48-hour creatinine

eGFR = estimated glomerular filtration rate; NSAIDS = nonsteroidal anti-inflammatory drugs.

4.2.5. Diabetes Mellitus

Patients with diabetes mellitus require precautions to prevent hypoglycemia. Insulin doses the night before are generally cut in half, and in the morning oral hypoglycemic and insulin are held. These patients should be scheduled early in the morning to avoid prolonged fasting. Blood glucose levels should be checked upon arrival in the precatheterization staging area and treated accordingly. Patients with normal renal function taking metformin are instructed to not take the metformin the day of the procedure and not to restart it for at least 48 hours afterwards and until an assurance of no contrast-related nephropathy (206). The danger of metformin and contrast media is the clinical syndrome of severe and persistent lactic acidosis. This syndrome invariably occurs in patients with renal insufficiency, and metformin should not be used in this group anyway. Because diabetes mellitus itself is an independent

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risk factor for contrast nephropathy, the current recommendations are to stop the metformin the day of the procedure and not resume (usually 48 hours) until a normal creatinine level has been documented (see Table 20).

4.2.6. Sedatives and Relaxants

Conscious sedation is most commonly used for the majority of procedures performed in the catheterization laboratory. Appropriate sedation is imperative and ensures patient comfort. Pre-medication with oral diphenhydramine and diazepam is common. IV sedative hypnotics and analgesic regimens vary. A combination of midazolam and fentanyl citrate is very popular. IV morphine, diphenhydramine, and hydromorphone hydrochloride are also used. Conscious sedation protocols must be strictly adhered to and excessive sedation should be avoided. All patients should have baseline blood pressure (BP), oxygen saturation, and heart rate and rhythm documented. These vital signs must be monitored closely throughout the procedure and in recovery. Reversal agents should be readily accessible in the laboratory.

General anesthesia is often used if transesophageal echocardiography is required for a procedure. Many patients undergoing valvuloplasty, percutaneous aortic or mitral valve procedures, and ASD and PFO closures are managed, with the assistance of an anesthesiologist, under general anesthesia.

4.2.7. Heparin-Induced Antibodies

Great precautions must be taken in patients with known antibodies to heparin. Heparinized flush is not to be used in the manifold system. Therefore, great care must be taken between catheter exchanges with wiping wires thoroughly, and extra attention to flushing the sheaths and catheters must be performed. If patients require anticoagulation, then direct thrombin inhibitors are used.

4.2.8. Pregnant Patients

Radiation exposure should be avoided as much as possible in pregnant patients. The concept of ALARA (As Low As Reasonably Achievable) in regard to radiation dose should always be followed. Despite the fact that direct x-ray targeting during the procedure mostly affects the upper torso, Compton scattering within the body results in indirect x-ray exposure to the developing fetus. Efforts to minimize x-ray dose should also include using low fluoroscopy settings or in-laboratory echocardiography rather than cineangiography, limiting total exposure time, using reduced framing rates, using the minimum number of contrast injections, and avoiding angulated or magnified views when possible. A lead apron between the x-ray tube and abdomen is recommended. The fetus is less vulnerable during the first 2 weeks of gestation but becomes especially vulnerable during the duration of the first trimester (206a).

4.3. Access Site (Femoral, Radial, Brachial)

The most common site for percutaneous arterial access for both diagnostic and interventional cardiac procedures is the common femoral artery. Localization of the appropriate access insertion using the radiographic femoral head as a marker has been popular and found helpful. The sheath entry should be located within the femoral artery at the medial third of the femoral head (207). The radial artery approach is gaining more and more popularity, especially for obese patients and outpatients. The use of the radial approach in the United States remains much lower than many other countries, despite fewer bleeding complications using the radial approach compared with the femoral artery approach in the elderly and those undergoing PCI for ACS (208). Brachial access is rarely used. Brachial cut-downs are, at this point, of historical interest only. Femoral cut-downs for large abdominal aortic aneurysm stent grafts or for percutaneous aortic valve replacement are still required at times. In cases where greater wound exposure is necessary, such as in pacemaker implantation or femoral cut-downs, a full surgical sterile technique should be used. A vascular sheath should be used to minimize vascular trauma, especially when multiple catheter changes are anticipated. Each percutaneous vascular site (femoral, brachial, radial, subclavian, or internal jugular) requires that the operator have specialized training. Although some aspects of percutaneous vascular access are similar for all sites, certain issues (e.g., compression and/or administration of heparin or intravascular verapamil or nitroglycerin) are unique to each site. If venous access is required, in most cases it should be performed using the femoral vein or the internal jugular vein. The use of ultrasound to localize and facilitate cannulation, particularly of the internal jugular and subclavian veins has become routine in many institutions. Multiple venous catheters can be safely inserted in the same femoral vein; multiple arterial catheters require separate arterial access sites. In radial artery access cases, it is routine and acceptable to obtain venous access via the femoral vein. Strict sterile procedures should be followed at each site.

4.4. During the Procedure

4.4.1. Medications

Adequate hydration, appropriate for the patient's underlying condition, is important before the procedure. Drugs, such as long-acting phosphodiesterase inhibitors (e.g., tadalafil) should be held in case nitrates would be needed. Chlorhexadine is now the preferred prep solution over the use of betadine.

Multiple medications can be administered during the catheterization procedure. These are related to sedation, procedural performance, and BP or heart rate changes. Anticoagulants, antiplatelet adjuncts, and emergency-related medications may also be used. Vasoactive medications for either high or low BP may be required depending on the clinical situation. The selection of the appropriate agent should be based on the

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individual patient, clinical setting, and etiology of the abnormal hemodynamic state. Hypertension is common, in part because of the heightened adrenergic tone from anxiety, as well as from the underlying condition. Treating high BP during a procedure (after adequate sedation) can be accomplished with IV boluses of hydralazine, labetalol, nicardipine, or metoprolol. Nitroprusside and nitroglycerin continuous infusions may also be of benefit. Caution should be exercised in patients with certain conditions, such as severe pulmonary hypertension or critical aortic stenosis. Hypotension must be diagnosed and managed aggressively, and management is critically dependent on the etiology. Vagal episodes are characterized by an inappropriately low heart rate in association with hypotension, whereas other causes of hypotension are generally associated with a high compensatory heart rate. IV fluid boluses with normal saline are often first-line therapy for hypotension from any cause. Patients are commonly dehydrated from having food and drink withheld for many hours prior to the procedure. If volume resuscitation is unsuccessful, dopamine, norepinephrine, and phenylephrine infusions can be started to maintain adequate BP. Specific conditions that need to be considered and treated include vagal reaction, hemorrhage, allergic reaction (anaphylaxis), cardiac tamponade, or cardiogenic shock.

During both diagnostic angiography and percutaneous coronary interventions, a variety of vasodilator agents may be required. These agents include intracoronary nitroglycerin, nitroprusside, verapamil, nicardapine, adenosine, and other vasodilators. There is a significant variation regarding the use of intracoronary vasodilators among hospitals. Cardiac catheterization labs should have standard medication doses and procedures regarding the use of these medications so that all personnel are familiar with the most commonly used and requested vasodilators in their region.

4.4.2. Sterile Techniques

Infection is rare after invasive cardiovascular procedures. The Occupational Safety and Health Administration recommends that preparation of all patients include the removal of hair from the site (electric clippers are preferred over typical razor-blade shaving to avoid skin abrasion), application of antiseptic to the skin, and the use of sterile drapes. Sterile covers for the image intensifier and protective operator shielding should be placed when these are used over or next to the sterile field. Systemic antibiotics are not required, although some operators use them with large-vessel noncoronary stents or other devices that will be left in the body. A generally sterile environment should be maintained during the procedure. Disposal of all materials should also follow local safety and infection control guidelines.

Although the strict sterile techniques used in the operating room are not necessary for most cardiac catheterization laboratory procedures, operators should use appropriate hand washing and wear a sterile gown and gloves. Personnel should wear hospital-based scrub attire. Occupational and Health Safety Guidelines (180) and Usual Precaution Guidelines suggest that masks, an eye shield, and protective caps should be worn during cardiac catheterization. These protect from accidental blood exposure to the operator as well as help preserve the sterile access field. Strict adherence to aseptic techniques are mandatory when devices are being implanted, such as those used in the treatment of structural heart disease.

4.4.3. Technical Issues

4.4.3.1. CORONARY ANGIOGRAPHY

The safe injection of a contrast agent into coronary arteries is predicated on the coaxial placement of the coronary catheter in the coronary ostium and the correct positioning of the tip of the catheter in the coronary artery. Assurance of an air-free connection between the contrast manifold port or syringe and the catheter must be established. To avoid red blood cell clumping and potential thrombus formation, the syringes should be flushed clear of blood. Careful replenishment of contrast in the injection syringe and the maintenance of an air-free environment is the responsibility of the operating cardiologist. Most invasive cardiologists inject the coronary arteries manually themselves or use support personnel to perform the injection. Specialized mechanical injectors can be used with appropriate equipment and training. Coronary injections should include a tiny test dose of contrast once the catheter tip is in position. This ensures that the catheter is not subintimal or under a plaque that might result in an extensive coronary artery dissection if a full injection of contrast were administered. Monitoring catheter tip pressure is obligatory. A "flush" injection into the respective coronary sinus may help define ostial coronary disease.

It remains the responsibility of the individual invasive cardiologist to ascertain whether nonphysician personnel or power injectors are capable of administering contrast into the coronary arteries. Physician extenders should never be primary operators. They can be secondary operators but should always be viewed as extensions of the primary operator's hands, with the responsibility for safety ultimately residing with the invasive cardiologist.

In the majority of cases, the use of single-plane x-ray imaging is satisfactory, recognizing that most laboratories do not have biplane capabilities. It is desirable for laboratories contemplating angiographic evaluation of patients with congenital heart disease, however, to have biplane capabilities. A biplane option also is useful to keep contrast volume at a minimum in patients with renal failure. In the case of left ventriculography in patients with coronary artery disease, an appropriate view should be selected to gain the most information regarding LV function. This may include a left anterior oblique view if left circumflex disease is discovered, and there is interest in observing lateral ventricular wall motion. The use of noninvasive modalities to assess wall motion and ejection fraction prior to the cathe-

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terization procedure has reduced the frequency with which LV angiography is now required.

The use of multiple orthogonal views of the coronary arteries is of obvious importance, as coronary lesions are defined by "worst view." The invasive cardiologist must be certain that appropriate information is obtained and recorded in order to make an accurate diagnosis and to determine suitability for PCI or CABG. Each segment of the coronary artery should be seen in at least 2 orthogonal views. Although it may be helpful and expeditious to have routine views performed on each coronary study, additional views should be obtained if the anatomy is not clearly presented or there are overlapping structures. The knowledge and application of additional views is the hallmark of excellence for angiographers.

In the case of right-heart and pulmonary angiography, it is important that the appropriate views be obtained to demonstrate the anatomy being interrogated. Because most cardiac catheterization laboratories have only a maximal 9-inch image intensifier, multiple images of the lung are usually required to interrogate the entire lung fields. If the aorta is to be investigated, cine aortography can be performed in the catheterization laboratory to ascertain the size of the aorta (in cases of aortic stenosis with anticipated aortic valve replacement) and to visualize the arch vessels. If detailed examination of the lung and aorta and arch vessels is required, it is often better to use a system with a larger-size image intensifier field of view designed for that purpose. It should be recognized that angiography in the catheterization laboratory is limited by 2-dimensional imaging, hence complete evaluation of the aorta and pulmonary arteries (PAs) may be difficult, and the potential use of alternative imaging modalities (i.e., CT or magnetic resonance imaging [MRI]) should be considered if clinically important.

4.4.3.2. VENTRICULOGRAPHY AND VASCULAR ANGIOGRAPHY

Power injectors are recommended for optimal opacification and visualization during ventriculography and large vessel angiography, such as aortography. Hand injection can be performed for selective subclavian, carotid, or renal angiography. Using a pigtail catheter appropriately placed in the mid–left ventricle usually avoids or minimizes inducing premature ventricular contractions or ventricular tachycardia. End-hole catheters should generally not be used for ventriculography power injections because of the risk of perforation or an intramyocardial contrast injection. At times, visualization of the pulmonary veins can be obtained by wedge angiograms (the injection of contrast into a pulmonary wedged balloon catheter then release of the balloon to observe the pulmonary veins during the washout period).

4.4.3.3. PRESSURE MEASUREMENT

During a routine left heart and coronary arterial catheterization, a preprocedural and postprocedural aortic pressure tracing, as well as the recording of the LV systolic and end-diastolic pressure should be obtained. Some laboratories find it useful to repeat the LV pressure after the left ventriculogram to report the LV end-diastolic pressure after contrast, although the clinical value of this exercise is questionable. During right-heart catheterization, the acquisition of right atrial (RA), right ventricular (RV), PA, and PA wedge tracings is routine, and sufficiently long strips of phasic recordings should be obtained to account for respiratory variation. Obtaining the end-expiratory pressure helps reduce the respiratory variation, although some patients are unable to hold their breath without performing a Valsalva maneuver, and thus the pressures are influenced by the resultant high intrathoracic pressure generated. The mean pressure in atrial and pulmonary chambers should be obtained over 10 beats to allow for correction of respiratory changes. A 10-beat average should also be reported in patients having atrial fibrillation.

If pullback pressures are used to measure valvular gradients, the patient should be in as steady a state as possible to diminish the likelihood of any respiratory variation between pressure measurements from 1 chamber to another. Simultaneous pressures to gauge gradients across valvular lesions are preferred to pullback pressures when feasible. Care should be taken if the femoral artery pressure is used as a substitute for aortic pressure in younger patients, as normally the femoral pressure is higher than the central aortic. If femoral pressure is to be used as the aortic pressure surrogate, documentation should be obtained that the pressures between the 2 sites are similar. Newer dual lumen catheters should generally be used for the measurement of aortic or pulmonic gradients.

On occasion, the pulmonary capillary wedge pressure will also not correspond well with the LA pressure (especially after mitral valve replacement), and a transseptal puncture with simultaneous measurement of the LA and LV pressure may be required for an accurate transmitral gradient. With the improvement in noninvasive assessment of valvular gradients, it is not uncommon that cardiac catheterization hemodynamics focus only on the pulmonary pressure, outputs and coronary anatomy and the valvular gradients are not directly assessed. Pressure wires are of small enough caliber that they can be used to cross even mechanical prosthetic valves safely.

4.4.3.3.1. HEMODYNAMICS. The importance of high-quality pressure measurements has unfortunately been deemphasized in most laboratory facilities. The availability of numerous types of hemodynamic equipment precludes detailed description here. Appropriate filtering of the pressure signal is important for adequate interpretation of individual waveforms. Careful balancing and zeroing of the system at the level of the mid-atria are necessary for each procedure. Often, simultaneous pressures are important, and frequently higher-speed recordings (100 mm/s) are needed to obtain adequate data for waveform analysis. It is the responsibility of the laboratory director to ensure that the equipment available produces the information desired. Detailed knowl-

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edge of each laboratory's transducers and recorders should be part of the orientation and a requirement for credentialing of invasive cardiologists in a particular catheterization laboratory. It is each invasive cardiologist's responsibility to direct the acquisition of appropriate pressures so that key hemodynamic data are obtained and not overlooked. Invasive cardiologists using the laboratory should review the quality of the pressure recordings obtained, and any deficiency should be corrected.

Accurate hemodynamic measurements aid in sorting out constrictive pericarditis from restrictive cardiomyopathy. In either instance, it is important that simultaneous measures of both LV and RV pressure during respiration are recorded to assess for ventricular interdependence (209). In patients with dyspnea, both a superior vena cava and PA oxygen saturation may be useful to exclude an unanticipated left-to-right shunt.

4.4.3.3.2. INTRACORONARY HEMODYNAMICS. Measuring the pressure gradient across a lesion in a coronary vessel may provide information regarding the hemodynamic significance of that lesion (210). Multiple studies have confirmed the use of pressure wires to assess pressure gradients across an intermediate angiographic stenosis (211–213). This information can now be used to guide whether or not stents should be placed (214,215). These studies have shown excellent outcomes in patients who have had insignificant gradients who did not have stents placed (216). The fractional flow reserve (FFR) is measured after the pressure sensor tip wire is placed distal to the lesion in question. Adenosine is administered intravenously or intracoronary to dilate the microvascular coronary circulation. An FFR measurement of >0.75 was initially used as the standard cut off to defer stent placement. The latest studies suggest an FFR >0.80 can be used with excellent long-term outcomes (212,213).

4.4.3.4. CARDIAC OUTPUT AND VASCULAR RESISTANCE MEASUREMENTS

Cardiac output measurements commonly used in the cardiac catheterization laboratory include the use of indicator dilution methods (typically thermodilution), the Fick method (use of pulmonary and arterial blood oxygen saturations and oxygen consumption), angiographic methods, and impedance estimates. Indocyanine green dye is no longer used as the indicator. As a consequence, most cardiac catheterization laboratories rely on either thermodilution methods or the Fick method for determination of cardiac outputs. Thermodilution methods use a thermistor on the end of a right-heart catheter. As a proximally injected bolus of saline traverses past the thermistor, the temperature change results in a curve similar to that observed with dye dilution methodology. Analysis of this curve allows determination of cardiac output by a variety of methods. Accurate measurement requires a concentrated bolus of saline. Thus, tricuspid or pulmonary insufficiency may significantly alter the results obtained. Fick cardiac outputs require measurement of oxygen saturation, hemoglobin, and oxygen consumption. Oxygen consumption is the most difficult variable to obtain. Most laboratories use an assumed value from an established reference table or an established formula. Direct measurement of oxygen consumption provides a more accurate assessment using a variety of instruments, but the unstable nature of some of these devices and the expense and time involved have discouraged direct oxygen consumption measurements in most catheterization laboratories. Angiographic cardiac output using area-length assumptions or Simpson's rule provides LV volumetric data useful for estimating valvular stenosis severity in the presence of valvular regurgitation (assuming only 1 left-sided valve demonstrates regurgitation). The regurgitant fraction can also be derived. Angiographic methods suffer from vagaries in the accuracy of shape assumptions and from the determination of the requisite correction factors needed because of x-ray divergence. Whatever method is used for determining cardiac output should be well understood by all personnel. Each cardiac output method has limitations and errors that can be minimized with careful attention to the inherent vagaries of each technique. Similar data are often obtained now from noninvasive methods.

Vascular resistance calculations require knowledge of the mean pressure before and after the resistance of interest and a measure of the flow through the area. Thus, for pulmonary vascular resistance, the pulmonary blood flow and the mean PA and the mean pulmonary capillary wedge pressure (or LA pressure if no pulmonary venous disease) must be recorded.

4.4.3.5. SHUNT MEASUREMENT

Important information regarding physiology of congenital heart disease is gathered from measurements of intracardiac shunts. Both right-to-left and left-to-right shunts must be able to be quantitated during the catheterization. Because of the need to determine intracardiac shunting, oxygen saturation samples are drawn from many sites rather than simply from the PA for mixed venous oxygen level and from the systemic artery for arterial oxygen level. The availability of oxygen saturation measurements and arterial blood gas determinations within the catheterization laboratory is useful for the efficient performance of the typical congenital cardiac catheterization. The availability of blood gas measurements also allows for the inclusion of dissolved oxygen in the determination of oxygen content.

4.4.4. Other Diagnostic and Therapeutic Procedures in the Cardiac Catheterization Laboratory

4.4.4.1. PULMONARY VASODILATORS IN THE EVALUATION OF PULMONARY HYPERTENSION

The World Health Organization classifies pulmonary hypertension into 4 categories (217). Pulmonary arterial hypertension, or "idiopathic" pulmonary hypertension, is associated with a normal pulmonary capillary wedge pressure and elevated pulmonary vascular resistance. The normal pulmonary pressure is generally considered to be 25/10 mm

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Hg with a mean of 15 mm Hg (range from 12 to 16 mm Hg). Pulmonary hypertension is considered present when the mean PA pressure is >25 mm Hg at rest or >30 mm Hg with exercise. The pathophysiology of pulmonary hypertension involves a reduction of flow through the lungs due to pulmonary vascular remodeling and vasoconstriction. Remodeling involves endothelial, smooth muscle, and fibroblast cell types, as well as inflammatory cells and platelets (218). Vasospasm plays a greater role early in the disease, and its presence can be assessed in the cardiac catheterization laboratory using 100% oxygen, adenosine, and epoprostenol and inhaled nitric oxide (usually 40 to 80 ppm). A 10 mm Hg fall in mean PA pressure and a final mean PA pressure of <40 mm Hg is considered a positive vasodilator response. Therapy for pulmonary arterial hypertension is then dependent upon the response to these vasoactive agents (219). In general, responders are treated with calcium channel blockers and phosphodiesterase inhibitors whereas nonresponders are considered candidates for endothelial-receptor blockers and prostacyclin analogs. The clinical functional class also plays a role in the aggressiveness of therapy (219).

Response to vasodilators has also been used to decide on surgical suitability for patients with congenital heart disease or transplantation. In those instances, the change in the resistance in the pulmonary circulation (Rp) over the systemic resistance (Rs) is often used, with high risk associated with an Rp/Rs ratio >0.7. One study shows the achievement of an Rp/Rs ratio of <0.33 and a 20% decrease in the ratio with vasodilators allowed for safe surgical intervention (220).

Of note, in pediatric catheterization laboratories, the pulmonary vascular resistance is calculated using the cardiac index rather than the cardiac output alone. Despite this correction making sense, the practice has unfortunately never been adopted in the adult cardiac catheterization laboratory.

4.4.4.2. VASODILATOR OR INOTROPIC STRESS TESTING IN AORTIC STENOSIS

Patients with aortic stenosis (AS) and depressed ejection fraction may have low valvular gradients despite significant AS by aortic valve area (<1.0 cm^2). Whether to replace the aortic valve in this situation is often a difficult clinical question. When data from noninvasive studies using dobutamine are not available or are equivocal, the use of either dobutamine or nitroprusside during cardiac catheterization to assess the response of the aortic valve area, gradient, and stroke volume has been used to help decide whether the stenosis is an actual or a pseudo-stenosis due to low output. An increase in the aortic valve area and a little increase in the aortic valve gradient suggest the primary problem is myocardial and not valvular stenosis. Graded doses of dobutamine (5 mg/kg/min, 10 mg/kg/min, 20 mg/kg/min) to test whether there is "contractile reserve"—a >20% increase in stroke volume—have been used to separate those who are candidates for surgical intervention from those who are believed to be too high risk (221). Nitroprusside may be used to improve cardiac output in patients with atrial fibrillation to help prevent the rapid ventricular response often seen with the administration of dobutamine. Patients in atrial fibrillation with a wide variability in the ventricular response are best studied with RV pacing greater than baseline to control the heart rate before and after the infusion. There are data that suggest the use of brain naturietic peptide (BNP) may influence whether the results truly separate the operable candidate out from the inoperable candidate, with poor outcomes regardless of the result in those with BNP levels >550 pg/mL (222). In addition, using contemporary surgical methods, some have demonstrated excellent surgical results despite failure to demonstrate any contractile reserve in this patient population (223). The threshold for therapy in these difficult patients may also be changing with the availability of the percutaneous aortic valve replacement procedure.

4.4.4.3. TRANSSEPTAL CATHETERIZATION

Transseptal catheterization is performed from the femoral artery by placing a long, pointed, sheathed introducer with a hollow Brockenbrough needle first into the superior vena cava then rotating into the foramen ovale. The stiff system is "locked" into the foramen ovale and pressure applied to the foramen ovale. In about a third of cases, the system will push open the septum primum in the foramen ovale. If the system does not cross, then the needle is extended just past the introducer tip and the interatrial septum is punctured. A change in the waveform reflecting LA pressure should be evident before advancing the catheter and sheath. Once LA pressure is obtained, the needle is withdrawn and a guidewire inserted into the LA. The sheath and transducer are advanced into the LA and once inside, the introducer is withdrawn and the sheath remains. Catheters can then be inserted through the sheath into the LA. Transseptal catheterization to obtain LA pressures is primarily used in the adult catheterization laboratory during the performance of balloon mitral valvuloplasty or mitral repair using the eValve mitral clip. It is required to perform stenting of pulmonary vein stenosis or in the EP laboratory during atrial fibrillation ablation. Hemodynamically, the LA/LV pressure gradient may be different from the pulmonary capillary wedge/LV pressure gradient, especially in patients with mitral valve replacement, and it is useful to document the difference. Entry into the LA allows entry into the LV when crossing the aortic valve retrograde is not feasible or desirable and LV pressure is necessary. Percutaneous aortic valvuloplasty or valve replacement can be performed in this manner. In congenital heart disease, at times the only access to the pulmonary arterial pressure is retrograde through the pulmonary veins and both hemodynamics and pulmonary angiography can be performed via a reverse wedge in most patients when this is the case. The procedure is also required for the placement of an LA appendage occluder. Complications related to transseptal puncture include perforation of

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the RA or LA with subsequent pericardial effusion or tamponade, pain perception by the patient while crossing the septum, vagal stimulation, or inadvertent entry into the ascending aorta. Care must be taken to avoid air entry into the LA or thrombus formation. Recently, the addition of intracardiac echocardiography/Doppler methods can be used to help guide the transseptal procedure.

4.4.4.4. LV PUNCTURE

There is essentially no longer any indication for percutaneous LV puncture to assess the LV pressure. Echocardiography/Doppler methods and MRI are adequate to evaluate combined mitral disease and a mechanical aortic prosthesis. Fine pressure wires have also been used to cross even bileaflet mechanical aortic valves or the Starr-Edwards aortic prosthesis with little risk. Surgical LV puncture may be used for the placement of the percutaneous aortic valve and to stabilize guidewires when attempting to plug paravalvular leaks in a hybrid room situation.

4.5. Therapeutic Interventions for Hemodynamic Compromise

4.5.1. Improving Cardiac Output

4.5.1.1. INTRA-AORTIC BALLOON PUMP

The intra-aortic balloon pump (IABP) improves cardiac output, improves myocardial perfusion and reduces myocardial demand by maintaining diastolic pressure and reducing afterload. This is because maintaining diastolic pressure improves coronary and systemic perfusion, whereas the afterload reduction reduces myocardial demand. It is particularly useful in situations of hypotension due to low cardiac output and in patients with refractory unstable angina. The intra-aortic balloon pump is a thin synthetic balloon positioned within the descending thoracic aortic about 2 cm below the normal takeoff of the left subclavian artery. It is inflated with helium during ventricular diastole and deflated during ventricular systole. Cyclic obstruction of the aorta in this manner increases diastolic aortic pressure and helps maintain coronary perfusion (primarily an early diastolic phenomenon, especially in the left coronary). Systolic deflation of the balloon unobstructs the aorta, and cardiac ejection occurs against a markedly lower aortic impedance and peripheral vascular resistance, improving stroke volume. The physiology is ineffective if significant aortic regurgitation, excessive tachycardia or other arrhythmias are present. The latest meta-analysis of the use of IABP therapy in STEMI suggests, however, that there was no impact on mortality (224) despite short-term hemodynamic improvement.

Balloon placement is not feasible unless the aortoiliac vessel lumens are large enough (>7 mm) to accommodate the device. Aortic dissection and extreme tortuosity may not allow for the IABP placement. Because the device is placed in the femoral artery and aorta, it could obstruct flow to the limbs, and lead to limb ischemia and even a compartment syndrome. Renal failure can occur if placed too low in the aorta over the ostia of the renal arteries. Other possible complications include cerebral embolism during insertion, infection, dissection, or perforation of the aorta or iliac artery, and hemorrhage into the mediastinum. The balloon may fail to deflate or may rupture, requiring surgical removal. Showering of aortic atherosclerosis particles can lead to leg ischemia from cholesterol embolization or from thrombi originating on the balloon's surface—this is especially a risk during balloon removal. Mechanical failure of the balloon may require vascular surgery for removal.

4.5.1.2. OTHER CATHETER DEVICES TO IMPROVE CARDIAC OUTPUT

Several newer percutaneous devices have become available to augment cardiac output during high-risk cardiac catheterization. These include the Impella device (Abiomed, Inc., Danvers, MA) and the TandemHeart (Cardiac Assist, Pittsburg, PA). Both have been used in a variety of situations. The Impella device is a 12-F rotary micropump catheter able to produce continuous flow up to 2.5 L/min. It is placed across the aortic valve and augments LV output directly into the aorta. The TandemHeart is placed into the LA via a transseptal puncture using a 21-F venous catheter. It pulls oxygenated blood from the LA and returns it to the femoral artery via a 15-F catheter. It is capable of continuous flows up to 5 L/min. Early studies comparing the results with that of an IABP suggest that the acute hemodynamics are superior, but there is no difference in early survival (225). ECMO can also be used to provide both cardiac and respiratory support via either veno-veno or veno-arterial cannulation. The role of all these types of devices to augment cardiac function during cardiac catheterization remains to be further defined.

4.6. Pericardiocentesis

The performance of pericardiocentesis is a critical skill that every invasive cardiologist should acquire. Although the methods may vary, the importance of being able to remove pericardial fluid in a patient who is experiencing tamponade physiology is critical, especially when the fluid has resulted from a complication of a catheterization procedure. All invasive cardiologists should be able to recognize the hemodynamics associated with cardiac tamponade, including equalization of the end-diastolic RA, RV, and LV pressures, and usually an associated paradoxical pulse (a fall in the pulse pressure and systolic central BP with inspiration). Emergency echocardiography is critical to define the effusion and assess for RA collapse and RV diastolic collapse. Most acute pericardial effusions are not large, and the use of echo-guided aspiration is generally preferred. A defined sterile pericardiocentesis package should be part of any cardiac catheterization laboratory so that there is no scrambling for the items required to perform an emergency tap of the pericardium. The director of the cardiac catheterization laboratory should define what equipment is in the package and ensure it is available at all times within the laboratory area. All operators should be familiar with the contents of this package for any

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given institution and should understand how to use the equipment if the need arises.

4.7. Coronary Artery Catheter Imaging Devices

A variety of diagnostic and some therapeutic catheters are now either available or are being tested for use within the coronaries during cardiac catheterization. IVUS devices have the longest track record, and a consensus document from the ACCF still provides important information on the proper use of these tools (226). Both mechanical and phased-array catheters are available. IVUS studies have provided information regarding the unreliability of angiography to define lesion severity. IVUS studies also provide valuable information at times on plaque composition and remodeling, stenosis severity (especially in left main disease), the satisfactory deployment of intracoronary stents, and in cardiac transplant vasculopathy. It has also been a valuable tool to assess plaque burden over time in some clinical trials, to identify thrombus, and to help assess bifurcation lesions. The use of IVUS catheters in any laboratory setting is undoubtedly dependent on the skills and the enthusiasm of the operators for these procedures. Its use is not without a small risk; an early European registry found a 1.1% complication rate due to spasm, dissection, or wire entrapment (227). Competence in using these devices holds sway over any established guidelines, and all of these devices have a learning curve, not only in their placement, but more importantly in the interpretation of the images and then appropriately altering therapy based on the results.

Newer coronary imaging devices are being investigated including such devices as forward looking IVUS, plaque imaging with virtual histology, and tissue ingrowth assessment using optical coherence tomography, for instance. The proper use of all of these novel devices requires the ongoing QI program to be involved so that proper technique is followed and all complications are reviewed and discussed. If the device is still under investigation, it is vital that all local policies regarding investigational devices be followed, and appropriate oversight by the institutional review board at the facility be established.

4.7.1. Intracardiac Ultrasound and Doppler

Intracardiac echo cardiography/Doppler is now being used to visualize the atrial septum during transseptal catheterization to facilitate left-sided EP ablation studies, mitral valvuloplasty, appendage occluder implantations, and ASD or PFO occlude positioning. The devices have also been used in complex myocardial biopsy procedures. Doppler methods help define flow and are of particular value in balloon sizing of ASD defects to detect when total occlusion has occurred. There are no data specifically addressing the incidence of complications related to these devices, but the complication rate is acknowledged to be low. Known complications include cardiac tamponade from perforation, thrombus formation in the sheath, and air emboli. In the face of no established guideline, competence assessment is left to the QI process with oversight by the director of the cardiac catheterization laboratory. Similar to all the procedural methods that are used in only a small number of patients, there is a learning curve, and there needs to be a careful review of any complications associated with the use of intracardiac ultrasound.

5. Postprocedural Issues

5.1. Vascular Hemostasis

The most frequent complication of coronary angiography and coronary interventions occurs at the vascular access site. Although careful vascular entry is essential in reducing such complications, vascular hemostasis obtained after the procedure is a crucial component of the procedure. Methods to achieve hemostasis include manual compression, mechanical compression, percutaneous vascular suture, and staples or clips, vascular plugs, and topical hemostatic pads.

5.1.1. Routine

In cases of femoral puncture, where a vascular closure device is not used, it should be routine to assess the ACT value before access-site compression following interventional procedures whenever heparin has been used. Once the ACT has returned to near normal (<180 s), sheaths can be removed and manual pressure or mechanical pressure clamps applied. If lytic agents have been used, prolonged vascular compression may be necessary. The size of the sheath roughly determines the length most patients should be confined to bed after manual compression. A minimum of 1 to 2 hours after the procedure for 4- to 5-F sheaths, whereas 2 to 4 hours for 6- to 8-F sheaths is common practice. The use of the radial or brachial artery approach obviates the need for prolonged bed rest, but hemostasis must still be achieved by manual or device pressure. All patients should have the puncture site auscultated before discharge and, if a mass is palpated and/or a new bruit audible, then a vascular ultrasound should be obtained to exclude a vascular pseudoaneurysm or fistula that may need repair. Most pseudoaneurysms are now closed with percutaneous thrombin.

5.1.2. Use of Vascular Closure Devices

The last decade has seen revolutionary changes in the development of vascular closure devices. Local femoral angiography is generally performed to assess puncture site, size of common femoral artery, and extent of atherosclerosis and calcification in order to properly place these devices. Although they do not decrease all complications compared with manual compression, they have become the standard of care in many cardiac catheterization laboratories because of the convenience and economic pressures to reduce length of stay. Whether they are being placed by the invasive cardiologist or a physician extender, adequate education and hands-on training is necessary to become consistently pro-

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ficient in utilizing these devices and achieving excellent results and very low complication rates. A bleeding risk model has been developed using data from the ACC-NCDR database. The bleeding risk score assigns points to a variety of variables including STEMI (10 points), cardiogenic shock (8 points), age ≥85 (8 points), sex (6 points), prior CHF (5 points), age 76 to 85 (5 points), no prior PCI (4 points), NYHA (New York Heart Association) functional class IV (4 points), NSTEMI (3 points), peripheral vascular disease (2 points), and age 66 to 75 (2 points). The risk of a postprocedural bleed was then 0.7% for those with ≤7 points, 1.8% for those with 8 to 17 points, and 5.1% for those with ≥18 points (136). Using similar data from the ACC-NCDR database to test the association between the use of bleeding avoidance strategies and post-PCI bleeding, Romaguera et al. found some advantage to the use of both bivalirudin and vascular closure devies (213).

The failure of these devices does occur (228), however, and not all reviews suggest a great advantage of the vascular closure devices in low-risk patients (229). Because of the expense of these devices, each laboratory should systematically review whether they are being used in a cost-effective method. In many cases, the radial approach appears to reduce the vascular risk compared with the standard femoral approach, and this may be an appropriate alternative (72). An AHA Scientific Statement on the use of vascular closure devices has been published (230). This committee reviewed those recommendations and endorse the suggestions outlined.

5.2. Medications Postprocedure

5.2.1. Pain Control and Sedation

Patients should not require substantial pain control or sedation postprocedure. If patients have access site discomfort, fentanyl hydromorphone hydrochloride, or morphine can be used. If sheath removal will require prolonged manual or mechanical compression pain management will be necessary. Patients who appear to be oversedated or are not regaining appropriate level of consciousness should be given naloxone and/or flumazenil to reverse the effects of any narcotics or benzodiazepines they received during the procedure.

5.2.2. Hypertension

Severe postprocedural hypertension can cause increased vascular site bleeding complications, myocardial ischemia, and with associated diastolic dysfunction, pulmonary edema. Postprocedural hypertension should be managed relatively aggressively. Patients can be given doses of their outpatient medications and/or can be given IV doses of antihypertensives. Hydralazine, labetalol, nicardipine, or metoprolol are commonly used as IV push medications; nitroglycerin infusions can be used as well. In general, the goal BP should be 140/80 mm Hg. More aggressive reduction in BP is not necessary. Hypertension could be a sign of an overdistended bladder; therefore, placement of a temporary Foley catheter if the patient is unable to void may resolve the hypertension. The use of bedside bladder ultrasound devices may be confirmatory.

5.2.3. Vagal Complications and Hypotension

Vagal responses occur most commonly after sheath removal. The pain, from manual or mechanical compression, generally triggers this response. Pre-medication of patients with subcutaneous lidocaine or the use of fentanyl or morphine prior to sheath removal may diminish vagal reactions. The hypotension and bradycardia must be recognized promptly. Rarely, severe vagal complications result in asystole and the need for CPR. Treatment with boluses of normal saline followed by a saline infusion plus the use of atropine 1 mg IV help counteract this complication, since vagal reactions usually include both vasodilatory and a cardiodepressor component. Nurses who care for post-cardiac catheterization patients must be trained to recognize this and treat it promptly and aggressively. Vagal responses can also occur with loss of hemostasis and abrupt hematoma and pseudoaneurysm formation as well as pseudoaneurysm rupture. A retroperitoneal bleed can often be confused with a vagal reaction and must be considered, particularly if patients are complaining of flank pain and are not responding rapidly to treatments. A mass may be perceived, and usually the heart rate is increased (unless the pain has resulted in a vagal component). In many situations, the most rapid and appropriate diagnostic procedure is to return to the cardiac catheterization laboratory for contralateral access and identification of any bleeding site angiographically. Balloon occlusion may then prevent further bleeding until a more definitive procedure can be carried out. Abdominal noncontrast CT is usually definitive in assessing the presence of a retroperitoneal bleed when there is no sense of urgency or hemodynamic compromise.

6. Personnel Issues

6.1. Personnel

A cardiac catheterization laboratory requires a critical mass of interdisciplinary personnel to allow safe and optimal performance of catheterization-based procedures, including minimum key personnel. Most of the technical staff should be certified by the appropriate certifying body. The laboratory staff should meet ongoing continuing education requirements for current registration and institutional employment. The following is an outline of pertinent personnel requirements, roles, and obligations.

6.1.1. Attending Physician

The attending physician is the physician in charge of the procedure. The attending physician is considered the primary operator for the procedure. He or she must hold a valid medical license and be credentialed by the institution.

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He or she must be experienced in all aspects of the performance of the procedure, including procedural indications or contraindications, preprocedural and postprocedural evaluation and care of the patient, and the management of periprocedural complications. If 2 attending physicians participate in the procedure, only 1 may be the attending of record for the purpose of billing. Adjunct attending physicians may be responsible for specific aspects of the procedure, such as the performance of transesophageal echocardiography or general anesthesia, and they may bill appropriately for the additional services provided, if these services are required for the proper performance of the catheterization procedure.

6.1.2. Teaching Attending Physician

A teaching attending physician meets the requirements of an attending physician in a program instructing graduate physicians in the performance of the procedure and transmission of information to the trainee physician(s). A teaching attending physician must be present for all critical aspects of the cardiac catheterization procedure, and should be board certified or eligible. Attending physicians directly supervising fellows in the performance of interventional procedures should perform a minimum of 75 interventions per year at the primary training institution and meet all other hospital credentialing requirements for the performance of the procedure.

6.1.3. Secondary Operators

Secondary operators are additional "attending" physicians, physician extenders, or cardiovascular trainees who assist the primary attending physician. These physicians may fulfill the some of the requirements for an attending physician, but they are not in charge of the procedure at hand and are not considered the primary operator. Cardiology fellows are secondary operators but may be considered supervised primary operators for the purpose of the ACGME requirements. Secondary operators should not take credit for the case for the purpose of fulfilling minimum performance volume physician requirements or for billing.

6.1.4. Laboratory Director

The laboratory director should be a physician with the experience and leadership qualities needed to monitor and control the laboratory environment. The director is charged with the responsibility for policy development, quality control, and fiscal administration. Depending on the type of laboratory and type of patients studied, the director may be either an adult cardiologist or a pediatric cardiologist and may have special interests such as in interventional cardiology or electrophysiology. The director should be an attending physician who is board certified and thoroughly trained in cardiac radiographic imaging and radiation protection. The director must be proficient in performing procedures specific to the laboratory and supportive to the needs of the operating physicians. Ideally, the director should be knowledgeable of all the major procedures being performed in the catheterization laboratory; however, with emerging technologies and the evolution of subspecialty areas (e.g., labs that offer a large range of interventional, peripheral, and EP services), the director may necessarily collaborate with other attending physicians for management regarding specialized procedures. He or she must have the necessary skills to address emergent complications.

It is the director's responsibility to ensure the laboratory has the equipment necessary to competently perform the catheterization or interventional procedures, as well as the tools and personnel required to address complications should they occur. The director's qualifications should include at least 5 years of cardiac catheterization experience and possess recognized skill in the laboratory. He or she should be board certified in interventional cardiology if interventional procedures are performed in the laboratory, though exceptions may occur in special instances with approval of the facility leadership and the credentials committee at the specific institution. Directors that have not had time to accumulate 500 PCI cases should have a QA system in place, as noted previously, wherein a random number of cases are reviewed by a large-volume PCI center. This should be on a continuing basis until the minimum 500 PCI cases have been satisfactorily achieved and competence established.

For centers with cardiovascular, interventional, or EP fellowship training programs, the catheterization laboratory director must work in collaboration with the training program director (if different) to assure the proper training and supervision of the trainees. The interventional program director must also be board certified in interventional cardiology. This assures that the laboratory provides an environment conducive to teaching the requisite knowledge and skill sets, and that teaching attending physicians meet the volume and professional standards necessary to qualify them as educators.

The director is responsible for a wide range of personnel management. The director shall set criteria for granting privileges to physicians and then review and make recommendations about applications for those privileges. The director must periodically review physicians' performance, make recommendations for renewal of laboratory privileges, review performance of trainees and nonprofessional staff, and provide necessary training to personnel. The director shall establish and monitor quality control, including morbidity and mortality, and program and policy development, including incorporation of guidelines and defining monitoring plans for guideline compliance. He or she must be an active proponent of a CQI and QA program for the laboratory, as established earlier in this document.

In addition, the director should have the responsibility of advocating and ensuring adequate healthcare resources (devices, equipment, and supportive personnel) for the catheterization laboratory. Necessary emergency equipment must be available in the lab. Other important equipment might

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include new devices, x-ray or imaging equipment, information technology resources, integrated imaging resources, nurse or technical specialists, diagnostic technology, point of care testing, patient transport resources, or other healthcare resources.

The director must work in collaboration with the institution (including occupational and radiation safety) and with a qualified medical or health physicist to ensure personnel safety and compliance regarding the use of x-ray–generating equipment, including compliance with local regulations and laws. This includes advocating for adequate radiation safety training and protective equipment for catheterization laboratory personnel, patient and personnel monitoring for radiation exposure, and a system to address occupational exposures and injury.

The duties and responsibilities of the director are thus multiple and wide-ranging and demand strong management skills. The role should be appropriately compensated by the hospital, group, or health system in charge of the laboratory as these responsibilities are always in addition to other clinical duties. Adequate time should be provided along with adequate financial compensation.

Other responsibilities include oversight of patient scheduling, referral services, postprocedure reporting and tracking of quality measures (including complications), establishing quality improvement programs, procurement and maintenance of equipment and supplies, budget preparation and monitoring, organization of regular conferences for laboratory personnel, and regular reports on laboratory activity. The director shall maintain communication and cooperation among laboratory staff, clinicians, and the hospital administration to ensure that the patient is best served. The director must designate a substitute who will act in his or her absence.

6.1.5. Operating Physicians

All physicians credentialed to operate in the catheterization laboratory must have proper training and meet all credentialing requirements for the facility. This includes those classified as the attending physician and those functioning as teaching attending or secondary operators. This training may be in adult or pediatric cardiology. Clinical training in any of these fields should fulfill requirements for that specialty board and preferably from an ACGME-certified program. The physician should be deemed competent to perform the procedures by the program director of his or her training institution. A laboratory physician should be a fully accredited member of the hospital staff and ideally be specialty certified or have completed formal training in the area he or she practices. An operating physician who provides only laboratory service without being a full member of the hospital staff should not be the attending of record. The physician must also be trained in general emergency and critical care, which includes a minimum of current advanced cardiac life support certification. This should also include training and competence in emergency scenarios that commonly occur in the specific procedural setting (diagnostic or interventional). Operating physicians must also be trained in patient and staff radiation safety, and meet the institutional standards for the operation of fluoroscopic/x-ray equipment that pertains to the procedures performed. Finally, the physician should meet the institutional requirements for the administration of conscious sedation. Operating physicians must participate in the laboratory's QA program, including peer review. Physicians performing electrophysiological procedures should have completed formal training or be certified in electrophysiology. The performance of complex electrophysiological procedures, such as atrial fibrillation ablation, requires additional training and experience, and the credentials committee must certify anyone contemplating these procedures is adequately trained.

6.1.5.1. CARDIOVASCULAR TRAINEE (FELLOW)

The primary role of the cardiovascular trainee is to obtain the cognitive knowledge and technical skills necessary to competently perform cardiac catheterization procedures. This includes the indications, contraindications, and limitations of the procedures; pre- and postprocedure patient care; analysis, interpretation, and reporting of hemodynamic and angiographic data; and management of complications related to procedure performance (111). Combined with the core training that occurs within a cardiovascular training program, trainees obtain the critical skills necessary to become qualified attending physicians. Trainees may perform all functions of the procedure as the primary operator would, but only under the direct supervision of a credentialed attending physician who assumes responsibility for the procedure. In this capacity, the use of house staff not directly engaged in a formal cardiovascular training program is inappropriate. Outlines for current volume recommendations for the various levels of training are addressed in Tables 17 and 18.

6.1.6. Use of Physician Extenders (Physician's Assistants and Nurse Practitioners)

Increasingly, "physician extenders" (e.g., physician's assistants and nurse practitioners) are being used clinically as patient care assistants in the provision of medical services within the field of cardiology. In regard to cardiac catheterization and intervention, trained and credentialed physician extenders may perform preprocedural evaluation and postprocedural follow-up of cardiac catheterization patients. In some medical centers, specially trained and qualified physician extenders may have an expanded role to assist the physician with the invasive or interventional procedure itself (231).

It should be recognized that extenders can never be primary operators and should work only under the direction of an attending cardiologist. The physician extender should be proficient in both the technical and cognitive aspects of cardiac catheterization, including 1) preprocedural evalua-

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tion; 2) indications; 3) cardiac physiology and pathophysiology; 4) emergency cardiac care; 5) radiation safety; and 6) application of diagnostic catheterization data regarding the procedure.

The primary operating physician must be in the catheterization suite during the procedure when secondary operators are performing the procedure and direct the physician extender as well as provide all clinical decision making. Specially trained nurses/nurse practitioners may assist attending physicians in much the same role as physician's assistants in the performance of procedures. They may be able to assist in place of cardiovascular trainees, but they require even greater supervision during all aspects of the procedure.

6.1.7. Nursing Personnel

The type and number of nursing personnel required in the catheterization laboratory depend on the laboratory caseload and types of procedures performed. This support group may include nurse practitioners, registered nurses, licensed vocational or practical nurses, or nursing assistants. In most laboratories, the laboratory supervisor is a registered nurse. This nurse must be familiar with the overall function of the laboratory, have strong management skills, help set the tone of patient surroundings, and influence the efficiency and safety of procedures. The nurse supervisor may also directly participate in observation and nursing care of the patient during catheterization and should be ready to respond to any emergency. The nursing supervisor should be in charge of the preprocedure and postprocedure holding areas. Although variation exists among institutions, in general, the nurse supervisor should ensure that institutional guidelines for patient monitoring, drug administration, and protocols for patient care (including protocols for handling potential complications) are established, and that all catheterization laboratory nurses are properly trained) for the level of patient care that they deliver. The nurse manager, in collaboration with the hospital pharmacy and other clinical managers, should work to ensure appropriate medications are immediately available for administration in the catheterization laboratory, particularly those needed in emergency situations. In laboratories in which nursing personnel administer conscious sedation (under physician direction but in the absence of an anesthesiologist), the training, qualifications, and safety of conscious sedation should be in accordance with hospital policy, with compliance monitoring by the nurse supervisor.

The background of a catheterization laboratory nurse preferably includes critical-care experience, knowledge of cardiovascular medications, the ability to start an IV infusion and administer drugs, and experience in sterile techniques. Ideally, there should be some formal training, though certification programs have yet to be a prerequisite. The committee would endorse a movement toward such certification measures. Experience with vascular catheter instrumentation, especially with identification, cleaning, sterilization, and storage, is helpful and should be part of training. Knowledge of vascular catheter materials and the proper catheter size, appropriate guidewire, and adapters is also valuable. Some familiarity with the manipulation of manifolds, injection of contrast, and changing of guidewires and catheters is important. The catheterization laboratory nurse must have a thorough understanding of the flushing of catheters and syringes to prevent clots or air emboli. The nurse in the catheterization laboratory must also have essential skills to monitor the patient's vital status, including BP, heart rate, oxygenation, general neurological function, and pain. For nurses administering conscious sedation, institutional training and guidelines for patient monitoring and drug administration protocols must be followed. A nurse with the primary responsibility of the patient should be able to assist in acute cardiac care, including resuscitation and related therapeutic efforts.

A licensed practical nurse with the proper background and experience may have duties similar to those of the registered nurse. However, a licensed practical nurse should not supervise laboratory nursing. In some laboratories, an appropriately trained nursing assistant may be responsible for some duties. The nursing assistant may be a cardiopulmonary technician who is familiar with procedures in associated disciplines and is thereby able to function in the dual capacity of cardiopulmonary technician and nursing assistant.

Nursing personnel (registered nurse or licensed practical nurse), when properly trained, can manage blood samples, perform point-of-care testing (such as ACTs), and perform blood gas measurements and saturations. In addition, team training on simulators, especially for rarely done or more complex procedures, may help ensure an understanding of the optimal techniques and management issues.

6.1.8. Non-Nursing Personnel

Several kinds of technical knowledge are required in the cardiac catheterization laboratory, and a single person may not possess all the different types of technical expertise. At least 1 technologist, preferably a certified radiological technologist, should be skilled in radiographic and angiographic imaging principles and techniques. This technologist should be experienced in the proper performance of x-ray generators, cine pulse systems, image intensification, pressure injection systems, video systems, cine and digital imaging and storage, and radiation safety principles. He or she, in cooperation with electronic and radiological service engineers, should be responsible for routine care and maintenance of the radiological equipment. A basic ability to troubleshoot this equipment is advantageous. This technologist, in cooperation with a qualified medical physicist, should monitor radiation safety techniques for both patients and laboratory personnel. Immediate availability of a radiological engineer in the event of equipment failure is highly desirable. The technologist, with the service engineers and

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qualified medical physicist should ensure optimal image quality while limiting radiation exposure to staff and patients. This technologist may also assist with the data storage and report generation system.

Each laboratory should also be reviewed and managed by a qualified medical physicist in order to provide appropriate teaching, to ensure optimal monitoring equipment is being used and to assist with the actual monitoring of radiation exposure to patients and laboratory personnel. A program of radiation safety should be in place in every cardiac catheterization laboratory.

Laboratory technologists should be skilled in managing blood samples, and performing blood gas measurements and calculations. They should be qualified to monitor and record electrocardiographic and hemodynamic data and have enough skill and experience in interpreting these data to report significant changes immediately to the physician responsible for the patient. During any single procedure, the monitoring technician or nurse must have no responsibility other than monitoring and observing patient status. It is encouraged that during each procedure at least 1 technologist (and/or physician) should be skilled in radiographic and angiographic imaging techniques. In facilities performing interventions, other equipment related to imaging, diagnosis, and treatment is generally available. This ancillary equipment necessitates at least 1 available technologist within the laboratory to be proficient in the equipment use, maintenance, and general troubleshooting. These technologies may include the use of digital subtraction angiography, intracoronary ultrasound, FFR or Doppler coronary velocity, intracardiac echocardiography, optical coherence tomography, atherectomy, rotational atherectomy, angioscopy, intra-aortic balloon counterpulsation, and percutaneous mechanical cardiopulmonary support devices. In addition, an increasing number of laboratories, particularly those performing EP procedures, are integrating noninvasive imaging directly into the catheterization lab suite for use during the invasive procedure. The technologist should be familiar with these multimodality integrative technologies so as to be able to help troubleshoot when issues arise.

For technologists participating directly in patient care, skills are necessary in patient preparation and for assistance in acute cardiac care, including resuscitation and related therapeutic efforts. Technologists at diagnostic and interventional labs should be trained in the sterile techniques as well as emergency procedure (basic and preferably advanced cardiac life support) and in the use of onsite equipment, such as intra-aortic balloon counterpulsation and temporary transvenous pacemakers, defibrillators, and mechanical cardiopulmonary resuscitative vests if these are available. Technologists often directly assist the primary operator with the procedure.

A technician with expert computer skills is a very valuable addition to the team to assist with the handling of image transfer methods and archival storage devices, image compression, and to maintain the digital libraries. Because of the complexity of digital archival storage and database management many catheterization laboratories will also require dedicated information technology support.

On occasion, additional administrative personnel may assist in the optimal functioning of the cardiac catheterization laboratory. Such personnel may include a dedicated case manager, scheduler, inventory manager and related staff, compliance monitor, and database or administrative staff for CQI and QA. In addition, some laboratories have dedicated employees that apply groin compression devices and report follow-up groin and other complications.

6.2. Staffing Patterns

A credentialed attending cardiovascular physician must be present in the laboratory during each procedure and must be responsible for the outcome as the primary operator. To maintain effective and safe laboratory operation, each basic support function should be performed by adequately trained personnel who constantly maintain their skills and credentials. There should be adequate cross-training among laboratory staff so that personnel can rotate responsibilities and provide 24-hour coverage of essential team functions.

Complex studies, especially those of children and acutely unstable patients, require personnel with special training. In complex cases and procedures, the presence of a second physician may be needed for optimal care. The requirements for a full-service facility are listed in Table 2.

6.3. Cardiopulmonary Resuscitation

All members of the catheterization team (physicians, nurses, and technologists) should complete a basic course in CPR. Certification in advance cardiac life support is also strongly urged, especially for all members that are part of the actual procedure. Recertification is to be expected every 2 years.

7. The Hybrid Cardiac Catheterization Laboratory

7.1. Overview and Patient Selection

The hybrid cardiac catheterization/operating room represents an integrated procedural suite that combines the tools and equipment available in a catheterization suite with anesthesia facilities and sterility of a fully equipped operating room. A key feature is that the suite meets all the standards of an operating room as well as all the standards of a catheterization laboratory. Although the hybrid suite is designed to meet the needs of an increasingly complex patient population, it also serves as a platform for collaborative work between subspecialists. In some hybrid suites, operators can perform cardiovascular procedures ranging from the most straightforward PCI to aortic arch reconstruction. As a result, different teams across different subspecialties can benefit from the hybrid suite.

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Hybrid catheterization laboratories require fixed imaging equipment that has greater resolution and better image storage capacity compared with mobile C-arms previously used in some operating rooms. Higher-quality imaging is required for many new techniques such as hybrid coronary stenting and CABG and percutaneous aortic valve placement.

Hybrid suites must also meet the strict environmental standards of state-of-the-art open operation rooms to reduce the risk of wound infection associated with surgical cut-down for vascular access, large prosthetic devices (e.g., valves and stent grafts), and open cardiac surgical procedures. These standards include a closed environment, traffic control specifications, specific HVAC requirements, the availability of vacuum equipment, and structural designs to promote a sterile environment. Because many will be placed in the traditional cardiac catheterization suites, special attention to converting a portion or all of the catheterization area into a sterile environment is often required.

Procedures best suited for the hybrid laboratory include those where surgical vascular access is required for large endovascular devices that are deployed using high resolution imaging (e.g., percutaneous aortic valves or aortic stent grafts), where conversion to open surgery may be required if endovascular procedures are unsuccessful (e.g., aortic stent grafts), or for hybrid treatments such as PCI with minimally invasive valve or CABG (Table 21).

Table 21. Examples of Procedures for a Hybrid Catheterization Laboratory

Surgical vascular access required for large endovascular devices
Percutaneous aortic valves
Thoracic and abdominal aortic stent grafts
Large-bore percutaneous ventricular assist devices
Conversion to an open surgical operation may be required
Percutaneous aortic valves (apical approach or bailout)
Thoracic and abdominal aortic stent grafts
Percutaneous ventricular septal defect closure
Hybrid treatments
Combined percutaneous coronary intervention and minimally invasive or open coronary bypass grafting
Combined percutaneous coronary intervention and minimally invasive cardiac valve surgery
Combined iliac stenting and distal bypass grafting
Endomyocardial/epicardial atrial fibrillation ablation
Apical access to assist in percutaneous closure of paravalvular leaks
Electrophysiology device placement
Implantable defibrillators
Temporary rhythm recorders (e.g., loop recorders)
Removal of pacemaker leads
Emergency procedures
Extracorporeal membrane oxygenation
Emergent thoracotomy

Modified with permission from Hirsch (232).

7.2. Special Considerations

7.2.1. Staffing

The hybrid laboratory must serve as both a surgical suite and cardiac catheterization laboratory facility. The operation can only be done properly if there is a team approach, with each team member contributing differing expertise. As a generality, a specific team of nurses, technicians, and clinical staff familiar with the room and the goals of the procedure being performed is necessary for optimal care. These staff should be selected and trained for use in this room rather than rotating individuals unfamiliar with the stringent sterile requirements and diverse nature of the procedures to be performed. As each institution will use the hybrid room for different procedures, a definitive staffing pattern is facility- and procedure-dependent. Laboratory staff must understand there can be no compromising either the surgical procedure or the cardiac catheterization if the laboratory is to be used safely and effectively.

7.2.2. Location

The location of the hybrid suite is related to the availability of space and to the training and experience of those who will primarily use the facility. Some are located in the cardiac catheterization (232) or interventional suites, while others are upgraded operating rooms (233,234). Ideally, the hybrid suite would be located in a single cardiovascular procedural area, where standard catheterization laboratories are in the same general area as open heart surgical suites, so that the people (cardiologists, surgeons, catheterization technicians, operating room technicians, perfusionists) and equipment (catheters, stents, cardiopulmonary bypass, perfusionist equipment, surgical equipment) are readily available for all conventional catheterization laboratories, operating rooms, or hybrid suites.

Hybrid suites are designed to maximize sterility and conform to operating room guidelines that may differ state to state. These include laboratories located off a clean core or semirestricted corridor where staff are required to wear scrubs, hats, and masks. Scrub alcoves are located outside the hybrid laboratory with a window into the laboratory to observe patient and staff movement. A separate control room with wide windows permits technicians to observe the procedure and assist running the x-ray equipment without jeopardizing the sterility of the hybrid room. Alternatively, a monitor station can be used within the hybrid suite. Audio and video monitoring assists communication between operators and other staff (see Section 7.2.8).

Although design standards for hybrid catheterization laboratories are evolving, operating room standards serve as a guide for hybrid suites. Veterans Affairs standards suggest cardiac surgical operating rooms be a minimum of 65 m^2 (700 ft^2), with an upper limit for special purpose operating rooms being 75 m^2 (800 ft^2) (235). Given the extra space requirements for x-ray imaging, anesthesia equipment, the additional staff and equipment compared with con-

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ventional cardiac catheterization laboratories and operating rooms, 70 m^2 (750 ft^2) may be a reasonable minimum guideline for the hybrid suite. We believe that 90 m^2 (1,000 ft^2) will provide the needed space for safe performance of hybrid procedures.

7.2.3. Room and Floor Design

Walls and flooring should generally follow seamless designs prevalent in operating rooms to avoid joins and cracks that may trap blood and other body fluids that can form a nidus for bacterial growth.

The hybrid laboratory requires x-ray shielding on walls and doors and a structure that is able to support the weight of the x-ray equipment. Floor trenching is required to run equipment infrastructure such as cable and conduit from the control room and the table to the C-arm.

Power outlets should include a range of high-voltage outputs (e.g., for laser catheters and cardiopulmonary bypass), regular-voltage outputs, and emergency (backup) power outlets. These should be distributed on the walls, from pull-down columns, and under the table (235).

Each room should have wall-mounted video monitors connected to the appropriate PACS server to call up CT, MRI, and other x-ray reference images. Because hybrid procedures usually require constant reference to multiple imaging modalities (e.g., angiography, ultrasound, FFR) as well as hemodynamic monitoring (e.g., indirect and direct arterial pressure, heart rate, electrocardiogram, oxygen saturations), these should be displayed simultaneously on multiple monitors or a large flat screen mounted on a movable ceiling-mounted boom adjacent to the table.

7.2.4. Ceiling Lighting and Design

In general, dim lighting is used in catheterization procedures to help view the images on the monitors. However, surgical operations use bright lighting that includes fixed ceiling fluorescent lights and movable ceiling mounted surgical lights. Therefore, the hybrid room needs a range of flexible lighting options to accommodate the needs of x-ray guidance and the operative stages of a procedure.

Many new hybrid suites use a ceiling-mounted (rather than floor-mounted) C-arm gantry. Ceiling mounted C-arms can be moved further away from the table during surgical procedures and are arguably easier to clean as they are less likely to have crevices where blood or bacteria can accumulate. However, ceiling mounted C-arms have tracks that protrude over the table, and track placement must not interfere with lighting or with laminar airflow. The C-arm needs to move in and out of the operating field and allow angulations (cranial–caudal and oblique angles) without interfering with anesthesia needs. Some operators prefer floor-mounted C-arms despite these issues.

In general, the mounts for the surgical lights are not directly over the table as this zone is preserved for the supply air outlet. However, these need to avoid the ceiling track of the C-arm and not interfere with angulations of the C-arm. Fifty percent of fluorescent lighting should be on emergency power with battery backup (235). Dimmable recessed lighting is distributed around the ceiling over the table for the x-ray procedure.

7.2.5. Anesthesia Requirements

General anesthesia requires greater space at the head of the table for staff and equipment compared with conventional cardiac catheterization laboratories. This area should have dedicated medical gas supplies (vacuum, medical air, nitrogen, nitrous oxide, oxygen, and waste gas lines)... similar to an operating room, and space for the transesophageal echocardiography. Inventive solutions include incorporating these equipment into movable ceiling booms so that they may be moved in and out of place as needed (232). Monitoring cables and other equipment should be radiolucent if at all possible.

7.2.6. HVAC Standards

HVAC should meet operating room standards for the number of air exchanges per hour, laminar air flow over the operating table, positive air pressure, and optimal temperature and humidity (235). The hybrid laboratory should have thermostat and humidistats for recording temperature and humidity.

7.2.7. Table Requirements

The surgical table needs to meet the individual requirements of interventional cardiologists, surgeons, and their teams. Surgeons need a fully motorized table and tabletop. In special circumstances (such as performing an aortic valve replacement), often the best position is to have the patient "sitting up," in reverse Trendelenburg, with the head up to 30° from the horizontal. The interventional cardiologist requires a radiolucent table with a full range of motion and a floating tabletop to allow fast movements during angiography. Both requirements are satisfied by a nonmetallic, carbon-fiber surgical table, with floating table-top and lateral and vertical tilt (234). Most tables designed for hybrid suites include in their specifications adequate weight tolerance (e.g., over 450 lb), longitudinal and lateral displacement, height displacement (e.g., 28 to 48 inches [685 to 1180 cm]), lateral tilt (e.g., 20° or more), and Trendelenburg and reverse Trendelenburg tilt (20° or more). The table can be positioned horizontal or diagonal in the room, depending on the size of the hybrid suite and the location of ancillary equipment.

7.2.8. Audio Video Inputs and Outputs

As procedures in a hybrid laboratory may involve many operators, audio and video monitoring may help to orientate anesthesia staff, staff in an adjacent control room, or those outside the sterile field. It may also provide an opportunity to educate staff and students without them entering the sterile zone around the table. Multiple video cameras that

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are remotely operated with zoom function may be mounted on a wall, the x-ray monitors, or the surgical light handle. Key operators may choose to wear microphones and headsets to request equipment or to inform or receive requests from other team members (232).

7.3. Representative Procedures Suitable to the Hybrid Room Environment

Table 21 outlines some of the types of procedures that may benefit from the use of a hybrid cardiac catheterization laboratory.

8. Ethical Concerns

A physician's primary obligation is to act in the best interest of his or her patient. Associated with this is the obligation to "do not harm," and respect patient autonomy (236–238). The respect for autonomy mandates that patients be given appropriate and uncoerced choices about their health and potential medical care and requires that physicians provide accurate and unbiased information about the patient's medical condition, and disclose all potential avenues of care. The physician is responsible for obtaining satisfactory informed consent, and delineating the potential risks, benefits, and alternatives of the agreed-upon diagnostic and/or therapeutic strategy (236). The physician is responsible for documentation of the indication for the procedure and to document review of appropriate data (e.g., noninvasive tests). In addition, the physician must be transparent concerning any and all potential ethical or financial conflicts concerning therapies or devices employed in the patient's care.

Changing practice patterns in medicine, including the increased pressure for productivity from practice and hospitals due to declining reimbursement, and other nonmonetary factors (academic promotion, etc.) have altered the relationships among physicians, patients, and payers, creating potential conflict of interest in maintaining the patient's best interest (237,239,240).

Physicians may now serve simultaneously as physician, inventor, and investigator of new therapies for vascular intervention. Similar issues exist with respect to the conduct of clinical research, in which the patient may be encouraged to participate in clinical protocols that may lead to little personal benefit (and potential risks), by physicians who may have a direct or indirect financial interest in their participation (112,239,241). This practice cannot be condoned.

8.1. Operator Assistant's Fees, Sharing of Fees, Fee Splitting, and Fee Fixing

There has been close scrutiny by third party payers and the federal government of the ethical (and financial) relationships between the referring physicians and the interventional cardiologist. Although some procedures may be optimal with the participation of 2 operators (e.g., percutaneous mitral repair, percutaneous aortic valve replacement, complex coronary procedures, or pediatric intervention), it is only ethical and legal for a cardiologist to charge an operator assistant's fee when he or she has directly participated in the procedure and was necessary for the performance of the procedure. Only 1 may be the primary attending physician as noted earlier. Furthermore, offering or providing a shared fee with another physician for the performance of cardiac catheterization is unethical and illegal.

It is also not ethical for a cardiologist to receive an admission fee, referral fee, or other "kickback" or commission for admitting or referring a patient to a hospital or cardiac catheterization facility (242). This principle applies not only to fees, commissions, and compensation received from other physicians and hospitals, but also to those received from manufacturers of catheters, medications, instruments, devices, or supplies that may be used in the catheterization laboratory. Great care must be exerted to avoid procedural incentives, as more and more cardiologists become employees of healthcare systems and hospitals, and incentives for increased productivity may be construed as violating the principles behind the Stark laws. Furthermore, such collusion may be illegal when such arrangements involve Medicare funds and are construed as inducement for referral. Collusion with other cardiologists in an attempt to fix fees for catheterization services may also violate antitrust laws.

8.2. Unnecessary Services

Duplication of services with additional charges or performance of unnecessary procedures or add-on procedures (right-heart catheterization, temporary pacemaker insertion) without specific indications and documentation of those indications is unethical and potentially illegal. A charge to over-read data by a physician who has not performed the procedure is also an unnecessary duplication of services and fees (241).

The overuse of tests as a means to protect providers from medical malpractice is an issue that needs further examination. Any unnecessary testing is discouraged and may place the patient at unnecessary risk as well as incurring unnecessary cost.

8.3. Self-Referral, Self-Ownership, and Self-Reporting

Physician self-referral is the practice of a physician referring a patient to medical facility in which the physician or an immediate family member has a financial interest. That interest may be in the form of ownership, investment, or like compensation (237,239,243–246). In response to the suggestion that self-referral unnecessarily increases the cost of medicine by overutilization of services, the Stark Laws were introduced. Stark I was introduced into law in 1989 (Omnibus Budget Reconciliation Act of 1989) (246a) and prohibited self-referrals of services of Medicare beneficiaries

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except where provide by specific exceptions. This was expanded to include Medicaid beneficiaries in 1993 and extended in 2007 (246b).

Critics of physician-owned facilities, whether hospital or laboratory, consider them a source for overutilization and unnecessary increase in the cost of medicine, whereas backers of physician-owned facilities point out that individual procedures are cheaper, and there is a significant convenience for the patient.

A provision in the recently enacted health reform law (Patient Protection and Affordable Care Act of 2010) now places major limits on physician ownership of hospitals (246c). New doctor-owned facilities that are not certified as Medicare participants by December 31, 2010, no longer will be allowed into the program. Existing physician-owned facilities are currently being reconsidered and debated and may face restrictions on expansion.

8.4. Informed Consent

Informed consent is a legal procedure to ensure that a patient knows all of the benefits and risks involved in a treatment. The elements of informed consent include informing the client of the nature of the treatment, possible alternative treatments, and the potential risks and benefits of the treatment. The patient should be informed of the experience of the primary operator responsible for the procedure. In order for informed consent to be considered valid, the patient must be competent and the consent should be given voluntarily. In the absence of a patient's ability to understand or give informed consent, a person holding power of attorney may act as a surrogate.

Patient autonomy mandates that informed consent be obtained before performance of any invasive diagnostic or therapeutic cardiovascular procedure. Informed consent is an "ongoing process," and the education can be presented by any of the personnel involved in the procedure and may involve the use of written or video material, as well as traditional oral explanation. Although, there may be multiple people involved in obtaining informed consent, the physician is responsible for presenting him/herself to the patient and family and for the consent process. Informed consent must include an accurate description of the procedures, benefits, risks, and potential complications. Although not every eventuality can be predicted, it is adequate to present the common and usual risk and complications. The risks and complications must be presented accurately and must not be understated. They must be presented at a communication level that the patient and family can understand. If a physician extender (e.g., physician's assistant or nurse practitioner) or cardiology trainee is to perform any part of a procedure, this should be stated. If an "ad hoc" PCI procedure is anticipated immediately after a diagnostic procedure, then consent for this should be done prior to any sedation for the diagnostic procedure.

Informed consent must be obtained in a nonpressured environment when possible, but in situations (such as primary PCI for AMI) it is recognized that the environment may not allow a leisurely description, but nonetheless must be complete. Written informed consent should be obtained and documented in the medical record before the procedure.

Frequently, interventional procedures are performed as ad hoc procedures where the intervention immediately follows the diagnostic procedure. Ad hoc angioplasty has several inherent advantages; it expedites patient care, avoids a second invasive procedure with its associated risks and recognized morbidity, and reduces total x-ray exposure and therefore cost. However, it is associated with a larger volume of procedural contrast and ideally requires interventional pretreatment. A staged procedure allows ample time to review the angiogram; plan the procedural strategy; discuss the risks, benefits, and alternatives with the patient and family; and give informed consent based on the anatomy. Previous documents (110) have endorsed the recommendations from the SCAI (247) that ad hoc PCI be individualized and not be the standard or required strategy for all patients. Whenever there is a medical advantage to staging the procedures, this should be strongly considered. The convenience and cost advantage of ad hoc procedures, however, has made this practice commonplace and perfectly appropriate for most situations. The European Society of Cardiology has emphasized the importance of engaging the patient in any decision regarding an interventional procedure and making sure the patient has the final decision when there are several therapeutic options with no clear evidence for a particular strategy over another (248).

8.5. Ethics of "Teaching"

Although teaching hospitals have been essential to medical training for decades, patients admitted to a "teaching" hospital have a right to be aware of the level of training of the various physicians and related personnel involved in their care. It is ethical for the cardiologist to delegate the performance of certain aspects of the procedures to assistants, such as physician's assistants or fellows, providing that this is done transparently with the patient's consent and under the attending physician's supervision. Fellows or physician's assistants, if qualified, can also perform certain components of the invasive procedures, provided that they are supervised at all times by the attending cardiologist. It is not ethical to delegate the entire responsibility of invasive procedures to anyone not appropriately experienced and properly trained in the performance of the procedure. The attending physician must be responsible for all major decision making and must physically be present during all the critical points in the procedure.

8.6. Clinical Research Studies During Diagnostic and Interventional Cardiac Catheterization

An increasing number of teaching and community hospitals participate in clinical research protocols. Local institutional review boards now require a higher standard of disclosure for research studies than that required for clinical practice.

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Accordingly, extra time should be taken with patients asked to participate in clinical research to ensure that all questions have been addressed. Research studies should not increase the risk of major complications disproportionally to the possible benefit when combined with diagnostic catheterization and interventional procedures. The investigative procedure should be performed after the essential information has been obtained if possible, but only if the patient's condition is stable and the diagnostic procedure has been performed in a timely fashion. Research procedures performed during the catheterization must be reviewed and approved by an institutional review committee.

Safeguards for ensuring that patients are appropriately enrolled in clinical research trials are as follows: that the clinical investigator has thoroughly reviewed the protocol for its scientific validity; the patient has met all the inclusion criteria and none of the exclusion criteria; the patient has been fully informed about the risks, benefits, and alternative therapies; and the clinical investigator follows the clinical protocol without unjustified deviation. In fact, most clinical investigators are ethical individuals whose motivations are to further scientific knowledge. Strict adherence to the clinical protocol is the best assurance that conflicts of interest will be minimized.

Although many challenges face cardiologists today, high ethical standards, including maintenance of proficiency, avoidance of real or perceived financial conflict of interest, disclosure of potential conflicts, and, most important, maintaining the patient's best interest as primary, remain of paramount importance. Only with attention to these issues will our profession continue to be viewed by the public (and our patients) as trustworthy and deserving of their respect.

8.7. Physician– and Physician Group–Industry Relations

Physicians and industry have a common interest in advancing medical knowledge. Nonetheless, the primary goal of the physician is to promote the patient's best interests, whereas promotion of profitability is a goal of industry. Although partnerships between physicians and industry can result in impressive medical advances, they also create opportunities for bias and can result in unfavorable public perceptions even if unintended. Accepting industry hospitality and gifts, even drug samples, can compromise judgment about medical information and subsequent decisions about patient care. It is unacceptable for physicians to receive gifts from industry. Physician–industry conflicts of interest can arise from other financial ties between physicians and industry, whether to outside companies or self-owned businesses. Such ties include honorariums for speaking or writing about a company's product, payment for participating in clinic-based research, and referrals to medical resources. All of these relationships have the potential to influence a physician's attitudes and practices (249). Excessive fees for speaking on behalf of industry or for participation in advisory boards are to be avoided. Most institutions have in place well-defined conflict of interest statements where gifts and income of even a modest amount from outside the respective institution are reported, and then reviewed by disinterested parties (usually a conflict of interest committee). These can then be judged whether appropriate. It is the responsibility of each physician to honestly and completely report such gratuities, honoraria, or income to these governing bodies.

Similarly, providers of medical education to interested groups of medical personnel have a duty to present objective and balanced information and should not accept any funds that are tied to industry-shaped programming. Medical educators have the sole responsibility to evaluate and control the planning, content, and delivery of education. They should disclose industry sponsorship to medical education participants and should adopt explicit organizational policies about acceptable and unacceptable interactions with industry (250).

8.8. Hospital Employment of Physicians

With wholesale changes in the U.S. healthcare system occurring currently, many cardiologists are being targeted to become employees in an effort to control costs. Physicians should never compromise patient care nor perform unnecessary procedures to satisfy a corporate or hospital "expectation." All decisions regarding the delivery of care should be focused on providing better patient results and not corporate profits.

9. X-Ray Imaging

Significant qualitative and quantitative changes in x-ray systems have transpired since the previous ACCF/SCAI consensus document on Catheterization Laboratory Standards published in 2001 (2). The qualitative changes reflect the migration to digital image acquisition, processing, and archiving, whereas the quantitative changes reflect the extent of market "penetration" of these digital systems. Consequently, the following discussion will be limited to significant advances in the field since the 2001 publication. Details of analog and digital imaging chains can be found in previous ACCF/AHA documents (1,251), past proceedings of the SCAI Melvin P. Judkins Imaging Symposia, NCRP Report 168 (252), as well as classic textbooks on the subject (253,254).

Continuing improvements in gantry design, ergonomics, and room layout belie the fundamental use of this equipment in the contemporary cardiac catheterization laboratory—the performance of potentially high-dose, fluoroscopically guided interventions. In 2000, the International Electrotechnical Commission published an interventional standards document in which a number of key technical and performance criteria were delineated (255). These standards were updated in 2010 (255). These standards are the basis of many of the FDA legally enforceable regulations (256).

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Importantly, manufacturers of x-ray units built after this date, and designated for the purpose of high-dose, fluoroscopically guided interventions, must demonstrate compliance with these criteria. Additional criteria were added by the FDA in 2005 for all such units manufactured after that date (257). A number of these criteria are discussed below, but it is important to point out that some portions of these standards are not applicable to simple mobile gantry systems. Any x-ray unit used for high-dose, fluoroscopically guided cardiovascular interventions should be compliant with the IEC interventional standard.

9.1. Equipment and the "Imaging Chain"

9.1.1. Image Formation

The advent of digital x-ray systems has fundamentally transformed the process of image formation and, consequently, image quality (Table 22). Although "analog" and "digital" systems share a common means for generating x-rays using high-output, micro circuitry-driven generators and similar x-ray tube technologies, it is the "detector" that has fundamentally changed the way in which images are formed and processed. "Flat-panel" detectors (and their inherent charge-coupled device technology) have not only physically replaced the image intensifier and television camera in traditional analog imaging chains, but have improved the overall efficiency of the process of image formation. Although a detailed description of the physical design and electronic configuration of these detectors is beyond the scope of this document, the translation of information contained within the pattern of x-rays exiting the subject to that contained within an electrical (digital) video signal created by the flat panel detector is a major improvement over the sequential conversions (and consequent loss of information) of x-ray energy to light energy (image intensifier) and light to electrical/video signals (TV "pick-up" tubes, video scanners). Such improved process performance with flat-panel systems is measurable and expressed as greater detective quantum efficiency, or DQE (258). Flat panel detectors have enhanced image uniformity, uniform brightness, and dynamic range when compared with the image intensifier. However, there are scant objective, comparative data on other measurable parameters of digital fluoroscopic "image quality" (e.g., high-contrast spatial resolution and low-dose, low-contrast resolution) between flat panel systems and traditional image intensifier–based systems (259). The use of the National Electrical Manufacturers Association fluoroscopic phantom (260), although developed for image-intensifier–based technology, is a significant advance in this area and may allow for such cross-system comparisons. Importantly, despite initial aspirations to the contrary, the consequences of these improved performance characteristics have not been consistently shown to result in reduced x-ray dose (258).

Just as an understanding of the generation of x-rays is fundamental to the process of image formation, so is an understanding of the control of the dose-rate (strength) of the x-ray beam. The importance of dose-rate control for both image quality and patient and staff safety is discussed elsewhere in this document. However, an understanding of the characteristics of the x-ray beam, and its modification, is critical from a catheterization laboratory standards viewpoint. Although none of these factors is uniquely different in flat panel systems, they may be overlooked owing to the other (perhaps forgiving) features of flat panel detectors (e.g., greater dynamic range and improved contrast). In addition, in most flat panel systems, image, or quantum, noise may be reduced with special recursive filtering and image processing algorithms, resulting in a more attractive visual image display.

The main "beam factors" that affect image formation, and patient dose, are beam penetrating power (hardness), scatter, and signal-to-noise ratio. The current generation of x-ray tubes and generators are designed for the high-performance, high-power requirements of interventional cardiology. High heat load capacity x-ray tubes in combination with the filtering of "soft" (low-frequency) x-rays from the beam prior to patient entrance enhance the "hardness" of the beam in order to reduce patient dose and improve overall image quality. The amount of scattered radiation—the result of Compton interactions within the patient—is directly related to the primary dose. Scattered radiation not only degrades image quality and reduces contrast, but is the main source of staff exposure as well as patient exposure outside of the primary field. It is difficult to overheat state-of-the-art x-ray tubes.

In traditional "analog" catheterization laboratories with a classic image intensifier, the level of light intensity at the

Table 22. Summary of Major Changes in the Contemporary Catheterization Laboratory Imaging Chain Over the Last Decade

X-ray generator: electronic control/high-frequency/high-output; automatic dose control; pulse and continuous modes of operation with a large selection of "stations" corresponding to different procedure types, as well as multiple dose/exposure settings for each procedure.

X-ray tube: high-heat capacity tubes with more efficient anode cooling mechanism; more effective collimation (automatic); more effective spectral filtration ("beam hardening"); use of wedge filters.

Flat panel detector: improved "dynamic range"; improved uniformity of image/brightness; improved contrast; improved detective quantum efficiency.

Image processing: recursive filtering; edge enhancement/"smoothing" algorithms.

Image display: in-room liquid crystal display flat panel monitors; improved dynamic range.

Dose monitoring: dose-area product monitoring/display/reporting (suggested); interventional reference point cumulative dose monitoring/display (FDA mandated since 2006).

Dose management: virtual collimation permitting collimator settings without fluoroscopy, fluoroscopic last-image-hold; retrospective storage of fluoroscopy data.

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output phosphor was fed back to the generator in order to maintain a preset, calibrated level of intensity on the phosphor (automatic brightness control, or ABC). In "digital" catheterization laboratories with flat panel detectors, the flat panel–produced digital video signal is fed back to the generator in order to maintain the preset, calibrated voltage output from the detector (automatic dose-rate/exposure control, or ADC). Variability in patient body habitus or angled gantry configurations will be sensed by the generator/x ray tube unit as conditions requiring greater beam penetrating power (increasing kVp and/or increasing mA) and subsequently increased dose-rate.

Unavoidable variability in the construction of the detector itself may result in an inherently "noisier" image, particularly at the lower dose rates employed during fluoroscopy, thereby necessitating a higher dose- rate of x-ray. While the higher dose-rate may result in an "improved image," the need for total dose monitoring under such conditions should be obvious. Thus, U.S. federal and international standards for dose monitoring and dose limits are important additions to catheterization laboratory safety and performance standards. Operators need to be aware of the dose-monitoring capabilities of newer x-ray systems as this information can be used to minimize patient radiation exposure.

9.1.2. Digital Storage and Display

The increase in information content and flux that occurs with digital imaging requires a commensurate increase in storage capacity and system "bandwidth" to facilitate "online" and postacquisition review and archiving of studies. "In-room" central processing units with storage capacity in the terabyte range are not unusual nor are archiving systems with multiterabyte capacity. The fundamental requirement for online, immediate review of portions of a coronary interventional procedure mandate fast Ethernet-transmission speeds for the acquired images at mega-pixel resolution that are then "processed," "filtered," and presented for review. The importance of high-resolution, in-room, table-side monitors cannot be overstated. Although the latter are often incorporated into the entire "package" of a newly purchased x-ray system, "retrofitting," "upgrading," and "refurbishing" of extant in-room monitors are still frequently encountered and may be primarily responsible for less-than-expected improvement in fluoroscopic image quality. Careful attention must be paid to the calibration, resolution (contrast and spatial), and dynamic range of these monitors, including those installed as part of a new system.

9.1.3. Quantitative Measures

Although multicapability "software" packages and modules are now universally available with the purchase of a new x-ray system, the full extent of use of such capabilities is unknown. In contrast to the near-universal use of administrative and logistical (scheduling, billing, coding, etc.) software modules—all provided in one form or another with the purchase of a new catheterization laboratory—the quality-assured, routine use of quantitative ventriculographic, hemodynamic, and/or coronary angiographic software is less widespread. Even less frequent is onsite validation of the information provided by such user-interfaced software. This is particularly important in instances of "lesions of borderline significance" and likely contributes to the still widespread practice of ad hoc PCI (99). Similar issues abound with incorrectly obtained hemodynamic information "processed" with such software, the consequences of which may lead to erroneous conclusions regarding condition severity (261). The importance of "acceptance testing" or onsite validation of such software cannot be overemphasized, and physician diligence and clinical judgment is always critical for the proper interpretation of these data.

9.2. Radiation

9.2.1. Biological Risks

The biological risks of x-radiation have been discussed in great detail in The NCRP Report 168 and in standard texts (262) in addition to recently updated reports and expert consensus documents (251,263–267). X-rays produce cellular injury primarily by causing fractures in the DNA backbone. X-ray radiation risks can be broadly categorized as 1) deterministic—that for which a "dose–injury" relationship exists and for which a threshold dose has been determined and 2) stochastic—that for which the probability of injury is related to dose and for which no threshold dose has been defined ("linear–no-threshold" hypothesis). The former relates most importantly to the risk of skin injury and possibly cataract formation whereas the latter relates to the long-term risks of radiation-related cancer. When enough cells of a particular organ (such as the skin) are injured so that its function is impaired, that defines a deterministic risk, and the dose when that occurs is the threshold dose. In contrast, a stochastic injury occurs when there is injury to the DNA backbone that does not properly heal itself, and the result is not cell death but a mutation leading to either a cancer or a genetic abnormality. A single x-ray photon may cause this change and is not directly dose related, though the risk of acquiring such injury increases with dose. Risks to the germ plasm, and offspring of the x-radiated subject are stochastic in nature albeit substantially lower than the risk of cancer development to the subject. Although the clinical manifestation of deterministic injury is seen in characteristic skin lesions (268–270), there is, at present, no validated or reliable "biomarker" for stochastic risk. Risks to the irradiated fetus can be considered deterministic (a defined threshold dose), although periods of highest vulnerability to radiation-related effects are time dependent and confined to the first trimester. Doses to the fetus of >100 mGy may result in mortality or failure to implant during the first couple weeks, but it is unlikely a fetus would receive this amount from cardiac catheteriza-

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tion. Surviving fetuses during this initial period of exposure have few lasting effects due to the fact that the embryo is composed of only a few cells that will eventually differentiate into multiple organs (206a). The stochastic risk of cancer induction in a fetus is considered similar to that of a newborn.

9.2.2. Measuring Radiation Exposure and Radiation Dosimetry

Monitoring of personnel in the cardiac catheterization laboratory is important to detect potentially unsafe working practices and to remediate them whenever possible. It is the individual's legal and ethical responsibility to wear radiation badges to monitor their exposure to ionizing radiation. If specific individual records reveal unusual dose exposure, a review of the individual practice is warranted (252) and corrective action should be undertaken.

The International Commission on Radiation Protection recommends 2 monitoring badges, 1 under the radiation protection garment (between the waist and chest) and 1 on the collar (271). The NCRP accepts a single outside collar monitor, though prefers the 2 monitor suggestion (272). The SCAI suggests a single monitoring device worn on the collar is acceptable. If a worker declares she is pregnant, a fetal monitor under the lead apron is required at waist level (273).

Table 23 provides the standard terminology and definitions for catheterization laboratory–based considerations of radiation exposure.

Further, and more detailed, explications of the terminology employed can be found in authoritative review articles on the subject (271). Importantly, although "exposure" to x-radiation can be directly measured, the dose to internal organs cannot be directly measured and must be estimated. Thus, the measure of risk is imprecise, subject- and procedure-dependent, and ultimately, obtained from epidemiologically derived associations of such estimated absorbed doses with long-term, clinically manifest disease. A detailed discussion of this subject is beyond the scope of this document, but the interested reader is referred to the latest publication of the BEIR VII report (264).

Of most relevance to the catheterization laboratory environment is the derivation, and meaning of, the effective dose (ED), as it is the latter that encompasses the stochastic risk associated with ionizing radiation. ED, a quantity derived from the weighted sum of Monte Carlo–derived estimates of individual organ doses, should more properly be viewed as a metric of radiation safety and used for interprocedural comparisons rather than a unique "dose" of radiation to a given individual (275). Given the above-noted complexity in the assessment of ED, an approximation of the stochastic risk associated a given x-ray procedure can be estimated by multiplying the DAP—the product of the air kerma at any point along the center axis of the x-ray beam and the beam cross-sectional area at that point—and an anatomically based and empirically derived conversion factor reflecting the conversion from DAP (Gy-cm^2) to ED (Sv) (276). The DAP is derived from a transmission chamber fitted to the output of the x-ray tube. It represents total x-ray energy directed toward the patient. The accumulated reference point air kerma when combined with gantry position and patient geometry provides a rough idea about how much x-ray dose the patient's skin received. The association between the risk of radiation-related cancer mortality and exposure is derived mainly from the atomic bomb survivor experience where exposure was whole-body (in contrast to localized, as in invasive procedures), averaged over a population of varying ages and gender (hence the need to specify age- and sex-specific risks of cancer mortality) and cancer-related deaths in individuals with exposures below 100 mGy. However, this latter dose is well above the reported range for EDs associated with most but not all fluoroscopically guided interventional procedures. Furthermore, the risk of radiation-related cancer development and mortality must be placed in perspective with respect to the overall lifetime risk of cancer mortality (~25% overall). Currently, the overall lifetime incremental risk of cancer-related mortality attributable to radiation exposure is estimated at 4% to 5% per Sv (264,277). A dose–response relationship between occupational exposure and posterior lens changes in the eyes has also been suggested recently (278).

Table 23. Relevant Nomenclature for Radiation Exposure and Dosimetry

Term	What Is Being Measured	Unit of Measure	Conversion
Exposure	Ionization produced in air by x-rays	Roentgen, R, or coulomb/kg air	1 R=2.58 $\times 10^{-4}$ coulomb/kg air
Air kerma	The sum of the initial kinetic energies of all the charged particles liberated by uncharged particles	Rad, or gray (Gy)	100 Rad=1 Gy
Absorbed dose	The energy imparted to matter by ionizing radiation per unit mass of irradiated material at the point of interest	Rad, or gray (Gy)	100 Rad=1 Gy
Effective dose	Estimated total body dose	REM or sievert (Sv)	1 Rad=10 mGy

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9.2.2.1. PATIENT EXPOSURE

There is an extensive literature on patient exposure during coronary angiographic procedures. The majority of this literature was generated in the "pre-flat panel" era, but remains applicable. Overall, estimated patient ED for diagnostic coronary angiographic procedures ranges from 2.3 to 22.7 mSv with a mean of 7 mSv (279,280), whereas EDs for simple coronary interventional procedures range 50% to 100% higher than those for diagnostic studies and, on average, are approximately 15 mSv (281). To put this into some kind of perspective, the average nonmedical background radiation dose in the United States is about 3.0 mSv per year, and the average dose from a routine chest x-ray is about 0.02 to 0.10 mSv. Manufacturer-originated claims have suggested reduced patient exposure with flat panel systems, although these claims are likely confounded by secular trends in enhanced awareness of radiation safety and improved operator technique. The need for vendor-independent, geographically disperse data in this regard is significant.

The increased complexity of interventional procedures—coronary as well as peripheral vascular, valvular, and congenital heart disease—is of increasing relevance in any contemporary consideration of patient exposure. A median ED in the pediatric diagnostic catheterization experience has been reported at 4.6 mSv and that for therapeutic procedures at 6.0 mSv (282). Similarly, estimated EDs for complex electrophysiological procedures have been reported to average 50 mSv in men and 32 mSv in women (283). Limited data in the setting of complex structural heart disease interventions in adults suggest that, on average, ED exceeds that for coronary intervention by 25% to 50% (284).

A more immediate concern with increasingly complex and lengthy high-dose fluoroscopically guided interventional procedures is that of radiation-related skin injury (269,270,285). The awareness and likelihood of skin injury with increasing dose has focused attention on its recognition and prevention. The skin dose metric that is believed to best capture this deterministic risk is the peak skin dose. However, such a determination requires the placement of numerous dosimeters over, or adjacent to, the irradiated area—a cumbersome and infrequently performed routine. Analogous to the use of the DAP as an estimate of stochastic risk, the cumulative dose at the IRP—15 cm below isocenter—has been suggested as an alternative measure of deterministic risk (255). The 15 cm distance from the patient's isocenter is about the distance one would expect the skin to be located. Note that the displayed cumulative value of air kerma is not skin dose. It does provide a starting point for calculating skin dose. Other factors, including beam motion during the procedure, patient–gantry geometry, and backscatter from the patient, affect the amount of radiation received by the skin as well. A clinically useful simplification is to regard cumulative reference point values above 5,000 mGy as the threshold of a substantial dose (252,255). This is an amount that would be quite rarely received during cardiac catheterization but is not uncommon in complex interventions. Tissue skin reaction for various parts of the body is outlined in Table 24. Ideally an estimate of the patient radiation dose should be a part of every clinical report, and if a substantial dose has been delivered, the patient should be appropriately informed prior to discharge.

9.2.2.2. OCCUPATIONAL EXPOSURE

The major source of exposure to catheterization laboratory personnel is scattered radiation from the patient, with the latter strongly dependent on procedural length and complexity, operator technique, and gantry configuration (263,286). The extent of scatter radiation is closely associated with the DAP. In a review of the literature on occupational exposures in cardiac catheterization laboratories over the past 30 years, the authors identified primary operator EDs ranging from 0.02 to 38.0 μSv and 0.17 to 31.2 μSv, for diagnostic and interventional procedures, respectively (287). Exposure of support personnel working in catheterization laboratories, but not in immediate proximity to the tableside or image detector, receive the lowest exposures (272).

9.2.3. Minimizing Radiation Exposure

Professional societal guidelines directed towards radiation safety and the minimization of patient and personnel exposure have been available for 25 years (263,288,289) and have been recently summarized and updated (251). The mechanics of reducing patient exposure require proper use of the equipment itself (e.g., gantry positioning, degree of magnification, detector input dose, x-ray tube output dose rate, collimation and beam filtration; recognition of patient-specific factors; procedure-related factors, length and complexity of procedure, and proper use of control mechanisms).

The mitigation of patient exposure translates directly to mitigating the exposure of operator and staff because scatter radiation increases (decreases) as beam intensity increases (decreases). The driving principle behind reducing occupational exposure is the ALARA principle (290). Attention to "time" (beam on-time or the period in which x-rays are emitted from the x-ray tube), "shielding" (the use of lead-or its equivalent-lined aprons for the torso and waist, as well as thyroid collar and protective eyewear), and "distance" (establishing a safe working distance from the patient as well as image detector, utilizing the "inverse square law") are the most effective means of reducing occupational exposure. Tables 25 and 26 highlight the major means of reducing exposure to patients and staff, respectively.

9.2.4. Quality Management and Measurement of Radiation Exposure in the Cardiac Catheterization Laboratory

An effective QA/QI program in the cardiac catheterization laboratory must be centered on patient and staff safety.

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Table 24. Tissue Reactions From Single-Delivery Radiation Dose to Skin of the Neck, Torso, Pelvis, Buttocks, or Arms

Band	Single-Site Acute Skin-Dose Range (Gy)*	NCI Skin Reaction Grade†	Approximate Time of Onset of Effects			
			Prompt	Early	Midterm	Long Term
A1	0–2	NA	No observable effects expected	No observable effects expected	No observable effects expected	No observable effects expected
A2	2–5	1.	Transient erythema	Epilation	Recovery from hair loss	No observable results expected
B	5–10	1–2	Transient erythema	Erythema, epilation	Recover; at higher doses, prolonged erythema, permanent partial epilation	Recovery; at higher doses, dermal atrophy or induration
C	10–15	2–3	Transient erythema	Erythema, epilation; possible dry or moist desquamation; recovery from desquamation	Prolonged erythema; permanent epilation	Telangiectasia; dermal atrophy or induration; skin likely to be weak
D	>15	3–4	Transient erythema; after very high doses, edema and acute ulceration; long-term surgical intervention likely to be required	Erythema; epilation; moist desquamation	Dermal atrophy; secondary ulceration due to failure of moist desquamation to heal; surgical intervention likely to be required; at higher doses, dermal necrosis, surgical intervention likely to be required	Telangiectasia†; dermal atrophy or induration; possible late skin breakdown; wound might be persistent and progress into deeper lesion; surgical intervention likely to be required

Note: Applicable to normal range of patient radio-sensitivities in absence of mitigating or aggravating physical or clinical factors. Data do not apply to the skin of the scalp. Dose and time bands are not rigid boundaries. Signs and symptoms are expected to appear earlier as skin dose increases. Prompt is <2 weeks; early, 2 to 8 weeks; midterm, 6 to 52 weeks; long term, >40 weeks. *Skin dose refers to *actual* skin dose (including backscatter). This quantity is not the reference point air kerma described by the Food and Drug Administration (256) or International Electrotechnical Commission (255). Skin dosimetry is unlikely to be more accurate than ±50%. †Refers to radiation-induced telangiectasia associated with area of initial moist desquamation or healing or ulceration may be present earlier. Reprinted with permission from Balter et al. (285).

NA = not applicable; NCI = National Cancer Institute.

Building on a 20-year tradition of such efforts, SCAI published a monograph in 1999 in which seminal and relevant publications addressing the many dimensions of catheterization laboratory standards for the assessment of quality and safety can be found (291). A broader discussion of the assessment of procedural quality and outcomes is found elsewhere in this document. The ongoing assessment of quality and outcomes in the catheterization laboratory, a fundamental aspect of any continuous quality improvement process (292), must include dose monitoring for both patients and personnel. Although personnel exposure always needs to be monitored in the catheterization laboratory (293), there are surprisingly fewer sets of guidance data for patient exposure. Maximum allowable exposure limits for medical radiation workers exposed to various sources of ionizing radiation are explicitly described in Table 27 (272,288).

The FDA has set an upper limit to "tabletop" fluoroscopic exposure rate of 10R/min for systems with automatic exposure control (256); however, there are no regulatory limits on cine exposure rates. The fluoroscopic guideline, however, serves more as an indicator of x-ray generator and overall imaging chain function (294) than a direct measure of skin dose (and, therefore, deterministic risk). As noted earlier, differences exist between the FDA-specified air kerma determination 30 cm in front of the detector versus the IEC-recommended (cumulative) air kerma determination at the IRP 15 cm from middle of the patient to the source along the isocenter line (assuming that equates to where the skin lies). Unfortunately, neither measurement is an accurate indicator of stochastic (earlier) or deterministic (later) risk. However, all catheterization laboratory x-ray systems manufactured after 2005 and sold in the United States are now required to provide real-time information regarding total radiation exposure time (fluoroscopic and acquisition mode) and reference point air kerma; many systems also measure and display DAP. These data provide patients and physicians more meaningful estimates of risk. This information should be included in the procedural report. A summary of these records should be incorporated into the catheterization laboratory's performance improvement process logs. All of this information should be reviewed for internal consistency within the lab and in comparison to published external guidance data (252).

The measurement and management of radiation exposure in the catheterization laboratory environment cannot be divorced from the issues of competence, credentialing, and proficiency. Accordingly, physicians (and staff) must be knowledgeable in matters of radiation physics, radiation biology, and technological developments in x-ray imaging systems and x-ray dose management (251). A rigorous curriculum for the latter should be an integral part of every

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Table 25. Reducing Exposure to Patients

Minimize beam "on-time"
Minimize framing rates
Minimize total fluoroscopy time
Use pulse fluoroscopy whenever possible with frame rates <15 fps
Minimize use of "high dose" rate fluoroscopy
Minimize number of acquisition runs
Minimize use of geometric/electronic "magnification" modes
Keep tube current (mA) low
Keep tube potential (kVp) as high as possible without washing out image
Use collimation to irradiate only the area of interest
Use copper and other filters at the x-ray tube output to reduce unnecessary x-ray photons
Appropriate use of gantry configuration
Optimize the source-to-skin distance
Minimize the source-to-detector distance ("air gap") (source-to-image distance)
Minimize extreme compound angulations to reduce the x-ray beam path in the patient
Use multiple rotational and axial skew configurations
Do not work in 1 view exclusively to vary radiation distribution on the skin (if so, minimize need for extreme compound angulation (e.g., left anterior oblique projection)
Limit cineangiography acquisition and save fluoroscopic image data in its place when possible.

interventionalist's training and should comprise an important segment of the certifying examination. The increasingly complex clinical conditions seen in catheterization laboratories today require a more sophisticated understanding of, and approach to, the technical, pharmacological, and radiologic aspects of interventional cardiology. Rigorous training and ongoing assessment of each of these 3 "pillars" is, ultimately, the responsibility of each practitioner. Numerous excellent training and "refresher" curricula are currently available from authoritative sources (295,296) and are recommended readings.

10. Special Concerns for the Pediatric Cardiac Catheterization Laboratory

Routine cardiac catheterization of children is performed in most of the 120 children's hospitals in the United States. In general, these hospitals also provide the infrastructure for comprehensive pediatric cardiovascular centers, which support pediatric open-heart surgery, pediatric ECMO, advanced pediatric and neonatal intensive care, as well as noninvasive pediatric cardiology diagnostic services. Basically all facilities that perform cardiac catheterization on children must be full-service facilities as defined earlier.

Table 26. Reducing Occupational Exposure

Control dose to patient (see Table 27)
Implementation of time/shielding/distance
Correct positioning of staff relative to gantry
Staff education and training

Table 27. Maximum Allowable Radiation Limits for Medical Workers

Whole body	5 REM/y (50 mSv/y)
Skin	50 rad/y (500 mGy/y)
Lens of eye	2 rad/y (20 mGy/y)
Fetus (for pregnant worker)	0.5 rad (5 mGy) for the total pregnancy or 0.05 rad/month (0.5 mGy/month) (estimated by abdominal badge under lead apron
Cumulative exposure (lifetime)	1 REM × age (10 mSv × age)

In the context of the catheterization laboratory: National and international general recommendations have been reformatted to better distinguish between local dose (measured in rad or mGy) and effective dose (measured in REM or mSv).

Pediatric catheterizations are performed either in dedicated pediatric cardiac catheterization laboratories (PCCLs) or in catheterization laboratories used for both children and adults. Dedicated pediatric laboratories are most often components of free-standing children's hospitals. Joint-use laboratories are most often located in general hospitals that have either a large inpatient pediatric service or a closely affiliated neighboring children's hospital that shares core infrastructure with the general hospital.

Whether children have catheterizations in dedicated or in joint-use laboratories, it is appropriate for both catheterization laboratory environments to adhere to applicable guidelines of all catheterization laboratories outlined earlier in this Statement. Furthermore, additional PCCL guidelines and best practices designed to address the unique challenges and issues related to pediatric patients and to congenital heart disease should be instituted. These additional PCCL guidelines and best practices are the focus this section of the document.

10.1. Differences in Goals

The PCCL should function as one of the critical elements within a pediatric cardiovascular center. The goals of the PCCL within a center should be to provide the diagnostic information needed to support medical, interventional, hybrid, and surgical treatments, as well as to provide the full range of interventional and hybrid treatments needed to achieve high-quality outcomes in pediatric patients with congenital and acquired heart diseases (297). Diagnostic catheterizations in children and adults with congenital heart disease are distinct from typical adult catheterizations, because, by definition, they are designed to evaluate structurally abnormal hearts. Catheterizations usually include right (and left) heart catheterization, quantification of cardiac index, multichamber oximetry assessments, calculations of left-to-right and right-to-left shunts, and pulmonary and systemic vascular resistance. Cardiac index may be measured by thermodilution, but because of the presence of shunts, the Fick principle is more commonly employed, and oxygen consumption is usually assumed. Because of dramatic growth-related changes in pediatric body surface area and the need for comparative hemodynamic data, flow and resistance values are usually indexed for body surface area.

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Furthermore, in addition to demonstrating all aspects of coronary arteries, pediatric angiographic studies are usually intended to define and display complex intracardiac anatomy as well as pulmonary and systemic vessels. These imaging data may supplement or complement other common imaging modalities such as echocardiography, CT angiography, and MRI. A wide variety of congenital and acquired heart and great-vessel defects and abnormalities are investigated in the PCCL.

Interventional procedures are the primary or a secondary objective in up to three fourths of all catheterizations performed in the PCCL. A substantial number of unique interventional procedures are performed. Most of the individual procedures are performed in relatively small numbers. These procedures include atrial septostomy, valvuloplasty, angioplasty, stent implantation in large vessels, vascular closure (patent ductus arteriosus, other anomalous vessels, and fistulae), device closure of atrial communications and ventricular septal defects, transcatheter valve implantation, endomyocardial biopsy, foreign-body retrieval, pericardiocentesis, and a range of electrophysiological procedures (298,299). Expertise in these procedures is acquired during pediatric cardiology fellowship training and in pediatric cardiology post-fellowship training in the interventional cardiac catheterization laboratory (often during an additional training year) (300).

Hybrid procedures are an important activity in many PCCLs. These procedures are performed jointly or cooperatively by an interventional cardiologist and a cardiac surgeon. They are often performed in infants who have a thoracotomy exposing the surface of the heart. Interventional catheterization procedures are performed with access provided directly through the anterior wall of the right ventricle or the main PA. The most common interventions are Stage I palliation of hypoplastic left heart syndrome (stenting of the patent ductus arteriosus), angioplasty and/or stenting of PAs, and closure of muscular ventricular septal defects (301,302).

10.2. Who Should Perform Catheterizations in the Pediatric Cardiac Catheterization Laboratory?

PCCLs, whether dedicated or shared with adult cardiologists, should have a pediatric director. The director should be board certified in pediatric cardiology and should have additional training in pediatric cardiac catheterization and intervention (or qualifying experience). The director should be responsible for all aspects of the administration and function of the PCCL (including backup of other pediatric operators with less training or experience). In addition, QA and QI activities related to pediatric studies should be under the director's guidance.

Other attending physicians who perform cardiac catheterization in children are generally board eligible or board certified by the American Board of Pediatrics, Subspecialty Board of Cardiology. There may be exceptional cases in which a competent physician has gained extensive experience without formal board certification, but these physicians usually have been allowed privileges by a "grandparent" clause. Whether privileges for non–board-eligible physicians may be granted is left to the discretion of the individuals involved and the hospital credentialing process.

The pediatric age range is usually considered to be from birth through 18 (or 21) years of age. It is recommended that pediatric cardiologists perform catheterization on patients under the age of 18 years who require cardiac catheterization for congenital cardiac problems. Adult patients with previously diagnosed (repaired or unrepaired) congenital heart disease or with native congenital heart problems requiring cardiac catheterization should have the procedure performed 1) by a pediatric cardiologist; 2) by an adult cardiologist and a pediatric cardiologist collaborating during the procedure; or 3) by an adult cardiologist with an established special interest and expertise in adult congenital heart disease.

10.3. Quality Assurance Issues in the Pediatric Cardiac Catheterization Laboratory

New methodologies have recently been developed and applied to assessing adverse events occurring in the PCCLs (303). Contemporary complication rates for pediatric cardiac catheterizations have been defined in a large, well-structured, and controlled prospective multicenter catheterization laboratory registry study utilizing these methods (304). The median rate of overall adverse events is 16%: 10% for diagnostic cases and 19% for interventional cases—considerably higher than adult laboratories due to the marked difference in the patient population. Moderate severities to catastrophic adverse events are less common, occurring in 1% of endomyocardial biopsies, 5% of diagnostic cases, and 9% of interventional cases. Death occurred in 0.3% of cases. Previous studies reporting adverse events in the PCCL had been uncontrolled, retrospective, single-center studies, and/or reflected practice patterns and technologies from the 1980s and 1990s (305–307). These studies report lower rates of adverse events and are not so reflective of the contemporary era. Further prospective adverse events data in the PCCL are being collected by the IMPACT Registry.

The Bergersen et al. study (304) suggests that catastrophic complications (those resulting in death, rescue ECMO, or emergency surgery) should occur in well under 1% of all cases and in under 1% of interventional cases in a PCCL. Major complications (those requiring admission to the intensive care unit, emergent readmission to the hospital, a major nonsurgical intervention) should occur in <2% of all cases and in <4% of interventional cases. Informed consent for PCCL procedures is usually obtained from the patient's parents or guardians. This consent includes the physician's (or his or her designees, such as the cardiovascular fellows) explanation of the risks, benefits, and alternatives related to the procedure, with documentation of the explanation and of the parent/guardian understanding

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shown by a signature. In urgent or emergent cases, such as when a transferred patient requires emergency balloon septostomy and the parents are in transit, consent may be obtained by telephone or even assumed and the procedure performed. The committee recognizes that there are consent and assent procedures and guidelines that vary by jurisdiction (hospital, state, county) and defers to those where applicable. Age or other circumstances that afford competence to the patient vary as well. These will determine whether it is acceptable to obtain the patient's "assent" or whether formal consent is required.

10.4. Inpatient Versus Outpatient Setting for Procedures

Although outpatient procedures have become common in the PCCL, there is less uniformity in patient and parent suitability for hospital discharge shortly after catheterization than in adult patients. Infants and young children cannot be instructed or expected to remain still without moving their legs for a period after a procedure. Any volume of blood lost into the subcutaneous tissue or retroperitoneum or onto the bandage or bedclothes will have more significance if the patient is smaller. Given the small number of PCCLs, pediatric patients and their families often have to travel farther for treatment than adult catheterization laboratory patients. The pediatric patient may also be farther from appropriate medical attention after returning home. Despite the smaller size of the patient, the sheath sizes used in pediatric cases may be nearly the same size (5-F to 8-F) as those used in adults. For these reasons, it is suggested that overnight observation be anticipated and allowed whenever there is any concern about patient safety. Nonetheless, a set of written criteria should be established for same-day catheterization and discharge by each PCCL. These criteria would account for differences in procedure type, patient age and expected compliance, parent or guardian reliability, travel distance, procedure duration and time-of-day completion, and the cardiac physiology in determining which patients are eligible for discharge on the day of catheterization. These guidelines should establish discharge criteria such as absence of bleeding, presence and adequacy of pulses and perfusion, access to medical evaluation and care after discharge, and parental understanding and ability to observe overnight.

10.5. Operator and Laboratory Volumes

Although the committee recognizes that access to services is important, there is also the valid impression that an adequate and maintained level of experience is required for the cardiologist and staff to obtain and preserve proficiency. In its 2002 "Guidelines for Pediatric Cardiovascular Centers," the American Academy of Pediatrics elected to specify outcome benchmarks rather than to recommend minimum operator or PCCL volume (297). However, previous ACCF/SCAI statements have recommended that individual operator minimum annual caseloads to be in the range of 50 to 100 cases per year (1). The committee continues to believe that an individual cardiologist performing catheterization in the PCCL should have a minimum annual case number >50 per year. Furthermore, if a PCCL routinely performs <100 cardiac catheterizations per year, consideration should be given to whether the volume justifies the program. In addition, because the level of skill and expertise required and the complication rates are related to the type of intervention and to patient characteristics, credentialing for therapeutic cardiac catheterization should be procedure specific (308).

A number of considerations must be taken into account when a decision is made regarding the minimum operator or PCCL volumes and credentialing of operators for specific interventional procedures. Although there are ample data regarding adult interventional procedures, there are no data relating number of pediatric procedures to skill or outcomes. It is important that institutional, local, and personal factors be weighed.

Importantly, QA plans must be in effect in all PCCLs to monitor outcomes of pediatric cardiac catheterization. There are some similarities and differences between the strategies required for QA in the PCCL versus the adult cardiac catheterization laboratory. For example, there is not a prior acceptable rate of normal cardiac catheterizations. In patients undergoing cardiac catheterization for hemodynamic reasons or possible intervention, the rate of normal should be zero. Any number of patients may have electrophysiological abnormalities or acquired disease with structurally normal hearts but abnormal physiology, and these would not be considered to be in the "normal" group. The effort to operate within benchmark adverse event rates is the same in all laboratories, although the types and rates of complications in the PCCL are different from those in the adult laboratory. Although intervention procedures are usually planned well in advance, ad hoc procedures might well be required. Such procedures as coil occlusion or vascular plugging of a ductus arteriosus or an aortopulmonary collateral or balloon dilation with or without stent placement may be needed even when not previously planned. Diagnostic quality and accuracy of catheterizations and procedural outcomes should be examined, with each PCCL responsible for earmarking certain indicators and examining them with plans for improvement if warranted by the data.

10.6. Procedural Performance Differences Compared With Adult Cardiac Catheterization

10.6.1. Pre-Medication and Baseline Laboratory Data

In many pediatric laboratories, if the patient is in otherwise good health and on no medication, no preliminary laboratory tests are obtained prior to the cardiac catheterization procedure.

The choice, dose, timing, route, and overall use of pre-medication vary widely with age, size, and condition of patient and the experience and training of the operator. There is no "standard" pre-medication. Chloral hydrate,

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diphenhydramine, and diazepam are frequently given orally for sedation. Intravenously, midazolam, morphine, fentanyl, hydromorphone hydrochloride, and other medicines can be used with good effect. The advantages of midazolam are that it can be given by continuous infusion and it can be reversed if necessary. Reversal of midazolam with flumazenil (Romazicon) does not usually precipitate the severe discomfort and agitation seen with naloxone (Narcan) narcotic antagonism. Ketamine may be used in small intramuscular or IV bolus doses for rapid-onset anesthesia. This may help during precise intervention when patient movement might be detrimental to procedure success. Meperidine (Demerol) alone or in combination with promethazine is sometimes used intravenously or by the intramuscular route for analgesia and sedation. Chlorpromazine is used less often than previously, because of the availability of and experience with other medicines.

10.6.1.1. VASCULAR ACCESS ISSUES

Techniques for venous and arterial access are similar for children and adults. Most catheterizations are performed using the femoral vein and femoral artery. However, in a significant number of cases the left heart and aorta may be accessed through the venous approach, and retrograde arterial catheterization may not be required. Furthermore, transseptal procedures are commonly performed during diagnostic and/or interventional procedures in patients of a variety of ages (including infants). Properly performed, this approach does not add significantly to the incidence of complications. In general, newborn catheterization should be performed through the umbilical vessels when possible in order to preserve femoral vessels. In addition, because of the frequency of venous catheterizations and indwelling femoral venous lines in neonates and infants, limited or absent venous access from the femoral veins is not uncommon. Therefore, venous access from the internal jugular, subclavian, basilica, and transhepatic approaches are frequent. Alternative arterial approaches are also required in some children because of occluded femoral arteries. In young infants, a hybrid approach with carotid artery cut-down may be used to access the aorta in order to perform balloon valvuloplasty in critical aortic stenosis or for stenting of the patent ductus arteriosus in cyanotic infants. In addition, percutaneous brachial artery access or axillary artery cut-down may be used as alternative approaches in some children if femoral arteries are occluded.

The use of heparin in the flush solutions is routine, but the additional use of bolus-dose heparin depends on the patient's preprocedural ACT, procedure type, and vascular approach. It is common practice, for example, to avoid use of bolus heparin for right heart catheterization or prograde right and left heart catheterization, but heparin bolus is commonly used in retrograde left heart catheterization. At the end of a procedure, an ACT may be checked, and if necessary, the heparin effect reversed with administration of protamine sulfate in much the same manner as for adults. Some laboratories no longer use heparin during the cardiac catheterization procedure. Hemostasis is usually achieved by direct manual pressure followed by placement of an adhesive or elastic tape over a gauze pad on the percutaneous access site. However, percutaneous suture closure of suitable arterial and venous sites has become relatively common among suitable patients in the PCCL.

10.6.1.2. SEDATION AND ANESTHESIA FOR PROCEDURES

Medications used during the procedures in the PCCL are essentially the same as those noted earlier for premedication. Repeated bolus doses of sedatives may be used, and/or a continuous infusion of midazolam or other drug may be instituted. It is necessary that a nurse or physician assess and document the patient's condition after each bolus dose of sedative according to the institution's conscious-sedation guidelines. Systemic arterial oxygen saturation should be continuously monitored by pulse oximetry. General anesthesia is performed by an anesthesiologist or nurse anesthetist under supervision for all or most patients in many PCCLs. Indications for anesthesia include patient considerations and procedure characteristics. For example, a developmentally delayed teenager who is fearful may be unable to be sedated without general anesthesia. Patients who are critically ill or in pain will benefit from anesthesia. Prolonged procedures such as those that require transesophageal echocardiography may be greatly facilitated with general anesthesia. Certain interventional procedures such as aortic or mitral valve dilation, ASD occlusion, and others may be made significantly easier, safer, and more effective when performed with general anesthesia. The use of anesthesia is a judgment made by the attending cardiologist in consultation with the anesthesiologist, just as it is in surgery.

In the current era, the PCCL has become the site for more invasive percutaneous interventions as well as hybrid procedures. The opportunity for catastrophic or critical events is thereby heightened. Therefore the committee believes that the PCCL should have plans for and access to rescue ECMO, in addition to standard resuscitation methods and technologies, in order to provide definitive resuscitation of patients having such events in the laboratory (308).

10.6.2. Single-Plane Versus Biplane Angiography

The standard equipment in a PCCL includes biplane radiographic equipment. In general, pediatric and congenital cardiac catheterizations are performed using biplane fluoroscopy and angiography. This is important both for localizing the catheter in space within the heart and great vessels and for reduction in contrast dosage administration. Certain procedures can be routinely performed with single-plane fluoroscopy, including (in many laboratories) electrophysiological study and radiofrequency ablation, some types of ASD occlusion, and others. ASD occlusion is often performed with localization and positioning of the device using transesophageal or intracardiac echocardiography as

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well as fluoroscopy. Coronary arteriography in children may be performed with single-plane use, especially if it is assisted or performed by an adult cardiologist for whom performance of single-plane fluoroscopy/angiography might be standard.

10.6.3. Hemodynamics

As noted, right and left heart catheterizations are performed in combination in many pediatric and congenital heart catheterization procedures. In addition to the LV systolic and end-diastolic pressures and aortic or arterial pressures normally obtained in the adult cardiac laboratory, right-heart pressures are standard. Pressure waveforms and determinations of oxygen saturations are generally obtained from each chamber of the heart entered and from the PAs or veins, aorta, or systemic veins as indicated during any particular procedure. The routine pressure measurements and recordings necessary are difficult to specify, because they vary widely depending on the anatomy and physiology involved. For example, in a patient with pulmonary valve stenosis, an LV pressure may not be obtained at all, whereas an RV systolic and diastolic pressure recording is mandatory. On the other hand, PA pressure, routinely obtained in a right-heart catheterization, may be ill advised in a patient with severe tetralogy of Fallot. Even an invasive arterial or aortic pressure might not be obtained in the setting of a cardiac transplant repeat biopsy or other limited right-heart procedure. Pressures should be able to be recorded with excellent and reliable fidelity on scales, which range from a full scale of 10 mm Hg to 400 mm Hg. Rapid availability of oxygen saturations and blood gas determination is essential for interpretation of shunt physiology and for patient safety.

10.6.4. Angiographic Acquisition Differences

Angiograms are routinely performed with framing rates ranging from 7.5 to 30 fps (60 fps are rarely needed). The frame rate depends on the patient's heart rate and the types of images to be acquired. For example, during balloon dilation, images may be acquired at 15 (or 7.5) fps, whereas a ventriculogram in an infant with a high heart rate may require imaging at 30 fps. A wide variety of catheters, appropriate contrast materials, and injection techniques and parameters are available. Contrast is often injected at a faster rate in the PCCL compared with the adult laboratory, because fine details of the anatomy are sought rather than global function or regional wall motion abnormalities. In selected patients, 30 to 40 mL of contrast may be injected over 1 to 2 seconds, for instance. In addition, in most cases, premature ventricular beats or even ventricular tachycardia are better tolerated in younger patients with no ischemic heart disease. Angiograms should be available for immediate review after acquisition with instant-replay digital playback. Short- and long-term archival of digital data or cineangiograms does not differ from that described in prior sections.

10.6.5. Radiation Protection and Pregnant (or Potentially Pregnant) Patients

The same principles of radiation protection applied in the adult cardiac catheterization laboratory apply in the PCCL. In addition, girls and young women of child-bearing age should undergo beta-HCG testing to ensure that they are not pregnant before having a cardiac catheterization. This might be based on history in some cases (e.g., if a patient has an implanted chronic chemical contraceptive or if she has had a bilateral tubal ligation or hysterectomy), but it should otherwise include a serum or urine HCG level obtained within 2 weeks of the procedure. If a pregnant patient must be studied, the abdominal and groin areas should be shielded to help reduce any direct x-ray exposure, acknowledging that most of the fetal exposure is from scatter radiation. Efforts to minimize exposure should include using fluoroscopy or in-laboratory echocardiography rather than cineangiography and include all of the suggestions noted in Tables 25 and 26.

10.6.6. Shunt Measurements

Important information regarding physiology of congenital heart disease is gathered from measurements of intracardiac shunts. Both right-to-left and left-to-right shunts must be able to be quantitated during the catheterization. Because of the need to determine intracardiac shunting, oxygen saturation samples are drawn from many sites rather than simply from the PA for mixed venous oxygen level and from the systemic artery for arterial oxygen level. Therefore, the availability of oxygen saturation measurements and arterial blood gas determinations is essential for the efficient performance of the typical congenital cardiac catheterization. The availability of blood gas measurements also allows for the inclusion of dissolved oxygen in the determination of oxygen content.

10.7. Laboratory Personnel Issues

The laboratory staff in the PCCL should be specifically trained and experienced in the care of sick infants and children during performance of cardiac catheterization. The responsibilities within the laboratory may necessitate the services of 1 or more registered pediatric-trained nurses, a radiography technician, a certified catheterization technician, or others. It is the responsibility of the director and supervisor of the PCCL to ensure adequate staffing on a case-by-case basis. On-call cases must be considered, and a call schedule available in order to provide adequate staffing and anesthesia support in the PCCL for emergent and urgent pediatric catheterizations at all times. Timeliness of cases must also be part of the on-call planning.

ACCF Staff List

David R. Holmes Jr, MD, FACC, President
John C. Lewin, MD, Chief Executive Officer

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William J. Oetgen, MD, MBA, FACC, Senior Vice President, Science and Quality
Charlene L. May, Senior Director, Science and Clinical Policy
Dawn R. Phoubandith, MSW, Director, ACCF Clinical Documents
Tanja Kharlamova, Associate Director, Clinical Policy and Documents
Erin A. Barrett, MPS, Senior Specialist, Science and Clinical Policy
Grace Ronan, Specialist, Clinical Policy and Documents
Tiffany Jones, Specialist, Clinical Policy and Documents

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APPENDIX 1. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—2012 ACCF/SCAI EXPERT CONSENSUS DOCUMENT ON CARDIAC CATHETERIZATION LABORATORY STANDARDS UPDATE

Committee Member	Employment	Consultant	Speaker	Ownership/Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Thomas M. Bashore (*Chair*)	Professor of Medicine, Duke University Medical Center	None	None	None	None	None	None
Stephen Balter	Professor of Clinical Radiology, Physics and Medicine, Columbia University Medical Center	None	None	None	None	None	None
Ana Barac	Medical Director, Cardiac Rehabilitation Program, Washington Hospital Center Washington, DC	None	None	None	None	None	None
John Byrne*	Professor and Chairman, Department of Cardiac Surgery Vanderbilt Medical Center	None	None	None	None	• Edwards Lifesciences	None
Jeffrey Cavendish	Interventional Cardiologist, Kaiser Permanente, San Diego	None	None	None	None	None	None
Charles E. Chambers	Professor of Medicine and Radiology, Penn State, Milton S. Hershey Medical Center, PA	None	None	None	None	None	None
James Bernard Hermiller Jr*	Interventional Fellowship Director, St. Vincent Hospital, St. Vincent Medical Group	• Abbott Vascular • Boston Scientific • St. Jude	• Eli Lilly • Daiichi Sankyo	None	None	None	None
Scott Kinlay	Director, Cardiac Catheterization, VA Boston Healthcare System	None	None	None	None	None	None
Joel S. Landzberg	Clinical Associate Professor of Medicine, UMDNJ; Westwood Cardiology Associates	None	None	None	None	None	None
Warren K. Laskey	Professor of Medicine/ Chief Cardiology, University of NM	None	None	None	None	None	None
Charles R. McKay	Professor of Medicine, Harbor-UCLA Medical Center	None	None	None	None	None	None
Sandra Oliver McNeil	Cardiology Nurse Practitioner, William Beaumont Hospital	None	None	None	None	None	None
Julie M. Miller*	Assistant Professor of Medicine, Johns Hopkins, MD	None	None	None	• Toshiba Medical Systems	None	None
David J. Moliterno*	Chief, Cardiovascular Medicine, University of Kentucky	• Boston Scientific • Schering-Plough	None	None	None	None	None
John W. M. Moore	Chief, Pediatric Cardiology, University of California, San Diego	None	None	None	None	None	None

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Jeffrey J. Popma*	Director, Innovations in Interventional Cardiology, Beth Israel Deaconess Medical Center	• Boston Scientific • Cordis	None	None	• Abbott Vascular† • Boston Scientific† • Cordis† • Covidien† • Medtronic Vascular† • Terumo†	None	None
Carl Tommaso	Director, Cardiac Catheterization Laboratory, Skokie Hospital, IL	None	None	None	None	None	None

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Peer Reviewer	Representation	Consultant	Speaker's Bureau	Ownership/ Partnership/ Principal	Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
J. Dawn Abbott	Content Reviewer—ACCF Peripheral Vascular Disease Committee	• Medtronic	None	None	None	None	• Third party, interventional cardiology, 2010 • Plaintiff, interventional cardiology, 2010
Christopher Allen	Content Reviewer—ACCF Peripheral Vascular Disease Committee	None	None	None	None	None	None
Amjad AlMahameed	Organizational Reviewer—SVM	None	None	None	None	None	None
Robert J. Applegate	Organizational Reviewer—SCAI	• Abbott • St. Jude Medical	None	None	• Abbott* • St. Jude Medical* • Terumo*	None	None
John Baker	Content Reviewer—ACCF Cardiovascular Team Council	None	None	None	None	None	• Third party, case review, 2011
Eric R. Bates	Official Reviewer—ACCF Board of Trustees	• Bristol-Myers Squibb • Daiichi Sankyo • Eli Lilly • Sanofi-aventis	None	None	• Datascope	None	None

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Deepak L. Bhatt	Official Reviewer—ACCF Task Force on CECD	None	None	None	• Bristol-Myers Squibb* • Medtronic* • Sanofi-aventis*	None	None
James Burke	Content Reviewer—ACCF Interventional Scientific Council	None	None	None	None	None	None
Michael Y. Chan	Content Reviewer—ACCF Cardiovascular Team Council	None	None	None	None	None	None
Willy Chi (Yung-wei Chi)	Organizational Reviewer—SVM	None	None	None	None	None	None
Curt Daniels	Content Reviewer—ACCF Adult Congenital & Pediatric Cardiology Council	None	None	None	None	None	None
Jose G. Diez	Content Reviewer—ACCF Interventional Scientific Council	• Sanofi-aventis	None	None	None	None	None
Stephen G. Ellis	Content Reviewer—ACCF CIP CCS	• Abbott • Boston Scientific • Cordis	None	None	None	None	None
Steven R. Fern	Content Reviewer	None	None	None	None	None	None
Federico Gentile	Content Reviewer—ACCF Task Force on CECD	None	None	None	None	• NIH*	None
Hitinder Gurm	Content Reviewer—ACCF Peripheral Vascular Disease Committee	None	None	None	None	None	• Defendant, need for invasive therapy in patient with CHF, 2011
John W. Hirshfeld, Jr.	Content Reviewer—ACCF Fluoroscopy CCS	• St. Jude Medical	None	None	None	NIH, Data Safety and Monitoring—ATTRACT Trial	• Defendant, catheterization vascular access site complication, 2009
David Holmes	Content Reviewer—ACCF Interventional Scientific Council	None	None	None	None	Atritech	None
Fred Kushner	Content Reviewer—ACCF UA/NSTEMI Guidelines	None	None	None	None	None	None
Glenn N. Levine	Content Reviewer—ACCF PCI Guideline	None	None	None	None	None	• Defendant, patient nonresponsive after noncardiac surgery, 2010

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Lloyd W. Klein	Content Reviewer—SCAI Quality Improvement Committee	None	None	None	None	None	None
Shrihari Naidu	Organizational Reviewer—SCAI	• Abbott Vascular • Ablomed*	None	None	None	None	None
Bramajee Nallamothu	Content Reviewer—ACCF PCI STEMI/NSTEMI	• Abbott	None	None	NIH*	None	None
Patrick T. O'Gara	Content Reviewer—ACCF STEMI Guideline	None	None	None	• Lantheus Medical Imaging	None	None
Steven R. Ramee	Content Reviewer	• Neurointerventions*	None	• Access Closure* • Boston Scientific*	• Abbott • Boston Scientific • Edwards Lifesciences • Medtronic	• Hot Spur*	None
Charanjit Rihal	Content Reviewer—ACCF Interventional Scientific Council	• Paleon			• Edwards Lifesciences		
John F. Robb	Official Reviewer—ACC Board of Governors	None	None	None	None	None	None
John P. Reilly	Content Reviewer—SCAI Quality Improvement Committee	None	• Cordis • Lilly/ Daiichi Sankyo*	• Johnson & Johnson* • Medtronic*	None	None	None
James Tcheng	Content Reviewer—ACC-NCDR Board	None	None	None	• NIH*	None	None
Robert Vincent	Content Reviewer—ACCF Adult Congenital and Pediatric Cardiology Council	None	None	None	• AGA	None	None
Grayson Wheatley	Content Reviewer—ACCF Surgical Council	• Boston Scientific • Cordis • Medtronic • Pathway Medical • Spectranetics • W.L. Gore*	None	None	• Bolton Medical	• Bolton Medical	Plaintiff, aortic aneurysm, 2010
Christopher White	Content Reviewer—ACCF Interventional Scientific Council	None	None	None	• St. Jude	None	None
Mathew Williams	Organizational Reviewer—STS	• Abott • Edwards Lifesciences • Medtronic	None	None	None	None	None

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ACCF = American College of Cardiology Foundation; SVM = Society for Vascular Medicine; SCAI = Society for Cardiovascular Angiography and Intervention; CECD = Clinical Expert Consensus Documents; CCS = Clinical Competence and Training Statements; UA/NSTEMI = Unstable Angina/Non-ST-Elevation Myocardial Infarction; PCI = Percutaneous Coronary Intervention; NCDR = National Cardiovascular Data Registry; STS = Society of Thoracic Surgeons.

APPENDIX 3. ABBREVIATION LIST

ACS = acute coronary syndrome
ACT = activated clotting time
ADC = automatic dose control
ALARA = as low as reasonably achievable
AMI = acute myocardial infarction
aPTT = activated partial thromboplastin time
ASA = American Society of Anesthesiologists
ASE = American Society of Echocardiography
ASNC = American Society of Nuclear Cardiology
Atlantic C-Port-E = Atlantic Cardiovascular Patient Outcomes Research Team
AVA = Aortic Valve Area
BMS = bare-metal stent
BP = blood pressure
CABG = coronary artery bypass grafting
CARESS = Combined Abciximab Reteplase Stent Study in Acute Myocardial Infarction
CHF = congestive heart failure
CIN = contrast-induced nephropathy
CKD = chronic kidney disease
CME = continuing medical education
COCATS = The ACCF Core Cardiology Training Symposium
CON = Certificate of Need
COPD = chronic obstructive pulmonary disease
COURAGE = Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation
C-Port = Cardiovascular Patient Outcomes Research Team
CQI = Continuous Quality Improvement
CT = computed tomography
DAP = dose-area product
DQE = detective quantum efficiency
D2B = door-to-balloon times
ECMO = extracorporeal membrane oxygenation
ED = effective dose
eGFR = estimated glomerular filtration rate
FDA = Food and Drug Administration
fps = frames per second

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GFR = glomerular filtration rate
GRACE = Global Registry of Acute Coronary Events
HCG = human chorionic gonadotropin
HIPAA = Health Insurance Portability and Accountability Act
HIV = human immunodeficiency virus
HR = hemodynamic response
IHE = Integrating Health Care Enterprise
IMPACT = Improving Pediatric and Adult Congenital Treatment
IRP = interventional reference point
LA = left atrial
LCD = liquid crystal display
LM = left main
LV = left ventricular
LVEDP = left ventricular end-diastolic pressure
LVEF = left ventricular ejection fraction
MACCE = major adverse cardiac and cerebral events
MACE = major adverse cardiovascular events
MDRD = Modification of Diet in Renal Disease
MI = myocardial infarction
MRI = magnetic resonance imaging
NCDR = National Cardiovascular Data Registry
NCRP = The National Council on Radiation Protection and Measurements
NHLBI = National Heart, Lung, and Blood Institute
NRMI = National Registry of Myocardial Infarction
NSAIDs = nonsteroidal anti-inflammatory drugs
NYHA = New York Heart Association
PA = pulmonary artery
PACS = picture archiving and communication system
PCCL = pediatric cardiac catheterization laboratory
PCI = percutaneous coronary intervention
PFO = patent foramen ovale
QA = quality assurance
QI = quality improvement
RA = right atrial
RACE = Reperfusion of Acute Myocardial Infarction in Carolina Emergency Departments
RAID = redundant array of independent disks
RCT = randomized controlled trial
RV = right ventricular
STEMI = ST-elevation myocardial infarction
SVG = saphenous vein graft
SYNTAX = Synergy Between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery
TRANSFER-AMI = Trial of Routine Angioplasty and Stenting After Fibrinolysis to Enhance Reperfusion in Acute Myocardial Infarction

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EXHIBIT 5

Effective Date: 11/04/2009
Title: Section 709.14 - Cardiac services

709.14 Cardiac services. (a) These standards will be used to evaluate certificate of need applications for Cardiac Catheterization Laboratory Center services and Cardiac Surgery Center services. All need determinations are hospital site specific. It is the intent of the State Hospital Review and Planning Council that these standards, when used in conjunction with the planning standards and criteria set forth in section 709.1 of this Part, become a statement of planning principles and decision making tools for directing the distribution of Cardiac Catheterization Laboratory Center services and Cardiac Surgery Center services. These planning principles and decision making tools build on the existing regional resources that have been developed through the regulatory planning process. The goals and objectives of the standards expressed herein are expected to promote access to Cardiac Catheterization Laboratory Center services and Cardiac Surgery Center services, maintain provider volumes associated with high quality care, and avoid the unnecessary duplication of resources while addressing the geographic distribution of services necessary to meet the needs of patients in need of emergency percutaneous coronary interventional (PCI) procedures. Additionally, it is intended that the methodology provide sufficient flexibility to consider additional circumstances that reflect on the need for cardiac services.

(b) Cardiac Surgery Centers. The factors for determining the public need for Cardiac Surgery Center services shall include, but not be limited to the following:

(1) The planning area for determining the public need for Cardiac Surgery Center services shall include the applicant's designated Health Systems Agency (HSA) region and the use area of the applicant facility. For purposes of determining Cardiac Surgery Center services need, the use area of a facility is defined as the area within a 100 mile radius of the applicant facility.

(2) Planning for Cardiac Surgery Center services shall ensure that, to the extent possible, eighty percent of the total population of each HSA region resides within 100 miles of a facility providing cardiac surgical services.

(3) A facility proposing to initiate an Adult Cardiac Surgery Center must document a cardiac patient base and current cardiac interventional referrals sufficient to support a projected annual volume of at least 500 cardiac surgery cases and a projected annual volume of at least 300 PCI cases within two years of approval. The criteria for evaluating the need for additional Adult Cardiac Surgery Centers within the planning area shall include consideration of appropriate access and utilization, and the ability of existing services within the planning area to provide such services. Approval of additional Adult Cardiac Surgery Center services may be considered when each existing Adult Cardiac Surgery Center in the planning area is operating and expected to continue to operate at a level of at least 500 cardiac surgical procedures per year. Waiver of this planning area volume requirement may be considered if:

(i) the HSA region's age adjusted, population based use rate is less than the statewide average use rate; and

(ii) existing Adult Cardiac Surgery Centers in the applicant facility's planning area do not have the capacity or cannot adequately address the need for additional cardiac surgical procedures, such determinations to be based on factors including but not necessarily limited to analyses of recent volume trends, analyses of Cardiac Reporting System data, and review by the area Health Systems Agency(s); and

(iii) existing cardiac surgical referral patterns within the planning area indicate that approval of an additional service at the applicant facility will not jeopardize the minimum volume required at other

existing cardiac surgical programs.

(4) No finding of need for the addition of Pediatric Cardiac Surgery Center services will be made unless each existing Pediatric Cardiac Surgery Center service in the planning area is operating and expected to continue to operate at a level of at least 200 pediatric cardiac surgical procedures per year, and unless such existing Pediatric Cardiac Surgery Center services do not have the further capacity to meet projected need for additional pediatric cardiac surgical procedures. Where public need is established herein, a facility proposing to provide pediatric cardiac surgical services must demonstrate the ability to perform a minimum of 200 pediatric cardiac surgical procedures per year by the end of the second full calendar year of operation or demonstrate the ability to perform a minimum of 50 cases a year on-site and operate as part of a coordinated program based on a fully executed written agreement, approved by the Commissioner, with another pediatric cardiac surgery program in accordance with standards at 405.29(d)(5)(ii). For hospitals seeking approval as part of a coordinated program, the agreement must be submitted with the certificate of need application and must be approved by the Department prior to initiation of the service.

(5) A facility proposing to provide Adult and or Pediatric Cardiac Surgery Center services shall:

(i) submit a written plan to the Department of Health which, when implemented, will ensure access to cardiac surgical services for all segments of the HSA region's population. Such plan shall provide a detailed plan to reach patients not currently served within the planning area, ensure continuity of care for patients transferred between facilities, and shall otherwise promote planning for cardiac services within the region; and

(ii) propose a hospital based heart disease prevention program that, when implemented, shall include:

(a) Treatment plans for cardiac inpatients with a principal diagnosis of ischemic heart disease. These patients are at high risk for development of adverse cardiovascular events and the program shall provide for the following in a comprehensive, systematic way:

(1) protocols shall be developed and implemented for the assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle. Such protocols shall be in keeping with generally accepted standards;

(2) The hospital shall provide patient education that shall include, but not be limited to, information on the importance of assessing risk factors for heart disease in first-degree relatives, and the importance of cardiopulmonary (CPR) training for family members and care givers;

(3) Discharge plans must include:

(i) a request for consent to allow patient medical information to be shared with the patient's primary care providers;

(ii) patient referral to their primary care provider with documentation of treatments provided by the hospital and follow-up care recommended by the hospital; and

(iii) patient referral to cardiac rehabilitation programs appropriate to their needs.

(b) professional education:

(1) The hospital shall sponsor or co-sponsor at least three professional education programs per year

related to heart disease risk assessment and control and that are open to local community based health professionals.

(c) hospital-based heart health promotion:

(1) The program shall implement policies and health programs in the hospital and establish environments that promote heart-healthy behaviors among hospital staff, employees and visitors, including:

(i) prohibiting the sale and use of tobacco products on hospital premises;

(ii) offering and promoting, on a regular basis, healthful choices in hospital cafeterias and patient menus; and

(iii) offering employee wellness and fitness programs that provide opportunities for employees to make healthy choices.

(d) community based heart health promotion:

(1) The hospital shall organize or participate in a consortium of existing community-based organizations and key community leaders to engage in activities to improve cardiac health in the community; and

(2) organize or participate in at least one major community based campaign (not including health fairs) each year related to major heart disease risk factors.

(e) program administration:

(1) Hospitals shall identify a team within their organization to coordinate heart disease prevention activities. Members of the team shall include a broad range of expertise, including but not limited to: community organization, planning, and social marketing, public health skills and health education.

(6) When considering an application to meet public need for Adult and or Pediatric Cardiac Surgery Center services, priority consideration shall be given to the expansion of an existing service as opposed to the initiation of a new Cardiac Surgery Center.

(7) Where public need is established herein, priority consideration will be given to applicants that agree to serve the medically indigent and patients regardless of the source of payment.

(8) Applicants proposing to initiate an Adult and or Pediatric Cardiac Surgery Center service must:

(i) demonstrate the ability to comply with standards set forth in 405.29 (c), 405.29(d), and 711.4(h) of this Title; and

(ii) in addition, a facility providing Pediatric Cardiac Surgery Center services also must comply with the requirements specified in section 711.4(f) of this Title.

(9) All hospitals approved as Adult Cardiac Surgery Centers shall be approved as PCI Capable Cardiac Catheterization Laboratory Centers and must meet standards in Sections 405.29(c), 405.29(e)(1), and 405.29(e)(2) of this Title. All hospitals approved as Pediatric Cardiac Surgery Centers shall be approved as Pediatric Cardiac Catheterization Laboratory centers and must meet the standards at 405.29(c), 405.29(e)(1) and 405.29(e)(4) of this Title.

(c) For the purposes of this section the terms Cardiac Catheterization Laboratory Center, Percutaneous Coronary Intervention (PCI) Capable Cardiac Catheterization Laboratory Center, Cardiac Electrophysiology (EP) Laboratory Program and Pediatric Cardiac Catheterization Laboratory Center shall have the same meanings as in section 405.29 (a)(4) of this Title.

(d) Public need for Cardiac Catheterization Laboratory Centers:

(1) PCI Capable Cardiac Catheterization Laboratory Centers. The factors and methodology for determining the public need for PCI Capable Cardiac Laboratory Centers shall include, but not be limited to the following:

(i) PCI Capable Cardiac Catheterization Laboratory Centers at hospitals with a Cardiac Surgery Center on site. Applicants approved as Cardiac Surgery Centers are approved PCI Capable Cardiac Catheterization Laboratory Centers as provided under section 709.14 (b)(9) of this Part and must meet standards at Sections 405.29(c), 405.29(e)(1) and 405.29(e)(2) of this Title.

(ii) PCI Capable Cardiac Catheterization Laboratory Centers at hospitals with no cardiac surgery on site. Factors for determining public need for PCI Capable Cardiac Catheterization Laboratory Centers at hospitals with no cardiac surgery on-site include, but are not limited to:

(a) The planning area for determining the public need for PCI Capable Cardiac Catheterization Laboratory Centers at hospitals with no cardiac surgery on-site shall be the area within a 1 hour average surface travel time, as determined by the department of transportation and adjusted for typical weather conditions, of the applicant facility, unless otherwise determined by the Commissioner in accordance with section 709.1(c) of this title;

(b) Evidence that existing PCI Capable Cardiac Catheterization Laboratory Centers within the planning area cannot adequately meet the needs of patients in need of emergency percutaneous coronary interventions due to conditions such as capacity, geography, and or EMS limitations;

(c) Documentation by the applicant must demonstrate the hospital's ability to provide high quality appropriate care that would yield a minimum of 36 emergency PCI procedures per year within the first year of operation and would yield a minimum of 200 total PCI cases per year within two years of start-up.

(1) Documentation of the number of cardiologists on staff at the proposed site who currently perform percutaneous coronary interventions at other hospital sites and a summary of experience (including the most recent 3 years of volume and outcomes) for each.

(2) Documentation in support of volume projections must include, at a minimum: discharge data indicating the number of patients with a diagnosis of acute myocardial infarction (AMI) and/or other diagnoses associated with PCI, the number of doses of thrombolytic therapy ordered for acute MI patients in the applicant hospital's emergency department (as documented through hospital pharmacy records), and documentation of transfers to existing PCI Capable Cardiac Catheterization Laboratory Centers for PCI.

(3) Additional documentation that may be submitted in support of projected volume and need for a proposed PCI Capable Cardiac Catheterization Laboratory Center include:

(i) The number of acute care beds at the applicant hospital and the range of acute care services provided;

(ii) Documentation by the applicant of barriers that impact care experienced by specific population groups within the planning area and demonstration of cultural competency at the applicant site specific to the proposed populations to be served by the applicant;

(iii) Documentation by the applicant demonstrating outreach to underserved populations that identifies potential new PCI cases within the service area;

(iv) Emergency department discharge data;

(v) Documentation by the applicant of regional demographics and transport patterns within the applicant's Emergency Medical Service (EMS) Region that impact the provision of cardiac care;

(vi) The geographic distribution of PCI Capable Cardiac Catheterization Laboratory Center services and the ability of such existing centers to serve the patients in the applicant's service area;

(vii) Letters from local physicians quantifying the number of PCI referrals from their practice and the portion of those that would have been treated at the applicant facility if PCI had been available;

(viii) Additional information that may be considered in projecting volume for an applicant from an established Article 28 network, or multi-site facility as defined at section 401.1 of this Title, with an approved Cardiac Surgery Center within its system that is seeking to add a PCI Capable Cardiac Catheterization Laboratory Center at a non-cardiac surgery hospital site within the system and for a co-applicant proposing to operate a PCI Capable Cardiac Catheterization Laboratory Center without surgery onsite, under a co-operator agreement, approved by the department, with an existing Cardiac Surgery Center. Such additional volume projection criteria include documentation by the applicant of the number of patients residing in the service area of the proposed site who have received percutaneous coronary interventions at the Cardiac Surgery Center site and who would have been candidates to receive their procedures at the proposed non-surgery site.

(d) Existing referral patterns indicate that approval of an additional service at the applicant facility will not jeopardize the minimum volume required at other existing PCI Capable Cardiac Catheterization Laboratory Centers and one of the following conditions exists:

(1) The proposed PCI Capable Cardiac Catheterization Laboratory Center is located more than one hour average surface travel time, as determined by the department of transportation and adjusted for typical weather and traffic conditions, from the nearest existing PCI Capable Cardiac Catheterization Laboratory Center; or

(2) All existing PCI Capable Cardiac Catheterization Laboratory Centers within one hour average surface travel time of the applicant facility, as determined by the department of transportation and adjusted for typical weather and traffic conditions, perform and are expected to continue to perform at a level of at least 300 PCI procedures per year after the addition of the proposed new program. Evidence for evaluating this expectation shall include, but not be limited to:

(i) Data indicating the number of patients residing in the applicant's primary service area who are currently receiving percutaneous coronary intervention procedures at existing centers and the location of the centers where patients are receiving that care;

(ii) Volume at existing PCI Capable Cardiac Catheterization Laboratory Centers within one hour of the applicant hospital;

(iii) Analysis provided by the applicant evaluating the portion of its proposed patient case load that would result in a redistribution of cases from existing centers and the portion that would represent new cases from currently under served populations. Such analysis shall include documentation of any outreach programs by the applicant facility that would support projections of new cases.

(e) A written plan submitted by the applicant that demonstrates the hospital's ability to comply with standards for PCI Capable Cardiac Catheterization Laboratory Centers at sections 405.29(c), 405.29(e)(1) and 405.29(e)(2) of this Title;

(f) A written plan submitted by the applicant that outlines staff training and demonstrates the hospital's readiness to accommodate the needs of the PCI patients;

(g) A written plan has been submitted by the applicant which would promote access to Cardiac Catheterization Laboratory Center services for all segments of the hospital service area's population. The document shall include:

(1) a description of current and proposed initiatives for improving outcomes for patients with heart disease,

(2) a plan documenting the hospital's ability to maintain a comprehensive program in which high quality interventional procedures are provided as a component of a broad range of cardiovascular care within the hospital and within the community, to include an emphasis on processes of care and a description of how a patient will traverse through the system of care to be offered,

(3) a plan for ensuring continuity of care for patients transferred between facilities,

(4) documentation of outreach to regional EMS councils served by the applicant,

(5) documentation that EMS system capabilities have been taken into consideration in the delivery of cardiac services;

(6) a description of activities that promote planning for cardiac services within the region; and

(7) a description of current and proposed initiatives and strategies for reaching patients not currently served within the area.

(h) Comments and recommendations received from community organizations;

(i) The hospital shall propose and implement a hospital heart disease prevention program as set forth at section 709.14(b)(5)(ii) of this Part;

(j) Where public need is established herein, priority consideration shall be given to applicants that agree to serve the medically indigent and patients regardless of payment and can document a history of the provision of services to populations that experience health disparities.

(k) Where public need is established herein, priority consideration shall be given to applicants that can demonstrate projected volume in excess of 300 PCI cases a year.

(l) Where public need is established herein, priority consideration will be given to the expansion of an existing service as opposed to the initiation of a new service.

(m) A written and signed affiliation agreement with a New York State Cardiac Surgery Center, acceptable to the department, has been submitted in accordance with standards at Section 405.29(c)(8)(i) of this title.

(n) In addition, hospital applicants proposing to jointly operate a PCI Capable Cardiac Catheterization Laboratory Center at a hospital without cardiac surgery on-site under a co-operator agreement with a Cardiac Surgery Center must:

(1) Submit a written and signed operational agreement between the applicant Cardiac Surgery Center and the applicant hospital without cardiac surgery on site that demonstrates there will be an integration of expertise and resources from the Cardiac Surgery Center that would support a high quality program at the proposed site and that is acceptable to the department. The agreement must specify that the department shall be provided 60 day prior written notification of any proposed change, termination or expiration of the agreement, and any changes must be found acceptable to the Department prior to implementation. The agreement shall further provide that the parties agree that termination or expiration of the agreement shall result in closure of the co-operated Cardiac Catheterization Laboratory Center.

(2) Submit documentation that demonstrates high quality cardiac care is provided at the applicant Cardiac Surgery Center site and that expanding the service to the proposed site would serve as a benefit to patients and the community.

(3) Submit written documentation of governing body approval of the co-operator contract.

(2) Cardiac EP Laboratory Programs. Factors for determining public need for Cardiac EP Laboratory Programs shall include but not be limited to the following:

(i) Each applicant for a Cardiac EP Laboratory Program shall be an approved PCI Capable Cardiac Catheterization Laboratory Center or an approved Diagnostic Cardiac Catheterization Service operating in compliance with standards at sections 405.29(c) and 405.29(e). Applicants for EP laboratory programs will also be considered in conjunction with requests for approval of PCI Capable Cardiac Catheterization Laboratory Center services.

(ii) Each applicant shall submit documentation, describing how the hospital will comply with standards at 405.29(e)(5) of this Title.

(iii) Each applicant shall submit documentation of existing referrals for cardiac electrophysiology patients treated by cardiologists on staff at the hospital.

(iv) Applicants for cardiac EP Laboratory Programs at hospitals with no Cardiac Surgery Center on-site must submit a copy of the patient selection criteria for the proposed program in accordance with the standards at section 405.29(e)(5)(iii) of this Title.

(v) Hospitals approved as Cardiac Surgery Centers shall be deemed to have demonstrated public need to perform cardiac electrophysiology.

(3) Pediatric Cardiac Catheterization Laboratory Centers. Public need for a Pediatric Cardiac Catheterization Laboratory Center shall be determined only in conjunction with an application for a Pediatric Cardiac Surgery Center and when need has been demonstrated for Pediatric Cardiac Surgery Centers in accordance with standards at Section 709.14(b) of this Part.

July 12, 2012
TSH Page 268

Volume: D

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

July 12, 2012 VIA FAX

Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.
265 Chruch Street
Once Century Towner,
New Haven, CT 06510

RE: Certificate of Need Application; Docket Number: 12-31748-CON
Yale-New Haven Hospital and Greenwich Hospital
Proposal to Establish and Operate an Elective Angioplasty

Order

On July 12, 2012, the Office of Health Care Access ("OHCA") received a petition from The Stamford Hospital requesting Intervenor Status with Full Procedural Rights. Any responsive document shall be filed no later than 10 am, Monday, July 16, 2012.

Joanne V. Yandow, Attorney
Hearing Officer

Cc: Stephen M. Cowherd, Esq. Jeffers Cowherd, P.C.

****
*** TX REPORT ***
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RESULT	OK

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: JENNIFER GROVES, ESQ.

FAX: (203) 772-2037

AGENCY: UPDIKE, KELLY & SPELLACY

FROM: STEVEN LAZARUS

DATE: 7/12/12 **TIME:**

NUMBER OF PAGES: 2
(including transmittal sheet

Comments: Docket 12-31748-CON

PLEASE PHONE IF THERE ARE ANY TRANSMISSION PROBLEMS.

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*** TX REPORT ***
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TRANSMISSION OK

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STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: STEPHEN M. COWHERD, ESQ.

FAX: (203) 259-1070

AGENCY: JEFFERS COWHERD P.C.

FROM: STEVEN LAZARUS

DATE: 7/12/12 **TIME:**

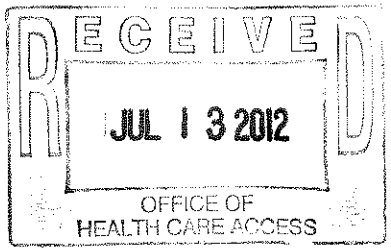
NUMBER OF PAGES: 2
(including transmittal sheet

Comments: Docket 12-31748-CON

PLEASE PHONE IF THERE ARE ANY TRANSMISSION PROBLEMS.

Greer, Leslie

From: Anna Mastroianni <AMastroianni@jeffers-law.com>
Sent: Friday, July 13, 2012 9:45 AM
To: Lazarus, Steven; Greer, Leslie
Subject: Missing Pages from TSH Pre-File
Attachments: 4 files [19 7-13-2012 09].ZIP



Steve,

Per our phone conversation, attached are revised copies of Drs. Kiely and Gray's pre-file testimonies. The only changes are found at the very end of the testimony with the insertion of **"THIS PAGE LEFT INTENTIONALLY BLANK"**. In addition to the PDFs of the testimonies, I have also PDFed only the pages that require insertion. Shall I still fax or do you prefer to print the pages from the PDF (rather than make copies of faxed pages?)?

Pages 19 and 20 should be submitted into Dr. Kiely's testimony and pages 12,13, and 14 should be submitted into Dr. Gray's testimony.

My apologies for the confusion and for the extra work this morning.

Regards,
Anna

Anna Mastroianni
Jeffers Cowherd P.C.
55 Walls Drive
Fairfield, CT 06824
Tel: (203) 259-7900 ext. 244
Fax: (203) 259-1070

BEFORE THE OFFICE OF HEALTH CARE ACCESS DIVISION OF THE DEPARTMENT OF PUBLIC HEALTH	:	Docket No. 12-31748-CON
IN RE APPLICATION OF YALE-NEW HAVEN HOSPITAL AND GREENWICH HOSPITAL TO ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM AT GREENWICH HOSPITAL	:	July 12, 2012

Pre-File Testimony of Sharon Kiely, M.D.

Good morning Deputy Commissioner Davis and Office of Health Care Access ("OHCA") staff. My name is Sharon Kiely, and I am Senior Vice-President of Medical Affairs and Chief Medical Officer for The Stamford Hospital ("Stamford" or the "Hospital"). I am here today to explain the reasons why Stamford strongly believes that, at a time when elective angioplasty volumes are flat to declining in the state and with no volume growth in Applicants' proposed service area, there is no clear public need for Yale-New Haven Hospital ("Yale") and Greenwich Hospital ("Greenwich") (collectively, the "Applicants") to establish an elective angioplasty ("PCI") program without on-site surgical back-up at Greenwich.

My remarks today will focus on the following four areas: (i) the stagnant PCI volume that I just mentioned as well as similar trend in cardiac catheterization procedures; (ii) the fact that Southwestern Connecticut and Eastern Westchester County residents already have ample access to high quality elective PCI programs, including the White Plains Hospital elective angioplasty program that did not even exist three years ago when Greenwich and Yale's prior application for a five-year demonstration project of this same service was denied; (iii) the very speculative nature of Applicants' volume projections and (iv) the fact that collaboration among hospital providers to better serve the residents of the service area

should override any institution's own self-interest in establishing this unnecessary program. A copy of my Curriculum Vitae is attached as Exhibit 1 to my testimony.

Elective PCI Volumes are Flat in Both Connecticut and the Proposed Service Area

In denying Greenwich and Yale's earlier application under Docket No. 08-31210-CON, OHCA cited "declining statewide PCI volumes" as one of the primary reasons it was "unable to conclude that the proposed demonstration project would improve the quality and accessibility of care provided in the Greenwich area..." Final Decision, Docket No. 08-31210-CON ("Final Decision") p. 16. OHCA also pointed out that this was particularly true "in light of the availability of full service cardiac care programs in Fairfield County." Final Decision, p. 16. Nothing has changed in this regard.

Statewide inpatient PCI volumes, which capture both primary angioplasty and elective procedures, have continued to decline through 2010 as evidenced by hospital discharges. This trend is displayed in the graph and table below which were prepared by OHCA and posted on its website as part of its Statewide Health Care Facilities and Services Planning activities.

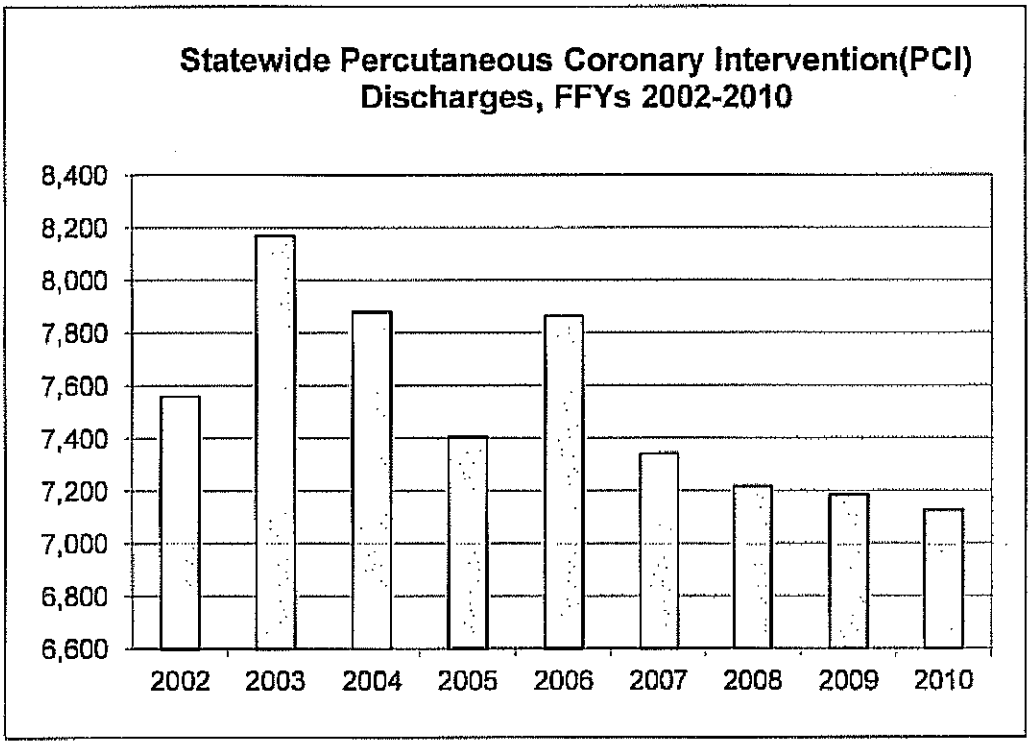


Table 2A: PCI discharges by provider, FFYs 2002-2010

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	FFY 06-10 (5-yr) % Change	FFY 08-10 (3-yr) % Change	FFY 09-10 (1-yr) % Change
Bridgeport	1,191	1,249	1,288	1,052	692	560	580	428	379	-45%	-35%	-11%
CT Children's								2	0	n/a	n/a	n/a
Danbury	0	0	0	0	453	409	330	326	277	-39%	-16%	-15%
Dempsey	452	464	453	519	401	353	376	334	368	-8%	-2%	10%
Greenwich	0	0	0	20	38	32	40	40	32	-16%	-20%	-20%
Hartford	1,312	1,463	1,321	1,282	1,246	1,206	1,093	1,031	1,122	-10%	3%	9%
Hospital of Central CT	0	0	0	26	61	70	60	74	69	13%	15%	-7%
Lawrence & Memorial	0	0	0	0	41	-	29	74	74	80%	155%	0%
New Milford	0	0	0	0	0	6	11	11	0	n/a	-100%	-100%
Norwalk								14	57	n/a	n/a	307%
St. Francis	1,192	1,253	1,349	1,223	1,170	1,188	1,171	1,232	1,030	-12%	-12%	-16%
St. Mary's	0	0	0	59	297	246	251	255	291	-2%	16%	14%
St. Raphael	715	970	924	708	680	632	595	534	523	-23%	-12%	-2%
St. Vincent's	1,063	1,035	1,085	1,150	1,181	1,101	1,124	958	925	-22%	-18%	-3%
Stamford	0	0	0	9	39	34	45	159	151	287%	236%	-5%
Waterbury	0	0	0	61	347	373	325	361	361	4%	11%	0%
Yale	1,635	1,715	1,460	1,297	1,218	1,131	1,186	1,352	1,469	21%	24%	9%
Total	**7,560**	**8,169**	**7,880**	**7,406**	**7,864**	**7,341**	**7,216**	**7,185**	**7,128**	**-9%**	**-1%**	**-1%**

Source : CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database

ICD-9-CM Procedure Codes: .66, 36.01, 36.02, 36.05, 36.06 and 36.07

Please note: unduplicated counts utilizing all procedure codes

(Available on OHCA website at http://www.ct.gov/dph/lib/dph/ohca/hc_facilities_advisory_body/actcarambusrg_subcomt_cardiachandout.pdf)

In order to account for the shift to outpatient PCI procedures, Stamford also looked to the Patient Census Report produced by the Connecticut Hospital Association ("CHA") which captures both inpatient and outpatient volume.[1] This data is presented in the table below and indicates that statewide PCI volumes, inclusive of both inpatient and outpatient PCIs, have declined in recent years.

FY 2008 -2011 Total PCI Volume Statewide

Year	Volume
2008	9,039
2009	9,287
2010	9,176
2011	8,882

Source: Connecticut Hospital Association, Patient Census Report. *See* Exhibit 2.

In addition, to the extent that cardiac catheterization volume is used to predict PCI volume, statewide cardiac catheterization discharges have decreased as well. The inpatient decrease through 2010 is clearly displayed in the graph and chart on the following pages that OHCA also prepared.

[1] Among the limitations of the PCR data are the facts that: 1) data self-reported by CT hospitals; 2) no independent validation of the data using a separate source; 3) reporting subject to different interpretations by individual hospitals of the definitions; and 4) difficulty in comparing an individual hospital's experience across fiscal years due to changes, for example, in coding and billing.

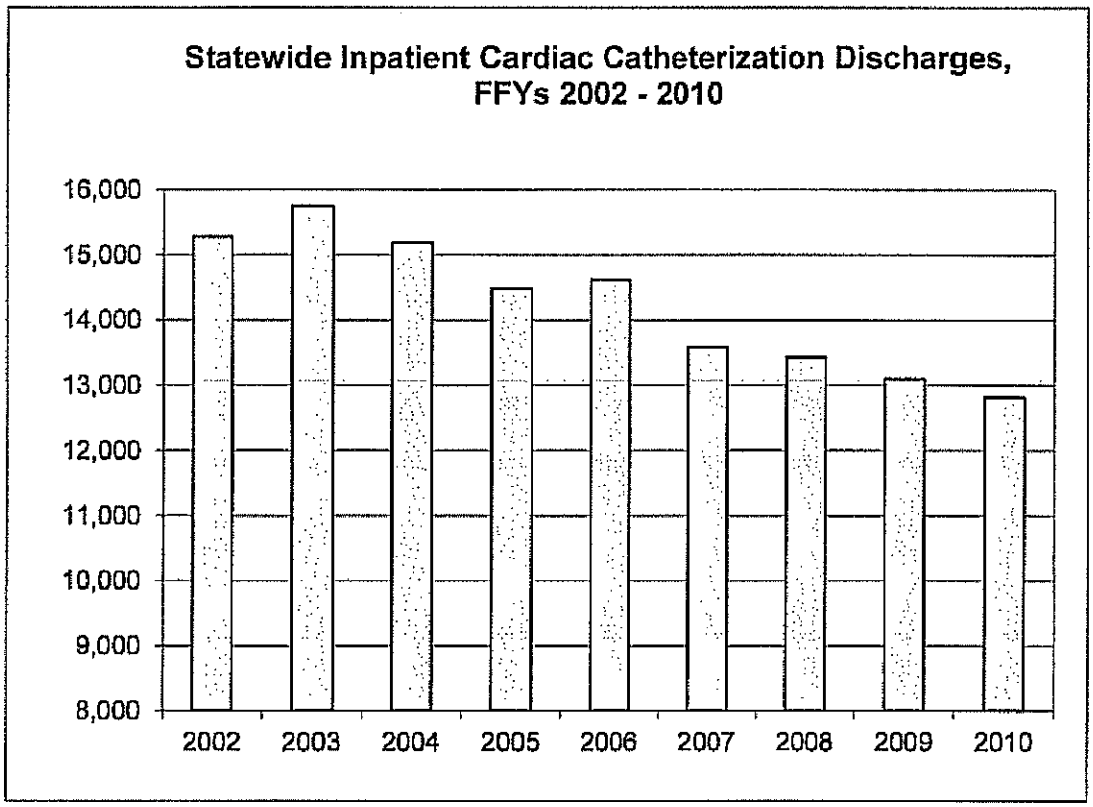

Statewide Inpatient Cardiac Catheterization Discharges,
FFYs 2002 - 2010
16,000
15,000
14,000
13,000
12,000
11,000
10,000
9,000
8,000
2002
2003
2004
2005
2006
2007
2008
2009
2010

Table 1A: Inpatient cardiac catheterization discharges by provider, FFYs 2002-2010

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	FFY 06-10 (5-yr) % Change	FFY 08-10 (3-yr) % Change	FFY 09-10 (1-yr) % Change
Backus	156	210	200	170	116	53	106	135	115	-1%	8%	-15%
Bridgeport	1,148	1,185	1,274	1,129	902	809	817	632	626	-31%	-23%	-1%
CT Children's								10	5	n/a	n/a	-50%
Danbury	263	299	260	327	748	533	475	452	418	-44%	-12%	-8%
Dempsey	519	564	633	640	487	439	480	419	462	-5%	-4%	10%
Greenwich	100	42	35	106	167	158	163	177	166	-1%	2%	-6%
Hartford	2,546	2,405	2,241	2,128	2,135	2,032	2,008	1,833	1,892	-11%	-6%	3%
Hospital of Central CT	448	465	409	411	436	401	319	344	269	-38%	-16%	-22%
Lawrence & Memorial	420	473	466	393	414	303	337	440	503	21%	49%	14%
Middlesex	28	169	168	150	182	142	161	138	138	-24%	-14%	0%
New Milford	0	0	0	22	37	38	65	37	0	-100%	-100%	-100%
Norwalk	247	203	195	182	128	67	77	104	126	-2%	64%	21%
Rockville	0	79	99	24	4	3	0	0	0	-100%	n/a	n/a
St. Francis	2,742	2,802	2,800	2,656	2,421	2,543	2,431	2,292	2,206	-9%	-9%	-4%
St. Mary's	291	299	260	307	519	469	455	480	469	-10%	3%	-2%
St. Raphael	1,744	1,878	1,833	1,496	1,383	1,200	1,113	1,062	1,098	-21%	-1%	3%
St. Vincent's	1,276	1,259	1,324	1,432	1,554	1,540	1,562	1,375	1,267	-18%	-19%	-8%
Stamford	354	352	296	299	311	297	293	358	321	3%	10%	-10%
Waterbury	451	477	367	412	658	622	611	675	608	-8%	0%	-10%
Yale	2,549	2,587	2,330	2,200	2,021	1,939	1,954	2,135	2,129	5%	9%	0%
Total	**15,282**	**15,748**	**15,190**	**14,484**	**14,623**	**13,588**	**13,427**	**13,098**	**12,818**	**-12%**	**-5%**	**-2%**

Source: CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database.

ICD-9-CM Procedure Codes: 37.21-37.23

Please note: unduplicated counts utilizing all procedure codes

(Available on OHCA website at http://www.ct.gov/dph/lib/dph/ohca/hc_facilities_advisory_body/actcarambusrg_subcomt_cardiachandout.pdf)

Again, to capture any shift to outpatient cardiac catheterizations, Stamford looked to the Patient Census Reports generated by CHA.[2] Like the total statewide volume of inpatient and outpatient PCIs discussed above, this data indicates that total statewide cardiac catheterization volume (inclusive of inpatient and outpatient procedures) is flat to declining as evidenced by the chart below.

[2] Please see footnote 1 for a discussion of the limitations of the PCR data.

FY 2008 -2011 Total Cardiac Catheterization Volume Statewide

Year	Volume
2008	21,777
2009	21,606
2010	22,533
2011	21,120

Source: Connecticut Hospital Association, Patient Census Report. *See* Exhibit 2.

This data certainly does not establish the need for an additional provider in Southwestern Connecticut. As you can also see from the charts prepared by OHCA above, the decreases in inpatient PCI and cardiac catheterization volume have been felt by almost every hospital provider in the state, including each of the four existing full service cardiac programs in Fairfield County (Danbury, St. Vincent's, Bridgeport and Stamford).

As for the specific service area that Applicants have identified for their proposed elective PCI program, the trends do not appear markedly different from what they are in Connecticut statewide. The tables on the next page, evidencing discharges of residents from Greenwich's Connecticut and New York service area from Connecticut and New York hospitals, show that from FY 2009 through 2011, inpatient cardiac catheterization and PCI volumes have decreased in the service area:

FY 2009-2011 Inpatient Cardiac Catheterization Volume in Proposed Service Area

State	FY 09	FY 10	FY 11
CT Service Area*	1,000	948	808
NY Service Area**	1,443	1,355	1,353
Total	2,443	2,303	2,161

*The CT Service Area is made up of Darien, Greenwich, New Canaan, Norwalk, Stamford, Weston and Westport. (*See* Application at p. 24)
** The NY Service Area is made up of Armonk, Bedford, Bedford Hills, Harrison, Hartsdale, Katonah, Larchmont, Mamaroneck, Mount Kisco, Mount Vernon, New Rochelle, Port Chester, Round Ridge, Purchase, Scarsdale, South Salem, West Harrison, and White Plains. (*See* Application at p. 24)
Source: CT Chime and NY SPARCS database. *See* Exhibit 3.

FY 2009-2011 Inpatient Coronary Angioplasty (PCI) Volume in Proposed Services Area

State	FY 09	FY 10	FY 11
CT Service Area*	598	610	429
NY Service Area**	844	775	772
Total	1,442	1,385	2,001

*The CT Service Area is made up of Darien, Greenwich, New Canaan, Norwalk, Stamford, Weston and Westport.
** The NY Service Area is made up of Armonk, Bedford, Bedford Hills, Harrison, Hartsdale, Katonah, Larchmont, Mamaroneck, Mount Kisco, Mount Vernon, New Rochelle, Port Chester, Round Ridge, Purchase, Scarsdale, South Salem, West Harrison, and White Plains.
Source: CT Chime and NY SPARCS database. .*See* Exhibit 3.

Applicants did not provide any of this data in their CON Application because they know it in no way supports their proposal. They also have not provided any credible reasons why these utilization trends will change in the future.

There also has not been any increase in Greenwich's own emergency PCI volumes that would suggest a need for an elective angioplasty program at their hospital. In the three year period before Greenwich submitted its prior application for an elective PCI program, it performed 38, 33 and 41 primary angioplasties, respectively, and in the three year period

before this Application, it performed 40, 32 and 38 primary angioplasties, respectively. Final Decision, pg. 4; Application, Docket No. 12-31748-CON ("Application"), p. 30. As you can see, Greenwich's own primary angioplasty volume has not grown at a level that suggests the need for an additional elective PCI program in the service area.

Residents of the Proposed Service Area Already Have Ample Access to PCI Services

The map titled "Cardiac Services in Connecticut – January 2011" from the State of Connecticut, Certificate of Need Database, (attached to my testimony as Exhibit 4) shows all four Fairfield County hospitals – St. Vincent's, Bridgeport Hospital, Danbury Hospital and Stamford – that operate within or adjacent to the Applicants' proposed Connecticut service area. Each of these hospitals offers primary and elective angioplasty services with cardiac surgery back-up. In addition, both Greenwich and Norwalk Hospitals offer primary PCI programs. Furthermore, Greenwich Hospital's Connecticut service area, as identified in the Application, is identical to Stamford's primary and secondary service area, and the two hospitals are located a mere six (6) miles apart. *See* Application, p. 24. For Applicants not to mention the existence of Stamford Hospital's cardiac program until page 28 of their Application and for them to state on page 29 that their proposal will not result in unnecessary duplication of existing or approved health care services is quite remarkable given these overlapping service areas and the close proximity of our hospitals. Even if you disregard the fact that Stamford Hospital and Greenwich Hospital operate right next to each other, one glance at the map we have provided is enough to tell you that if there is a need for a groundbreaking elective PCI program without on-site surgery in this state, it does not exist in Fairfield County.

In considering the lack of volume growth cited above, it is also important to note that the White Plains Hospital elective angioplasty program began operating in 2010, making the field of elective PCI providers in the Applicants' proposed service area even more crowded than it was in 2009 when Applicants' previous application was denied. White Plains Hospital is located approximately ten miles to Greenwich Hospital's west. This means that if this Application is approved, three (3) elective angioplasty programs will operate within sixteen (16) miles of each other. How can that possibly make sense or be an appropriate balance of health care services? The answers are that it doesn't and it can't, especially in a time of zero volume growth.

That the Greenwich Hospital and White Plains programs will severely overlap in the proposed New York service area is borne out by the data. In FY 2011, WPH performed 165 total PCIs, with 110 of these procedures performed on residents of Greenwich Hospital's New York service area. *See* Exhibit 5. Attached to my testimony as Exhibit 6 is a letter from Susan Fox, Executive Vice President of White Plains Hospital which describes that Hospital's elective angioplasty program in more detail and sets forth its position on the pending Application. This letter verifies that the Westchester County market targeted by Applicants is well served not only by WPH but by a host of other providers including the Westchester County Medical Center, Montefiore Medical Center, New York Presbyterian-Weill Cornell Medical Center, New York Presbyterian-Columbia University Medical Center, Lenox Hill Hospital and Mount Sinai Medical Center. This being the case, Applicants' certainly cannot rely on a lack of capacity in New York to establish clear public need for their proposal.

The situation in Fairfield and Westchester Counties is clearly different from the eastern part of Connecticut as presented by Lawrence & Memorial Hospital ("L&M") in its

recent application for an elective angioplasty program without on-site cardiac surgery in New London, a copy of which is attached hereto as Exhibit 7 ("L&M Application"). While Greenwich Hospital is located a mere 6 and 10 miles from Stamford Hospital and WPH, respectively, L&M is located 48, 49 and 61 miles from its nearest elective PCI providers.[3] L&M Application, p. 20. I would also note that L&M's annual primary angioplasty volume is approximately two times higher than Greenwich's. L&M Application, p. 40; Application, p. 31. At least with respect to these factors, L&M's application demonstrates that if OHCA were to approve an elective PCI program without surgical backup, such a program is far better suited for the eastern part of Connecticut where local access to elective PCI programs is much more limited.

This is in contrast to the towns and cities in the service area that Greenwich and Yale propose to serve in their Application, where there is a plethora of existing providers that can easily accommodate the number of cardiac patients that need elective angioplasty procedures. In sum, Applicants have not presented any data or other evidence of backlogs or scheduling problems at any of these hospitals, nor have they provided any evidence of existing facilities failing to provide high quality services to patients. Given the absence of any evidence of need and the absence of any evidence of a lack of access to elective PCI in the service area, Applicants' proposal should be denied.

[3] L&M is located 48 miles from St. Francis Hospital, 49 miles from Yale, 49 miles from Hartford Hospital and 61 miles from Miriam Hospital in Providence.

GH's Volume Projections are Suspect and Do Not Support Approval of the Proposal

With PCI and cardiac catheterization volumes remaining stagnant and more providers than ever vying to treat the same pool of patients, it also does not make sense that Applicants can now project even higher volumes in the first three years of operation for their current proposal (196, 217 and 242 cases, respectively) than they could three years ago in their prior application when they projected 120, 150 and 200 cases, respectively. Application, p. 31; Final Decision, p. 9. Furthermore, Applicants project a greater number of PCIs in the first three (3) years of their proposed program than L&M projects in the first three (3) years of its proposed program, despite the fact that L&M currently performs far more primary PCIs than does Greenwich Hospital, as discussed above. Application, p. 31; L&M Application, p. 41. This also seems illogical.

The present Application goes to great lengths to state that Greenwich Hospital's cardiac catheterization volumes are down because physicians prefer to refer patients to facilities that also perform elective PCI, and the Applicants predict this volume will rebound if the proposed elective angioplasty program is approved. Application, pgs. 23, 32-33. However, this argument is belied by the steady downward trend in inpatient cardiac catheterization at hospitals that already provide elective PCI. On this point, I refer you to the data for Stamford, Danbury, Bridgeport and St. Vincent's contained in the chart on page 6 of my testimony.

A flaw also exists in Applicants' methodology for estimating cardiac catheterization volume (which plays a role in their PCI volume projections). Greenwich's projected cardiac catheterization volume is based on the results of a telephone survey of cardiologists and large internal medicine practices on its medical staff who were asked to "estimate" the number of

cases that they would refer for cardiac catheterizations if Greenwich Hospital obtained approval for its elective PCI program. Application, p. 33. This is no way equates to utilization studies and other more traditional methods of estimating volume. Also, the Applicants state that the increase in "volume" will result from "the addition of New York interventional cardiologists who currently do not practice at Greenwich Hospital but have referral relationships with the cardiologists on the Hospital medical staff." Application, p. 34. This is simply a shift of existing volume, and Applicants fail to address the impact of this shift on existing providers.

Strip away the projected volume that comes from the speculative methodology that I have just described, and the average of 38 primary angioplasty cases per year that Greenwich and Yale also built into the volume estimates contained at page 31 of the Application, and what you are left with is an elective PCI program designed to serve an exceedingly small number of elective patients. This population is described by the Applicants as "approximately 50 patients each year who would not have to be transferred to another hospital if Greenwich Hospital could perform elective angioplasty." Applicants' Responses to Completeness Questions, Docket No. 12-31748-CON ("Responses"), p. 589; Application p. 31. These 50 cases are the only tangible volume on which Applicants can rely. Stamford Hospital respectfully suggests that approving an elective PCI program without surgical back-up to treat 50 patients per year in a market that is already well served is not a wise allocation of resources, especially when Stamford and White Plains Hospital are located just six and ten miles away from Greenwich Hospital, respectively.

Collaboration Not Self-Interest Should Take Precedence In Improving Care for Patients

In opposing this Application, Stamford Hospital also wishes to note that heart disease

is a public health issue that can be addressed in many ways besides creating an unnecessary proliferation of elective PCI programs. A report issued by the state Department of Public Health last November, that is attached to my testimony at Exhibit 8, states that heart disease death rates in Connecticut declined by 28.7% between 1999 and 2008 as a result of improved control of high blood pressure and high cholesterol, a decline in the prevalence of smoking and improvements in treatments, medications and quality of care.

All health care providers, Stamford, Greenwich and Yale-New Haven Hospital included, have a responsibility to see that these positive trends continue. In this case, there is more than adequate access to top quality elective PCI treatment in the proposed service area, but this does not foreclose other ways for hospitals and other healthcare providers to join together to combat heart disease.

The CON Application that is presently before OCHA clearly demonstrates that there is room for more collaboration between Stamford and Greenwich Hospitals as only 2 out of 246 patients requiring transfer from Greenwich to another facility for elective PCI since 2008 were transferred to our facility. This is despite the close proximity of the two institutions and despite Applicants' basing their Application on the need for local access to elective PCI. Application, p. 23 ("Patients prefer to be treated locally, close to their residence and family members.")

As my predecessor as Chief Medical Officer for Stamford Hospital, Dr. John Rodis, indicated during the public hearing on the Applicants' prior application three years ago, Stamford Hospital has an open medical staff and is more than willing to extend privileges to qualified physicians from the Yale School of Medicine and Greenwich's medical staff so that their patients can receive elective PCI at our facility and be followed during their course of

treatment. OHCA appropriately raised the question of why Stamford Hospital – which except for certain areas of Greenwich is closer in proximity than Greenwich Hospital to every Connecticut town that Applicants hope to serve through this proposal -- was being bypassed as a treatment site for its elective PCI patients. Responses, p. 587. The answers that OHCA received to this question, including the statement that "the medical staffs at the two hospitals are quite distinct and there are only a handful of physicians who treat at both locations," do not present any obstacles that cannot be overcome if our two hospitals are committed to working together for the good of the community. Responses, p. 588. This will avoid the unnecessary duplication of elective PCI services caused by this proposal, will foster collaboration and will improve the overall efficiency of the healthcare delivery system.

In addition, while I know Dr. Gray will speak about the clinical literature in more detail, I do want to point out that the *2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention* clearly states that "desires for personal or institutional financial gain, prestige, market share or other similar motives are not appropriate considerations for initiation of PCI programs without on-site cardiac surgery." *2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: a Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiogrpahy and Interventions,* Attachment VI to the Application, p. 164.[4] Again, OHCA appropriately inquired in its completeness questions as to how Applicants were acting consistently with this guidance if they were basing a good part of their need argument on the costs Greenwich presently incurs to support its primary angioplasty program and how an elective PCI program "would reduce the costs per case of the present

[4] Page reference is to Attachment VI.

arrangement." Application, pp. 15, 20; Responses, p. 598.

In their responses, Applicants stress that Greenwich Hospital's considerations for the proposed program "address cost-effectiveness and not institutional financial gain", but they then go on to say the following:

> The current primary angioplasty program is extremely costly to operate. ... By offering an elective angioplasty program along with the primary program, the additional case volume and associated revenues will help to offset the significant fixed costs which exist for the primary program alone and would help fortify the primary PCI program and ensure its continued survival for this necessary service needed by the community served by Greenwich Hospital.

Responses, p. 598 (emphasis added).

Applicants can engage in semantics if they want, but clearly the above language describes the financial gains that Greenwich Hospital hopes to realize if this proposal for an elective PCI program is approved. While Stamford Hospital is not unsympathetic to Greenwich's financial concerns, the fact is that all hospitals face enormous financial challenges in the current health care environment and most provide services to the public that lose money. Nevertheless, the 2011 ACCF/AHA/SCAI Guideline flatly states that financial considerations are inappropriate in this context, and we would urge OHCA to follow this important guidance by denying this unnecessary proposal.

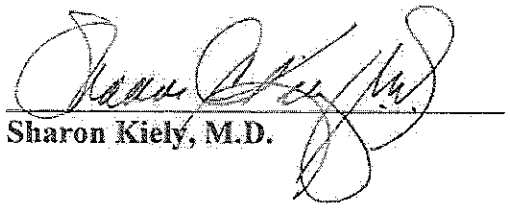
My final remark on this point is that it was less than a decade ago that Yale repeatedly went on record before OHCA stating that there was no need for additional interventional cardiac programs in Connecticut.[5] In the intervening years, three full service programs (two of which are in Fairfield County -- Stamford and Danbury Hospital) have been added, the use of non-interventional methods of treating heart disease have flourished and PCI volumes have not grown. It cannot be that an Applicant that did not see a need for expansion of PCI services then sees one now.

Conclusion

In summary, Stamford Hospital very much appreciates the importance of OHCA's mission to promote effective health planning in the state and its statutory duties to ensure access to high quality health care for Connecticut residents while avoiding unnecessary duplication. Effective health planning in this case would be to deny Applicants' proposal. To do otherwise would result in the establishment of what almost certainly will be a low volume program that will need to drive down volumes at neighboring intuitions, including Stamford Hospital, to survive. None of those outcomes would contribute to the provision of high quality health care or the financial stability of the delivery system.

[5] *See, e.g.,* YNHH Petition for Party Status in Danbury Hospital CON for Open Heart and Elective Angioplasty Services, Docket # 03-30143, p.5 ("There is clearly no need for additional cardiac surgery of elective angioplasty services in Connecticut."); YNHH Petition for Party Status in Waterbury/St. Mary's Hospital CON for Open Heart and Elective Angioplasty Services, Docket # 03-30176, p.5 ("There is clearly no need for additional cardiac surgery or elective angioplasty services in Connecticut."); YNHHHI Petition for Intervenor Status in Norwalk Hospital CON for Open Heart and Primary and Elective Angioplasty Services, Docket # 04-30286, p.10 ("The Applicant has not demonstrated any clear public need for such additional services, and granting the Applicant's proposal would be detrimental to quality and cost-effectiveness of cardiac care in Connecticut and thus inconsistent with the interest of patients and payors."); and YNHHHI Petition for Intervenor Status in Stamford Hospital CON for Open Heart and Primary and Elective Angioplasty Services, Docket # 04-30374, p. 6 ("Residents of the greater Stamford area have full and appropriate access to all levels of cardiac care.")

Thank you for the opportunity to speak with you today, and I am happy to answer any questions.



Sharon Kiely, M.D.

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BEFORE THE OFFICE OF HEALTH CARE ACCESS DIVISION OF THE DEPARTMENT OF PUBLIC HEALTH	:	Docket No. 12-31748-CON
IN RE APPLICATION OF YALE-NEW HAVEN HOSPITAL AND GREENWICH HOSPITAL TO ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM AT GREENWICH HOSPITAL	:	July 12, 2012

Pre-File Testimony of William A. Gray, M.D.

Good morning Deputy Commissioner Davis and Office of Health Care Access ("OHCA") staff. My name is William Gray, and I am an Associate Professor of Clinical Medicine at Columbia University and Director of Endovascular Services for the New York Presbyterian Hospital/Columbia University Medical Center ("NYP/C"). I am here today to speak in opposition to the Yale-New Haven Hospital and Greenwich Hospital (the "Applicants") Certificate of Need ("CON") Application to provide elective angioplasty ("PCI") without cardiac surgery on site ("SOS") at Greenwich Hospital.

NYP/C has worked closely with Stamford Hospital in the operation of its elective angioplasty and open heart surgery program. Accordingly, my remarks today will be focused in three areas. First, I will discuss the recent *2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: a Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions* (the "2011 ACCF/AHA/SCAI Guideline"), and the *2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update* (the "2012 ACCF/SCAI Update"), including what both documents state regarding PCI

without SOS and how these statements are relevant to the CON Application currently before OHCA.

Secondly, I will discuss the application of the 2011 ACCF/AHA/SCAI Guideline and 2012 ACCF/SCAI Update to the proposed service area. Finally, I will share my view of where the field of interventional cardiology is headed and why approval of this CON Application would appear inconsistent with creating the resources necessary to provide state-of-the-art care.

Professional Background

My professional background is described in the Curriculum Vitae attached as Exhibit 1 to my testimony. Briefly, I am a graduate of Temple University School of Medicine and did my postgraduate and fellowship training in cardiology as well as interventional cardiology at Brown University/Rhode Island Hospital. I am board certified in Internal Medicine, Cardiology and Interventional Cardiology as well as in Vascular and Endovascular Medicine and have focused my entire career on interventional cardiology. The interventional cardiology team with whom I presently practice performs more than 3,500 interventional procedures a year, and our cath lab has consistently achieved low morbidity and mortality rates to help NYP/C achieve ranking as one of the top heart hospitals in the U.S. During my career, I have performed approximately 4,000 coronary interventions.

The ACCF/AHA/SCAI Guideline Does Not Endorse Applicants' Program

If there is one concept that is important for OHCA to take away from my presentation today it is that the science is still evolving regarding the safety and efficiency of providing elective angioplasty without SOS. As I will explain in a moment, the 2011 ACCF/AHA/SCAI Guideline has only moved incrementally in this area. To my mind, that is a good thing because, despite reference in Yale and Greenwich's Application to "the routine nature" of elective PCI

procedures (Application, p. 19), we are still talking about a coronary intervention where any risk of complication can have dire consequences for the patient.

At the time of Greenwich Hospital's 2009 CON Application to establish an elective angioplasty without SOS demonstration project (the "Prior Application"), the then current PCI Guideline classified elective PCI performed in facilities without SOS as a Class III recommendation, stating that "elective PCI should not be performed at institutions that do not provide onsite cardiac surgery." *See 2005 ACCF/AHA/SCAI Guideline Update for PCI a Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines* ("2005 ACCF/AHA/SCAI Update"), p. 39, attached as Exhibit 2 to my testimony. The Class III recommendation meant that a "procedure/treatment should NOT be performed/administered SINCE IT IS NOT HELPFUL AND MAY BE HARMFUL." 2005 ACCF/AHA/SCAI Update, p. 5 (emphasis in original).

The current 2011 ACCF/AHA/SCAI Guideline, which is contained in Greenwich and Yale's current CON Application at Attachment VI, now assigns a Class IIb indication to elective PCI without SOS and states that it "might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical angiographic criteria are used for patient selection … (Level of Evidence: B)." 2011 ACCF/AHA/SCAI Guideline, p. 164 (page references are to Attachment VI). A Class IIb indication still bespeaks caution, however, since it means (i) that the benefit may equal or exceed the risk, (ii) that additional studies with broad objectives are needed and additional registry data would be helpful and (iii) that the procedure MAY BE CONSIDERED. 2011 ACCF/AHA/SCAI Guideline, p. 144 (emphasis in original). A Class IIb recommendation should give all of us in the health care community pause since it falls far short of both a Class I recommendation, which

means that the benefit of the procedure far outweighs the risk and should be performed and a Class IIa recommendation where the benefit is much greater than the risk and it has been determined that it is reasonable to perform the procedure. *Id.* (emphasis added).

In their CON Application, Yale and Greenwich Hospital also rely heavily on the results of the Cardiovascular Patient Outcomes Research Team Non-Primary PCI ("CPORT-E") trial to argue that elective PCI without SOS is both safe and efficacious. Application, p. 15. While I concur that the results of the CPORT-E trial were promising, I believe that this is too rash of a statement to make.

Attached to my testimony at Exhibit 3 is a recent New England Journal of Medicine article that summarizes the results of CPORT-E. The overall conclusion of the trial was that, with respect to all-cause mortality at 6 weeks and major adverse cardiac events at 9 months, outcomes at hospitals without SOS were "noninferior" to those at hospitals with SOS. Noninferior is a scientific term used in the context of clinical trials which means that a new treatment (here, elective PCI without SOS) was found to be equivalent to the standard treatment (elective PCI with SOS) in the study, but the term does not mean that the treatment is preferred over performing PCI with cardiac backup on site. Complications in elective angioplasty cases performed on low-risk patients are not common, but they happen. And when they do, it is far better to have cardiac surgical back-up on site than to have to transfer the patient to a full service hospital.

Even in the CPORT-E trial there were differences in outcomes that are worthy of further investigation. For example, the trial participants in CPORT-E that were treated at hospitals without SOS more frequently required target-vessel revascularization (6.5% among participants

at hospitals without SOS and 5.4% among participants at hospitals with SOS). Only further research will determine whether this finding is significant or not.

CPORT-E was a large, randomized clinical trial, but it is still only one study. While there have been other demonstration projects and non-SOS PCI programs established around the country, the 2011 ACCF/AHA/SCAI Guideline still states in pertinent part as follows:

> It is only appropriate to consider initiation of a PCI program without on-site surgical back-up if those programs will clearly fill a void in the healthcare needs of the community. Competition with another PCI program in the same geographic area, particularly an established program with surgical back-up, may not be in the best interests of the community.

2011 ACCF/AHA/SCAI Guideline, p. 164.

My understanding is that Yale and Greenwich have taken the peculiar position that the language quoted above pertains only to Class III indications because it follows the "Class III: Harm" heading in the 2011 ACCF/AHA/SCAI Guideline document (Responses to Completeness Questions, Docket No. 12-31748-CON ("Responses"), pgs. 592, 597-98). I do not agree and believe the more accurate interpretation is that this cautionary language pertains to all PCI programs at hospitals without SOS, as is suggested by the quoted text. My reasons for this view follow.

First, as discussed earlier, the "Class III: Harm" indication means that a procedure should not be performed since it may be harmful to patients. 2011 ACCF/AHA/SCAI Guideline, p. 144. Secondly, the Guideline definitively states that primary or elective PCI should not be performed at all in hospitals without SOS unless a proven plan for rapid transport to a nearby hospital with the appropriate facilities or appropriate hemodynamic support capability for transfer exists. 2011 ACCF/AHA/SCAI Guideline, p. 164. Accordingly, if a PCI program would lack the appropriate transfer methods such that it would be given a "Class III: Harm"

indication, there would be no need to consider initiation of the non-SOS PCI program in the first place. Additionally, it makes no sense to think that the 2011 ACCF/AHA/SCAI Guideline would not consider the relevant marketplace and availability of treatment from other providers when establishing this type of interventional cardiac service since the clinical literature on PCI has shown that there is a relationship between quality and the volume of cases performed by individual operators and hospitals. Therefore, the language about it being "only appropriate to consider initiation of a PCI program without on-site surgical back-up if these programs will clearly fill a void in the healthcare needs of the community" is relevant to all PCI programs at hospitals without SOS.

As further evidence of my position, the quoted language in the 2011 ACCF/AHA/SCAI Guideline appears immediately above Tables 5 and 6, which list the expert consensus document personnel and facility requirements for PCI programs without SOS. Applicants admit that these requirements are relevant to their proposal and, in fact, went to great lengths to provide OHCA with evidence of their compliance with the standards. Responses, pp. 592-97. Thus, despite these tables being listed after the "Class III: Harm" heading, and after the language which Yale and Greenwich contend does not apply to them, both hospitals acknowledge that the information in Tables 5 and 6 applies to their program. In short, the Applicants cannot have it both ways so that some of the information under the Class IIII Harm heading applies to them and some does not. The better interpretation is that this very common-sense and cautionary language from the ACCF/AHA/SCAI consensus document applies to any proposed program for elective PCI without SOS.

In addition, the 2012 ACCF/SCAI Update, attached as Exhibit 4 to my testimony, clearly states that the issue of performing PCI without SOS "remains controversial" especially when

other active PCI programs are located within the same geographic area. 2012 ACCF/SCAI Update, p. 19. Accordingly, the 2012 ACCF/SCAI Update states as follows: "It behooves the cardiology community to foster [elective PCI programs without SOS] only when such programs improve access to a higher level of cardiovascular care than would otherwise be available." 2012 ACCF/SCAI Update, p. 19. This statement, which echoes the language quoted above from the 2011 ACCF/AHA/SCAI Guideline, is not qualified as pertaining only to Class III recommendations since, as previously discussed, such a qualification would not make sense. What the language in the 2012 ACCF/SCAI Update does is reiterate the concept that such a program should be established in areas where access to programs with surgical back-up is lacking.

Lastly, I have been shown a copy of the Lawrence & Memorial Hospital ("L&M") CON Application that Dr. Kiely referenced in her testimony. Clearly, it is the aim of that hospital to partner with the Yale system to provide an elective angioplasty without SOS in the eastern part of Connecticut. And I note that, just as clearly, L&M readily accepts that part of its burden under the 2011 ACCF/AHA/SCAI Guideline and 2012 ACCF/SCAI Update is to show that the program it is proposing "clearly fills a void in the healthcare needs of the community." *See* L&M CON Application, pp. 13, 17, 21 and 34.

Application of the Guidelines to the Proposed Service Area

As has already been discussed by Dr. Kiely, there is no debating that lower Fairfield County and Westchester County residents already have ample access to elective angioplasty services. Two hospitals located within the proposed service area (Stamford Hospital and White Plains Hospital) already provide elective PCI while a number of others, including the New York Presbyterian-Columbia University Medical Center, also serve the residents of these communities.

This being the case, there is no void in the healthcare system that needs to be filled by yet another provider.

In addition, the 2011 ACCF/AHA/SCAI Guideline also states that competition with another PCI program in the same geographic area, particularly an established program with surgical back-up like Stamford Hospital's, may not be in the best interests of the community. 2011 ACCF/AHA/SCAI Guideline, p. 164. Here these are several reasons why approving the Greenwich-Yale proposal might be a disservice to the residents of Fairfield and Westchester counties.

First, given the lack of volume growth and the number of established programs in (and around) the service area, there is a real risk that the Greenwich Hospital program will not exceed 200 cases per year if approved. There is also a real risk, if this proposal is approved, that the region will then have three PCI programs – Greenwich Hospital, White Plains Hospital, which performed 290 PCI procedures in fiscal year ("FY") 2011 (250 elective and 40 emergency cases), and Stamford Hospital, which performed 250 PCIs in FY 2011 (191 elective and 59 emergency) – each performing fewer than 200 PCIs per year. The recommendations contained in the 2011 ACCF/AHA/SCAI Guideline at page 164 make clear that the goal of the White Plains and Stamford programs from a quality perspective should be to become high volume centers performing more than 400 procedures per year.

This is because, as I previously noted, there continues to be a correlation between quality and hospital volumes associated with PCI programs and falling below the 200-case volume threshold is not recommended. On this point, the 2011 ACCF/AHA/SCAI Guideline states that "[a]n institution with a volume of fewer than 200 procedures per year, unless in a region that is

underserved because of geography, should carefully consider whether it should continue to offer this service." 2011 ACCF/AHA/SCAI Guideline, p. 193.

Creating a scenario where three underperforming programs are in close proximity to one another could undermine quality of care at each hospital and, although I do not want to believe such a thing could happen, this could also result in doctors feeling pressure to refer patients for procedures to keep institutional volumes up. Occurrences like these will only drive up healthcare costs for payers and patients. These costs to the healthcare delivery system – not to mention the costs associated with poor patient outcomes due to any diminution in quality – are also likely to dwarf the savings on ambulance rides and other expenses that Applicants claim will be realized by no longer having to transfer approximately 50 patients per year from Greenwich to Yale for an elective PCI procedure. Application p. 20; Responses pp. 599-60.

It is my understanding that OHCA often looks to the laws and regulations of other states to help develop regulations and other CON guidance in Connecticut. In this spirit, it is worth noting that the State of New York has adopted special regulations for the determination of public need for PCI programs without SOS. These regulations are attached to my testimony at Exhibit 5. Notably, one of the CON requirements that New York has adopted for approving a new PCI Capable Cardiac Catheterization Laboratory Center (which is defined as a laboratory that performs percutaneous coronary and other percutaneous procedures to diagnose and treat abnormalities of the heart or great vessels in adult patients), is that:

> existing referral patterns indicate that approval of an additional service at the applicant facility will not jeopardize the minimum volume required at other existing PCI Capable Cardiac Catheterization Laboratory Centers and one of the following conditions exists:
>
> (1) The proposed PCI Capable Cardiac Catheterization Laboratory Center is located more than one hour average surface travel time ... from the nearest existing PCI Capable Cardiac Catheterization Laboratory Center; or

> (2) All existing PCI Capable Cardiac Catheterization Laboratory Centers within one hour average surface travel time of the applicant facility ... perform and are expected to continue to perform at a level of at least 300 PCI procedures per year after the addition of the proposed new program...

N.Y. Comp. Codes R. & Regs. tit. 10, § 709.14(d)(1)(ii)(d).

Accordingly, if Greenwich Hospital were subject to CON jurisdiction in New York, it is difficult to envision its current proposal gaining approval given the close proximity of both Stamford Hospital and White Plains Hospital and the respective PCI volumes of each institution.

In summary, there is no way to read the 2011 ACCF/AHA/SCAI Guideline without coming to the logical conclusion that PCI-only cardiac programs are best situated in geographic regions where access to PCI services is limited. This is not the case in either Southwestern Connecticut or Westchester County where access to many high quality programs abounds.

PCI-Only Programs Do Not Represent Interventional Cardiology's Future

In preparing for my testimony today, I also learned that, in addition to Greenwich Hospital, there are currently three other hospitals in this state operating standalone primary angioplasty programs and that at least two of those – Hospital of Central Connecticut and Lawrence & Memorial Hospital – have also applied to OHCA recently to be able to provide elective angioplasty without SOS. I realize that the potential of having every standalone primary PCI program in this state converted to an elective PCI program without SOS and perhaps every community hospital providing this same service creates some real policy and health planning challenges for OHCA. While I am not an expert in health policy or planning, I would like to close my remarks today by commenting briefly on why I do not see effective interventional cardiology programs at hospitals being built around the limited scope of services that PCI-only programs provide.

To the contrary, it is my view and the view of many of my colleagues that the future of cardiac care is moving toward the development of comprehensive centers of excellence, where, for example, the same facility can offer PCI as well as a variety of other interventional services. Rather than only focusing on angioplasty procedures, these state-of-the-art facilities will allow interventional cardiologists and surgeons to immediately follow a diagnostic procedure with a therapeutic one regardless of whether that entails a valve replacement, performing cardiac ablation, revascularizing a patient with a stent or performing another type of interventional procedure. For example, at NYP/C, we have several operating rooms that used to be dedicated exclusively to CABG and other types of cardiac surgery which have been converted to "hybrid" operating suites that are outfitted with the latest diagnostic imaging technology so physicians have the flexibility to perform many of these procedures. The treatment the patient receives combines some of the technological and clinical components of both PCI and cardiac surgery in many cases.

It is in these types of therapies, like transcatheter aortic valve implantation (TAVI) procedures that my colleagues at NYP/C have pioneered for patients with severe aortic stenosis, where the real breakthroughs in cardiac care are being made. Only full-service cardiac programs can support this work. To my mind, it is services like these – not the proliferation of low volume PCI programs without SOS – that will provide much more value to patients and the overall health care delivery system over the next 5 to 10 years.

Thank you for providing me with the opportunity to speak before you today, and I am happy to answer any questions.

William A. Gray, M.D.

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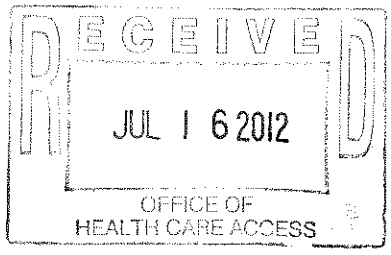
Greer, Leslie

From: Lazarus, Steven
Sent: Monday, July 16, 2012 9:55 AM
To: Hansted, Kevin; Martone, Kim; McGovern, Rosemary M.; Yandow, Joanne; Greer, Leslie; Olejarz, Barbara
Subject: FW: YNHH and GH Rebuttal Testimony and Procedural Motions DN: 12-31748
Attachments: DN 12-31748_GREENWICH_YNHH_REBUTTALTESTIMONY_MOTIONS_July 16 2012.pdf

Please see the attached information the Applicants filed as required before 10 am. They will bring hardcopies to the public hearing instead of having it delivered today, as they normally do.

Steven



Steven W. Lazarus
Associate Health Care Analyst
Office of Heaalth Care Access
A Division of Department of Public Health
410 Capitol Avenue
Hartford, CT 06134
Phone (Direct): 860.418.7012
Fax (Main): 860.418.7053

From: Banoff, Karen [mailto:Karen.Banoff@YNHH.ORG]
Sent: Monday, July 16, 2012 9:45 AM
To: Lazarus, Steven; Huber, Jack
Cc: JGroves@uks.com
Subject: YNHH and GH Rebuttal Testimony and Procedural Motions DN: 12-31748

Hi Steve and Jack-
Please find attached our rebuttal testimony and procedural motions for the above referenced Docket. Please email back that you received? We will be faxing a copy to Attorney Cowherd.

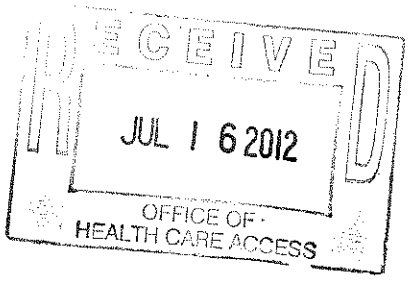
Hard copies will be delivered by noon to OHCA.

Thanks, Karen

Karen M. Banoff
(203) 459-1601

This message originates from the Yale New Haven Health System. The information contained in this message may be privileged and confidential. If you are the intended recipient you must maintain this message in a secure and confidential manner. If you are not the intended recipient, please notify the sender immediately and destroy this message. Thank you.

YALE NEW HAVEN HEALTH



July 16, 2012

Joanne V. Yandow
Hearing Officer
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P. O. Box 340308
Hartford, CT 06134

Re: Certificate of Need Application (CON); Docket Number 12-31748
Proposal to Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital

Dear Hearing Officer Yandow:

Please find enclosed an original and six (6) copies of our rebuttal testimony and procedural motions for tomorrow's public hearing on July 17, 2012.

We will bring signed copies of the rebuttal testimony to the hearing.

Thank you in advance for your time and effort on this critically important CON application.

Sincerely,

Gayle L. Capozzalo
Executive Vice President, Strategy and System Development

Enclosures

Copy to: Stephen M. Cowherd, Jeffers Cowherd P.C.

Yale-New Haven Hospital
Greenwich Hospital

Proposal to Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital

Docket Number: 12-31748-CON

Rebuttal Testimony

July 16, 2012

Certificate of Need Application Docket Number: 12-31748
Greenwich Hospital and Yale New Haven Hospital Elective Angioplasty Program
Rebuttal Testimony

Marna Borgstrom

I would like to begin by addressing some of the statements made by Dr. Sharon Kiely which are either incorrect or misleading.

- It is ironic that Dr. Kiely would raise the need for collaboration among Stamford, Greenwich and Yale-New Haven Hospitals in her testimony given Stamford Hospital's refusal to pursue such collaboration. Yale-New Haven Heart and Vascular Center (YNHHVC) began to discuss collaboration opportunities with Stamford Hospital in March 2012. There were a total of six telephone calls (3/9/12, 4/25/12, 5/4/12, 5/25/12, 6/21/12, and 7/3/12) and multiple email exchanges between Ms. Gayle Capozzalo, our Executive Vice President for Strategy and System Development, and Mr. David Smith, Stamford Hospital's Senior Vice President of Strategy and Chief Strategy and Network Development Officer. In addition, there was a face-to-face meeting held on May 22, 2012 with several representatives including cardiac surgeons and cardiologists from all three hospitals. Stamford Hospital representatives clearly communicated that they were unhappy with the level of support from New York Presbyterian (NYP) and were very interested in developing a relationship with YNHHVC. It was agreed by all three hospitals that there were many opportunities for collaboration, and in fact, an outline of principles was developed as well as a draft letter of intent (LOI) for the arrangement (See Attachment I). We were told by Mr. Smith, that the terms as outlined in the LOI were acceptable to Stamford Hospital. These terms included as an initial focus initiating an elective PCI program at Greenwich Hospital (Attachment I, Principles, Section 3). Our follow-up calls to Mr. Smith regarding the arrangement and the elective angioplasty program at Greenwich Hospital were abruptly discontinued on July 3, 2012, when Mr. Smith informed us that they will be opposing our CON application because he said there was not time to meet with NYP to discuss the concept of transferring an affiliation to

YNHHVC. Ms. Capozzalo will be in attendance at the hearing and can address her discussions with Stamford Hospital under oath.

YNHHVC and Greenwich Hospital fully intended to collaborate with Stamford Hospital in the area of cardiac care and had sought to help strengthen Stamford's open heart surgery program, which is suffering from low volume. The presence of Yale faculty based in southwestern Connecticut communities along with the YNHHVC's clinical program support and quality improvement systems would have significantly improved Stamford Hospital's cardiac surgery program's credibility, which is at significant risk, evidenced by the fact that they performed only 80 open heart cases last year and are on track to perform approximately 50 this fiscal year based on 6 months volumes from CHIME (see Table below).

Connecticut Inpatient Volume for Open Heart Surgery by Hospital for FY 2010 - FY 2012 (6 Months)				
Hospital	FY 2010	FY 2011	FY 2012*	
Bridgeport	152	127	140	
Danbury	181	182	150	
Dempsey	67	71	72	
Hartford	793	801	702	
HSR	343	313	300	
St. Francis	867	781	734	
St. Mary's	118	100	114	
St. Vincent's	239	223	200	
Stamford	54	80	54	
Waterbury	109	102	104	
YNHH	869	800	820	
TOTAL	**3,792**	**3,580**	**3,390**	
Source: CHIME				
*FY 2012 annualized based on 6 months actual				

It is clear that YNHHVC acted in good faith to create a cost effective care model for cardiology services in the Stamford and Greenwich area, but it is Stamford Hospital that does not want to collaborate.

- I would also like to point out that Stamford Hospital's extremely low cardiac surgery volume does not come close to meeting professional society recommendations or OHCA's own standards as outlined in the Agreed Settlement for Stamford Hospital (DN: 04-30374-CON) (see Attachment II). Condition #8 states:

  > "If TSH does not perform 125 OHS procedures within twelve months of the initiation of the OHS program, TSH shall submit monthly reports of OHS arrayed by physician to OHCA until such time as these volumes are met by TSH. **If these volumes are not met for a period of <u>two consecutive 12-month periods</u>, TSH's OHS program <u>shall be terminated</u>..."**

  We are not aware that this condition has been modified by OHCA based on a review of OHCA's website and modifications pursued by Stamford Hospital.

  According to OHCA's own data (see Attachment III) through 2010, Stamford Hospital has never come close to reaching 125 open heart surgeries in a year. In fact, it appears that its highest volume was 80 in FY 2011. As previously shown above, based on 6 months of CHIME data for 2012, they are on track to perform about 54 surgeries this year, less than half of the guidelines requirement. These low volumes have been of concern to YNHHVC physicians and we suspect have contributed to fewer referrals to their surgery program. Low surgical volume can also affect the physicians' decisions to transfer patients to Stamford for elective angioplasty, given the uncertain quality of the surgical backup available at that site. Such low surgical volumes present a significant quality concern as identified by the American College of Surgeons which published that an annual volume of 100-125 is **<u>necessary</u>** from a quality standpoint and this requirement has also been noted by OHCA in its draft Cardiac Services section of the new State Health Plan (see Attachment IV).

- Dr. Kiely states that OHCA should not approve Greenwich Hospital's proposed elective angioplasty program because elective angioplasty volumes are flat in Connecticut and the proposed service area. Stamford Hospital did not previously view flat or declining volumes as problematic when it pursued its full service cardiac program CON. At that time, their own cardiac catheterization volumes had been in decline as noted in OHCA's

Agreed Settlement's Findings of Fact #11 (previously referenced as Attachment II); statewide inpatient cardiac catheterization and angioplasty volumes had declined steadily between 2003 and 2005, as shown in Dr. Kiely's own testimony and open heart surgery volumes had also been declining between 2002 and 2005 as shown in the OHCA table and graph below.

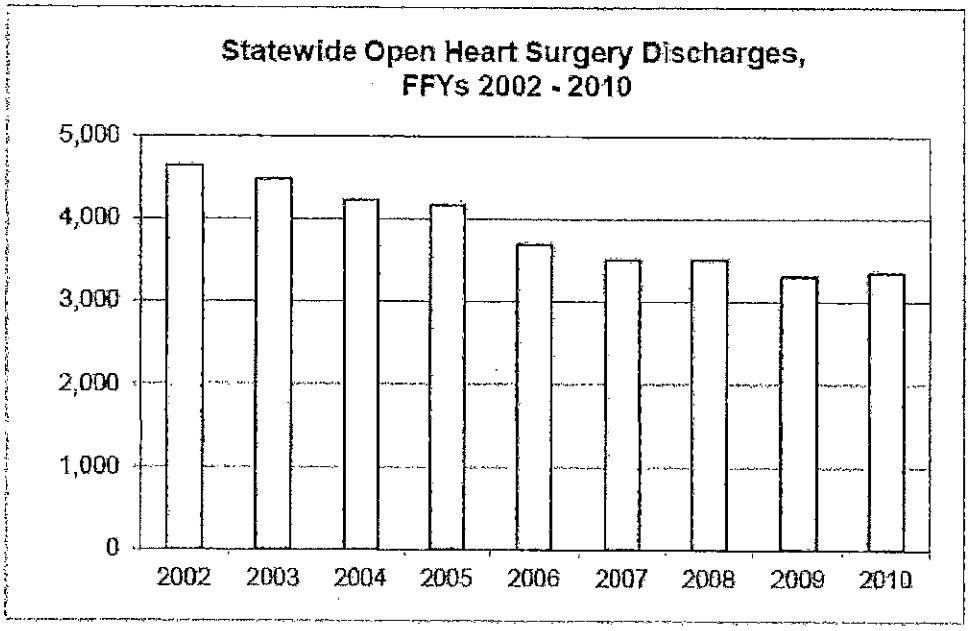
Table 3A: Open heart surgery discharges by provider, FFYs 2002-2010

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	FFY 05-10 (5-yr)% Change	FFY 08-10 (3-yr)% Change	FFY 09-10 (1-yr) % Change
Bridgeport	345	313	268	263	175	194	106	96	136	-22%	28%	42%
CT Children's								6	4	n/a	n/a	na
Danbury	0	0	0	114	177	121	162	148	174	-2%	7%	-9%
Dempsey	115	134	121	174	97	70	84	56	58	-40%	-31%	-33%
Hartford	901	844	756	726	742	685	671	652	695	-6%	4%	-3%
St. Francis	1,239	1,299	1,311	1,188	998	990	912	845	820	-18%	-10%	-7%
St. Mary's	0	0	0	19	72	100	85	114	112	56%	32%	34%
St. Raphael	761	687	617	510	353	342	321	299	318	-10%	-1%	-7%
St. Vincent's	310	296	293	291	259	232	257	219	195	-25%	-24%	-15%
Stamford	0	0	0	0	0	0	75	73	46	n/a	-39%	-3%
Waterbury	0	0	0	20	117	110	134	110	98	-16%	-27%	-18%
Yale	973	905	860	861	704	664	698	691	697	-1%	0%	-1%
Total	4,644	4,478	4,226	4,166	3,694	3,508	3,505	3,309	3,353	-9%	-4%	-6%

Source: CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database.

ICD-9-CM Procedure Codes: 35.10-35.28 and 36.10-36.19

Please note: unduplicated counts utilizing all procedure codes



All of these related and declining volumes did not seem relevant to Stamford Hospital or OHCA as a full service cardiac program was proposed and approved. Stamford Hospital expended more than $8 million dollars in capital expenses to develop their angioplasty and surgery program in a declining volume market (modified from the $5.4 million they estimated at the time of their original CON filing). They based their need on such factors as improved accessibility, continuity of care and improved quality. These are the same reasons why Greenwich Hospital seeks to offer elective angioplasty and can do so without any capital expense.

- Dr. Kiely's testimony includes conflicting statistics and information about New York programs. First, I would like to highlight the following statement from OHCA's 2010 Declaratory Ruling, Docket Number: 09-31433-DCR, which specifically states that:

  "...OHCA only has the authority to act on behalf of the state within the parameters of its enabling statutes and its jurisdiction is limited to health care facilities located within the state. Thus, OHCA has no jurisdiction over health care facilities located in other states just as those states have no authority to regulate facilities located within Connecticut."

Given the language from the above mentioned Declaratory Ruling, as well as the OHCA enabling statutes, it is clear that the agency has no jurisdiction over New York hospitals and their positions regarding this CON application are not relevant. This is likely why White Plains Hospital has submitted its arguments through Stamford Hospital rather than petitioning for status itself.

Even if one considers the information presented about and from White Plains Hospital, there are inconsistent and incorrect statements provided that call into question its credibility. Dr. Kiely states that White Plains Hospital performed 165 total PCIs in FY 2011 in her written testimony and attached a patient origin volume report with the same statistic. Ms. Fox states in her letter that in FY 2011, 290 PCIs were performed at White Plains Hospital. Additionally, Ms. Fox states in her letter that "two hospitals that serve Westchester County residents – Sound Shore Medical Center in New Rochelle and St. John's Riverside in Yonkers -...have been unsuccessful in attempts to gain regulatory approval from the New York Department of Health to provide elective angioplasty services." This statement is inaccurate and misleading. As shown in Attachment V, the email correspondences between Ms. Nancy Rosenthal, Senior Vice President – Health Systems Development at Greenwich Hospital and Anna Colello, Esq., Director of Regulatory Compliance and Cardiac Services Program at the New York State Department of Health, St. John's Riverside withdrew its application in April of this year and the Sound Shore application remains open.

It is also worth noting that within the email correspondences just referenced, New York State currently has 14 hospitals operating elective angioplasty programs without onsite cardiac surgery and one additional program was recently approved but has not yet opened.

- Dr. Kiely claims that flaws exist in our methodology for estimating cardiac catheterization and angioplasty volume. As OHCA is aware, developing projected volume for any proposed service involves multiple considerations and OHCA does not prescribe to a specific methodology for projecting need. Our projections include the

historical volume of emergency angioplasty, transferred (from Greenwich Hospital) elective angioplasty cases, cases referred to YNHH initially, as well as a conservative estimates provided by Greenwich Hospital cardiologists during a telephone survey conducted by Greenwich Hospital's Director of Planning, Ms. Nancy Hamson. Ms. Hamson personally spoke with the medical cardiologists on the staff of Greenwich Hospital, who are not active at Stamford Hospital and obtained their volume estimates. Ms. Hamson will be in attendance at the hearing and can address her methodology under oath. These physicians currently bypass Greenwich Hospital for cardiac catheterization referrals when they suspect an angioplasty procedure may be required, to save their patients from having to undergo two invasive procedures. They do not refer cases to Stamford Hospital. In addition, we have two interventional cardiologists who subsequent to the submission of the CON application have come forward and put in writing their intention to bring 80 – 105 angioplasty cases per year to Greenwich Hospital. These two physicians do not perform invasive cardiac procedures at Stamford Hospital. Their volumes were not even considered when the projections were developed and therefore demonstrate the conservative nature of our projections.

- Dr. Kiely states that since Greenwich Hospital's emergency angioplasty volume has not increased, there is no need for an elective angioplasty program. As I am sure Dr. Kiely is aware, the criteria for emergency angioplasty are very narrow and apply to only a small percentage of patients. The emergency angioplasty patient population is separate and distinct from the elective angioplasty patient population. Dr. Kiely's own testimony including data from White Plains Hospital shows that in FY 2011, the hospital performed 40 emergency angioplasty cases but 250 elective cases. Their emergency volume is quite similar to Greenwich Hospital's.

- I would also like to comment on Dr. Kiely's reference to previous testimony given by YNHH representatives at CON hearings for Danbury Hospital, Waterbury/St. Mary's Hospitals, Norwalk Hospital and Stamford Hospital. At the time of those hearings, which date back almost 10 years, it was clear to us that cardiac surgery volumes had been and were going to continue to decline. That certainly has proven to be true and

we continue to believe as we did then, that there was no need for additional open heart surgery programs. In the case of angioplasty, OHCA approved several emergency angioplasty programs without onsite cardiac surgery and these programs along with many others in the United States, as evidenced by the research we included in our application, have been shown to be safe for patients. In fact, our view regarding angioplasty has evolved as discussed in previously submitted testimony based on evidence described in medical literature, changes to clinical practice guidelines, and the opinions of our excellent cardiovascular physicians.

- Finally, Dr. Kiely's testimony references and attaches Lawrence & Memorial Hospital's recently submitted CON for elective angioplasty. This CON application is completely irrelevant to our application for the following reasons:
    - The CON is incomplete and should not be recognized by OHCA in this proceeding; and
    - The CON is for a program located approximately 90 miles away and serves a completely different service area.

We have separately moved to strike all references of this submission from Stamford's testimony.

ATTACHMENT I

Capozzalo, Gayle

From: Capozzalo, Gayle
Sent: Wednesday, June 20, 2012 7:43 AM
To: Smith, David
Cc: Leary, Tucker; Lombardi, Marc; Aseltyne, Bill
Subject: Cardiology
Attachments: Principle document 06.20.2012.doc; 2012 06 19-LOI-Stamford GH Interventional Cardiology-A-LRSD(ML).docx

David. Hope all is well. I am sorry that this took so long to get revised. Attached please find a new principle document that has been edited based on our discussions. I will call you this afternoon to discuss next steps. Gayle

Gayle Capozzalo
Executive Vice President
Strategy & System Development
Yale New Haven Health System
789 Howard Avenue
New Haven, CT 06519
203-688-2605

DRAFT –June 19, 2012
Confidential: Attorney Client Privilege

Principles
for
Yale-New Haven Heart and Vascular Services at Stamford Hospital and Greenwich Hospital

I. **Mission**

- Create a cost effective care model utilizing the most appropriate location to provide convenient patient access to safe, high quality care
- Develop a sustainable clinical business model with appropriate professional and technical resources allocated to each program or modality
- Maintain the highest standard of care and superior outcomes through comprehensive staff training and QA/PI programs
- Offer technological advances as these become economically and programmatically feasible to the greater Stamford and Greenwich communities through qualified physicians.
- Monitor operational performance to maintain regulatory compliance (CMS/DPH/TJC) and improve patient satisfaction
- Support other elements of the non-profit missions of Stamford Hospital, Greenwich Hospital, Yale School of Medicine and Yale-New Haven Hospital, respectively

II. **Participants**

- Stamford Hospital, as the principal provider and Connecticut Department of Health license holder for technical services rendered in Stamford, Connecticut, will also be responsible for the Conditions of Participation for CMS certification, where applicable.
- The Stamford Hospital Medical Staff, in particular, the employed CT surgeons, Cardiac Interventionalists and primary care cardiologists will participate in various cardiovascular service offerings.
- Greenwich Hospital, which may share coverage of the PAMI/PCI programs with Stamford Hospital and whose cardiologists may refer appropriate CT surgery cases to Stamford Hospital
- The Greenwich Medical Staff, in particular, the employed and independent Cardiac Interventionalists and the primary care cardiologists will participate in various cardiovascular services offerings
- The Yale-New Haven Heart and Vascular Center (YNHHVC), a virtual organization of Yale-New Haven Hospital (YNHH) and Yale University, that integrates the professional and technical service of select Yale University School of Medicine

(YSM) and YNHH Departments to provide care and clinical management services for the proposed programs.

III. **Scope of Strategic Partnership**

The following array of cardiovascular services may be offered to the greater Stamford and Greenwich communities. The initial focus will be on initiating an elective PCI program at Greenwich and strengthening Stamford CT Surgery building on the existing team and program, followed by the development of a heart failure program at Stamford and Greenwich. Clinical protocols and consultation systems will be developed for each service or program to address basic or tertiary services and low or high risk patients for each procedure.

PAMI at Stamford	PAMI at Greenwich	Elective PCI at Stamford	Elective PCI at Greenwich	Elective PCI at YNHH
Yale coverage potential	Yale Coverage	Yale coverage potential	Low risk	High risk and valves

Heart Failure/Cardiology at Stamford and Greenwich	Heart Failure/Cardiology at YNHH	CT Surgical Procedures at Stamford	CT Surgical Procedures at YNHH	Peripheral Vascular Procedures at Stamford	Peripheral Vascular Procedures at YNHH
Class A+B+C	Class C evaluations +D Transplant and VAD evaluations	CABG and valves	Minimally invasive, Transplant and, VAD	Basic	Advanced

- As a general principle, low and moderate risk interventional procedures will be performed at Greenwich under generally recognized criteria, unless patient insurance or personal preference directs another site of care.
- The presence of Yale faculty, based in the Southwestern CT communities coupled with Yale-New Haven Heart and Vascular clinical program support and PI/QA systems should enhance the program's credibility in the community of referring physicians and discerning patients.
- The CT Surgical Director at Stamford Hospital will discuss high risk cases with the YNHHVC CT Surgical Director and determine whether or not patients requiring cardiac surgery should be transferred to Yale-New Haven Hospital. The Y-Access transfer line may be employed for this purpose. Other coverage arrangements may be pursued in the future.

IV. **Physician Credentialing and Privileges**

All participating physicians performing these procedures must be members of the Stamford or Greenwich medical staff in good standing with delineated privileges for the proposed procedures. Minimum procedural volume requirements will be met by including procedures performed at all hospitals.

The hospitals will not limit participating physician eligibility for medical staff privileges based upon geographic considerations as long as comprehensive coverage is incorporated in the proposed service model.

V. **CON and Regulatory Approvals**

To the extent necessary, the Stamford Hospital CON will be amended to reflect this CT Surgery support.

VI. **Physician Employment, Revenue and Expense Allocations**

The entity that funds the cost of physician services will also provide a provider number for professional billing and receive the revenue credit. Physicians will assign their billing right to this entity. Each participating physician should have one employer to reduce tax liabilities and optimize personal benefit contributions. Participating physicians must abide by all principles and policies incorporated into this arrangement.

In certain subspecialties the most attractive candidates may prefer to be part of an academic medical center with access to new clinical trials, fellows and multidisciplinary specialists. The YNHHVC would recruit, if mutually agreeable, those physicians and deploy them at Stamford and Greenwich. YSM has created a clinician track without academic faculty ladder research expectations, which is appropriate for geographic full time physicians and for split and covering physicians.

Stamford and Greenwich would agree to exclusively obtain covering interventional and supporting surgical services from YNHHVC provided that CT Surgery and interventional coverage is maintained by YNHHVC. However, Stamford Hospital has sufficient coverage with two CT surgeons at this time.

Physician compensation should be at fair market value based on work RVUs, including stipends for night and weekend coverage, patient satisfaction and quality measures. Physicians should not have a financial incentive to perform a procedure at Greenwich, Stamford or YNHH so that care decisions may be made solely in the best interest of the patient.

VII. **Medical Directors**

Greenwich Hospital or Stamford Hospital and the YNH Heart and Vascular Center will jointly approve Surgical and Medical Directors. The Directors will have clinical management responsibilities for the program and a jointly approved position descriptions.

The Surgical and Medical Directors will have dual reporting relationships to the Chief of Surgery or Medicine/Chief of Staff at each hospital and to the Medical Director of the YNHHVC, Henry Cabin, M.D., and Surgical Director of the YNHVC, David Yuh, M.D.

VIII. **Branding/Marketing/Communications**

Stamford and Greenwich physicians who maintain voluntary or full-time faculty Yale appointment may reflect such in their practice profiles and on the Stamford and Greenwich website for physician search.

Recognizing that there will not be a discrete practice site of the Yale-New Haven Heart and Vascular Center with respect to the inpatient programs, Greenwich Hospital will represent

these services as the Yale-New Haven Heart and Vascular Center within the Hospital on its website, service line stationary and in community publications. Media advertising will require YNHH approval. Given the more limited direct clinical service provided by YNHHVC at Stamford Hospital this relationship will be initially described as a Stamford program affiliated with Yale-New Haven Heart and Vascular Center Any use of the brand will require YNHH approval. The parties will mutually decide if the branding relationship should be changed in the future.

A joint press release will be issued after formal agreement and any physician appointments. CME events will be organized for primary care physicians and other members of the Stamford and Greenwich medical staff. Participating physicians will support other Stamford and Greenwich community educational activities.

IX. Hospital and Program Staff Relationships

YNHHVC will assign an administrative officer to Stamford Hospital and Greenwich Hospital with matrix management responsibility for general management staff training, QA/PI programs and other YNHHVC duties under this agreement. Stamford and Greenwich will also designate an administrator responsible for local program development and operations. However, all on-site hospital staff responsible for the proposed services will be Stamford or Greenwich employees.

New clinical hospital staff will receive in-service training in the OR or Cath Lab YNHH. All employees will participate in periodic conference conducted by the Medical Directors and other YNHHVC specialists.

- All technical and nursing staff from the Stamford and Greenwich Hospital's OR and cardiac catheterization laboratories will participate in a mandatory education program consisting of didactic, one on one observational and hands on training. Training will include:
  - CT operating room equipment and procedures
  - Pump team training
  - Angioplasty equipment (guide catheters, guide wires and angioplasty catheters including balloons and stents)
  - Commonly used drugs
  - Assessment and monitoring of anticoagulation
  - Use of intra-aortic balloon pump equipment
  - Patient transfer
  - Items related to patient care before, during and after the procedure
- Hospital staff will also rotate through the YNHH OR and cardiac catheterization laboratory and shadow experiences in the CTICU, CCU and general floor units
- YNHHVC policies, protocols and procedures will be adopted by Stamford and Greenwich for program development, care management and staff training.

X. QA/PI Programs and Decision Support Tools

- The local cath lab conference will provide the foundation for full integration into the YNHHVC quality and safety improvement activities including monthly morbidity and mortality (M&M) conferences and quality indicator monitoring.

- Participation in YNHVC Surgical M&M and Heart Failure video conference will also be facilitated.

- Stamford and Greenwich will participate in the ACC benchmarking registry and Door to Balloon (D2B) benchmarking.

- Utilization and outcomes will be tracked by YNH Heart and Vascular Center and the Yale-New Haven Hospital Center for Outcomes Research and Evaluation (CORE) and provided to Stamford and Greenwich on a quarterly basis for ongoing quality improvement.

- Stamford and Greenwich may also participate in jointly approved state and national benchmarking projects.

- YNHH has piloted a patient consent tool that specifies risks of bleeding and other complications for use by Stamford and Greenwich nurses and the interventional attendings.

- IT interfaces will be enhanced, where feasible at Stamford. Greenwich Hospital will experience complete IT integration through Epic.

XI. **Fees**

An annual management fee of $250,000 will be paid by Stamford to YNHH for professional, management, training and QA/PI services described herein for which can be amended as additional programs are introduced. The management fee will include the achievement of quality indicators..

A more efficient coverage system may enhance the financial benefits of the programs. A review of service schedules and volume projections will be required to further this analysis.

XII. **Term and Amendments**

Stamford Hospital and Greenwich Hospital will agree to an exclusive arrangement with YNHH during the term of the agreement. A legally appropriate agreement will be developed with an initial five year term, with five year renewals. .

If this relationship becomes financially or clinically unstable or is in conflict with new regulations, the Participants agree to modify the agreement. Any unwind must minimize impact on care in the greater Stamford and Greenwich communities.

Additional services will be added after joint review of programmatic and financial feasibility. Most of the proposed services offering elements should not require a CON.

Draft June 19, 2012

YALE NEW HAVEN HEALTH

June ___, 2012

Stamford Hospital
30 Shelburne Road
Stamford, CT 06904
Attention: [_____]

Re: ***Letter of Intent Regarding Proposed Affiliation with Greenwich Hospital, Yale-New Haven Hospital and Yale University relating to Interventional Cardiology Services***

Dear [_____]:

Yale-New Haven Hospital ("***YNHH***") and Yale University, acting through its School of Medicine ("***Yale***") have long collaborated on various patient-care services, including cardiology services. Together, YNHH and Yale have established and supported the Yale-New Haven Heart and Vascular Center ("***YNHHVC***"), renowned for providing comprehensive cardiac and vascular care, including cardiac catheterization, emergency and elective angioplasty and open-heart surgery.

Greenwich Hospital has been affiliated with Yale-New Haven Hospital and the Yale New Haven Health System since 1996. Through this affiliation, Greenwich Hospital, YNHH and Yale collaborated to obtain regulatory approvals for Greenwich Hospital to provide, in addition to diagnostic cardiac catheterization services, primary angioplasty services for acute myocardial infarction ("***PAMI***") patients presenting with ST-segment elevation and left bundle branch blockage, with professional interventional cardiology services provided by Yale physicians (the "***Greenwich PAMI Program***"). Regulatory approval is currently being sought to expand this program to include elective angioplasty ("***Elective PCI***") services without open-heart surgery back-up.

Stamford Hospital currently provides a range of cardiovascular services, including PAMI, Elective PCI and open-heart surgery. A relationship with a quaternary center such as YNHH for surgical program support and consultation may strengthen Stamford Hospital's position and relationships with Greenwich Hospital cardiologists.

Each of YNHH, Yale, Greenwich Hospital and Stamford Hospital (each, a "***Party***" and, collectively, the "***Parties***") desire to enter into this letter of intent (this "***Letter of Intent***") to confirm their intent to collaborate to establish a cost-effective care model for heart and vascular patients that utilizes the most appropriate location to provide convenient patient access to safe, high quality care (the "***Collaboration***"). The Parties agree that the goal of the Collaboration is to ensure that patients can be cared for in the community when appropriate, but also have access to tertiary and quaternary care when medically required.

It is expressly understood and agreed that this Letter of Intent is only binding with respect to Section 2, Section 3 and Section 4. Any Party may, for whatever reason, terminate this Letter of Intent and further negotiations by written notice to the other Parties. In such event, there shall be no liability among the Parties hereto as a result of the execution of this Letter of Intent, any action taken in reliance on this Letter of Intent, or such termination, except as set forth in Section 2, Section 3 or Section 4.

1. Terms of Collaboration. Based upon the dialogue to date, attached as Exhibit A sets out the proposed principal terms of the Collaboration. During the Exclusivity Period (as defined below), the Parties will exercise good faith and use their reasonable efforts to negotiate and agree upon the terms and usual and customary covenants, conditions, indemnities, representations and warranties of the definitive agreements related to the Collaboration, all of which are to be generally consistent with the provisions of the Term Sheet. The parties acknowledge and agree that execution of any definitive agreements and consummation of the Collaboration may be subject to the approval of relevant government authorities, including the Office of Health Care Access, and agree to support each other's efforts in obtaining any such approvals.

2. Exclusivity. Each Party understands and agrees that it is a significant premise of its participation hereunder and agreement hereto that this Letter of Intent be exclusive as to the subject matter set forth above. Therefore, each Party agrees that for a period of **[six (6) months]** following the date hereof it will not (a) enter into any agreement (b) carry on or continue any discussions of any kind with a third party or (c) enter into negotiations concerning the subject matter of this Letter of Intent, and specifically, any affiliation relating to interventional cardiology or CT Surgery services in Fairfield County. Notwithstanding anything herein to the contrary, nothing in this Letter of Intent shall limit or restrict YNHH and Greenwich Hospital from collaborating to provide any services, including interventional cardiology services at facilities affiliated with the Yale New Haven Health System.

3. Confidentiality. In furtherance of the negotiations contemplated by this Letter of Intent, the Parties may request of each other certain information, some of which may be confidential. As a condition to, and in consideration for, each Party furnishing such information to the other Parties, each Party hereby agrees to treat the information furnished by the other Parties in accordance with the provisions of this Letter of Intent and to take or refrain from taking certain other actions as set forth herein.

For purposes of this Letter of Intent, the term "***Confidential Information***" means all information in whatever form furnished to any Party by or on behalf of any other Party, together with any other information concerning such other Party which has already been furnished to the Party receiving such information; provided that it does not include information which the Party receiving such information can demonstrate (a) is generally available to or known by the public other than as a result of disclosure by such Party or (b) was obtained by the Party receiving such information from a source other than the Party furnishing such information, provided that such source is not bound by a duty of confidentiality to the Party furnishing such information or another person or entity with respect to such information.

Each Party shall use Confidential Information solely to evaluate and consider a possible transaction among the Parties. No Party shall use any such Confidential Information to compete with or adversely affect the business or operations of the Party furnishing such information or its affiliates or those doing business with them, including the other Parties. Each Party shall keep the Confidential Information of each other Party strictly confidential and, except as authorized in this Letter of Intent, will not disclose or distribute the Confidential Information of the any other Party to any person or entity without the prior written consent of the Party furnishing such information. Each Party may disclose Confidential Information of the other Parties to such of its directors, officers, employees and agents (the "***Representatives***") who need to have the Confidential Information to participate in or contribute to the proposed transaction, so long as those Representatives agree to be bound by this Letter of Intent, and then only to the extent necessary to their participation or contribution. Each Party shall be responsible for any breach of this Letter of Intent by its Representatives.

Except as and to the extent mutually agreed in accordance with Section 4 hereof, or as required by law, no Party shall, and each Party shall direct its Representatives not to, directly or indirectly, make any public comment, statement or communication with respect to, or otherwise disclose or permit the disclosure of the existence of, this Letter of Intent or any discussions regarding a possible transaction between the Parties or any of the terms, conditions or other aspects of such transactions.

Upon request by any Party at any time, the other Parties shall promptly return to the Party furnishing such information the original and all copies of all non-oral Confidential Information furnished by such Party. Each Party shall, upon request of any other Party, certify as to its compliance with the preceding sentence.

4. Publicity. As the Parties evaluate the Collaboration, they shall also consult as to the propriety and need, timing, form and substance of any press release or other public disclosure (including without limitation disclosure to government regulatory agencies, government officials and community groups) related to the Collaboration. No such disclosure shall be made without the mutual consent of the Parties.

This Letter of Intent may be executed in counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument. Each Party acknowledges that in the event of the breach of this Letter of Intent by any Party, the non-breaching Parties shall be entitled to all remedies available at law or in equity for such breach.

* * *

If you are in agreement with the foregoing, please execute and return one copy of this Letter of Intent, whereupon each of the Parties shall be legally bound to the extent described herein under Connecticut law.

Sincerely,

YALE-NEW HAVEN HOSPITAL

By:_____
Richard D'Aquila
Chief Operating Officer

By:_____
Tucker Leary
Vice President
Heart & Vascular Center

YNHHS:
By:_____
Gayle Capozzalo
Executive Vice President

YALE UNIVERSITY

By:_____
Janet Lindner
Associate Vice President for
Administration

By:_____
Michael Berman, M.D.
Interim CEO, Yale Medical Group

By:_____
Henry Cabin, M.D.
Medical Director
YNHHVC

By:_____
David Yuh, M.D.
Section Chief, CT Surgery

Accepted and Agreed:

GREENWICH HOSPITAL

By:_____
Frank A. Corvino
President and Chief Executive Officer

STAMFORD HOSPITAL

By:_____
Brian Grissler
President and Chief Executive Officer

ATTACHMENT II

Office of Health Care Access
Certificate of Need Application

Agreed Settlement

Hospital:	The Stamford Hospital and New York Presbyterian Healthcare System, Inc.
Docket Number:	04-30374-CON
Project Title:	Establish Elective Angioplasty and Open Heart Surgery Program at The Stamford Hospital
Statutory Reference:	Sections 19a-638 & 639, Connecticut General Statutes
Filing Date:	August 15, 2005
Hearing Dates:	Public Portion: September 22, 2005 Technical Portion: October 6, 2005 and October 27, 2005
Commissioner & Presiding Officer:	Cristine A. Vogel
Agreed Settlement Date:	January 4, 2006
Default Date:	Not Applicable
OHCA Staff	Steven W. Lazarus Michael Sabados

Project Description: The Stamford Hospital ("TSH" and "Hospital") and New York Presbyterian Healthcare System, Inc. ("Applicants") propose the establishment of an elective angioplasty ("PCI") and open-heart surgery ("OHS") program, to be located at the Hospital, at a capital expenditure of $5,404,425.

Nature of Proceedings: On August 15, 2005, the Office of Health Care Access ("OHCA") received the Applicants' Certificate of Need ("CON") application seeking authorization to establish an elective angioplasty and open-heart surgery program, to be located at the Hospital, at a capital expenditure of $5,404,425. The Stamford Hospital is organized under the laws of Connecticut, and New York Presbyterian Healthcare System, Inc. is a corporation organized under the laws of the State of New York. The Hospital is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

Public hearings regarding the CON Application were held on September 22, 2005, October 6, 2005 and October 27, 2005. The Hospital was notified of the date, time, and place of the hearings and notices to the public were published prior to the hearings in *The Advocate* (Stamford) by OHCA. The hearings were conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the Connecticut General Statutes) and Sections 19a-638 and 19a-639, C.G.S.

Yale-New Haven Hospital, Bridgeport Hospital, and Greenwich Hospital collectively known as Yale-New Haven Heart Health Institute were granted Intervenor status with rights to cross-examine. St. Vincent's Medical Center was granted Intervenor status with the rights to cross-examine.

The Presiding Officer heard testimony from the general public, legislators, local officials and witnesses for the Hospital and Intervenors. In rendering this decision, the presiding officer has considered the entire record of the proceeding. OHCA's authority to review, approve, modify or deny this proposal is established by Sections 19a-638 and 19a-639, C.G.S. The provisions of these sections, as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were considered by OHCA in its review.

Findings of Fact

Clear Public Need
Impact on The Hospital's Current Utilization Statistics
Proposal's Contribution to Accessibility and Quality of Health Care Delivery in the Region

1. The Stamford Hospital ("TSH" and "Hospital") is a not-for-profit, 305-bed acute care hospital located in Stamford, Connecticut. TSH, as an affiliate member of the New York Presbyterian Healthcare System ("System"). TSH provides a comprehensive array of services including: Medicine, Surgery, Obstetrics/Gynecology, Psychiatry as well as Medical and Surgical critical care units. *(Completeness Responses, Proposed Resolution, August 15, 2005, Exhibit 3 and Certificate of Need Application, August 15, 2005, page 1-3)*

2. The New York Presbyterian Healthcare System, Inc ("NYPHS") coordinates a system of hospitals and other healthcare institutions throughout the tri-state area, including The Stamford Hospital ("TSH") and New-York Presbyterian Hospital ("NYPH"). NYPH operates New York-Presbyterian Hospital/Columbia University Medical Center ("NYP/C") in affiliation with Columbia University College of Physicians and Surgeons ("CU"). *(Certificate of Need Application, August 15, 2005, pages 2-3)*

3. TSH and NYPHS ("Applicants") propose the establishment of an elective percutaneous coronary angioplasty[a] ("PCI") and open-heart surgery[b] ("OHS") program, to be located at the Hospital. *(Certificate of Need Application, August 15, 2005, page 2)*

4. TSH's proposal is for a full-service cardiovascular services program in the lower Fairfield County. TSH is located in the region's largest population center. *(Prefiled Testimony of Brian Grissler, September 19, 2005,)*

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[a] Elective (Scheduled) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure performed in a catheterization laboratory whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a previously diagnosed blockage in the heart. An expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow.

[b] Open-heart surgery is a surgical intervention performed on the opened heart while the bloodstream is diverted through a heart-lung machine. Cardiac Surgery includes Coronary Artery Bypass Graft (CABG), Valvuloplasty, and Valve Replacement. CABG is where a vein from the chest or leg, or a prosthesis, is grafted onto either side of a blockage in the coronary artery. This reroutes blood flow around the blockage to the heart muscle. Valvuloplasty is where a balloon tipped catheter is inserted into plaque-blocked heart valves to widen and separate them through repeated balloon inflation. A Valve Replacement is a replacement of plaque-blocked heart valves with prosthetic or tissue graft.

5. On August 25, 2004, TSH received CON authorization from OHCA to perform primary[c] PCI services. *(Certificate of Need Application, August 15, 2005, page 2)*

6. The proposed program will augment existing cardiovascular services at the Hospital. The Hospital currently offers:

Primary Angioplasty	Electrocardiogram
Interventional electrophysiology (ablations)	Electrophysiology
Diagnostic cardiac catheterization	Holter monitoring
Coronary care unit	Intra-aortic balloon pump
Telemetry inpatient care	Nuclear stress testing
Cardiac imaging	Pulmonary function testing
Cardiac rehabilitation	Stress testing
Cardiac ultrasound	Tilt table testing
Cardiopulmonary testing	Vascular and thoracic surgical services

(Certificate of Need Application, August 15, 2005, pages 8-9)

7. TSH's cardiology primary and secondary service areas consist of the following Connecticut towns:

Table 1: Stamford Hospital's Proposed Service Area for this Proposal for FYs 2002 – 2005 (1st Two Quarters)

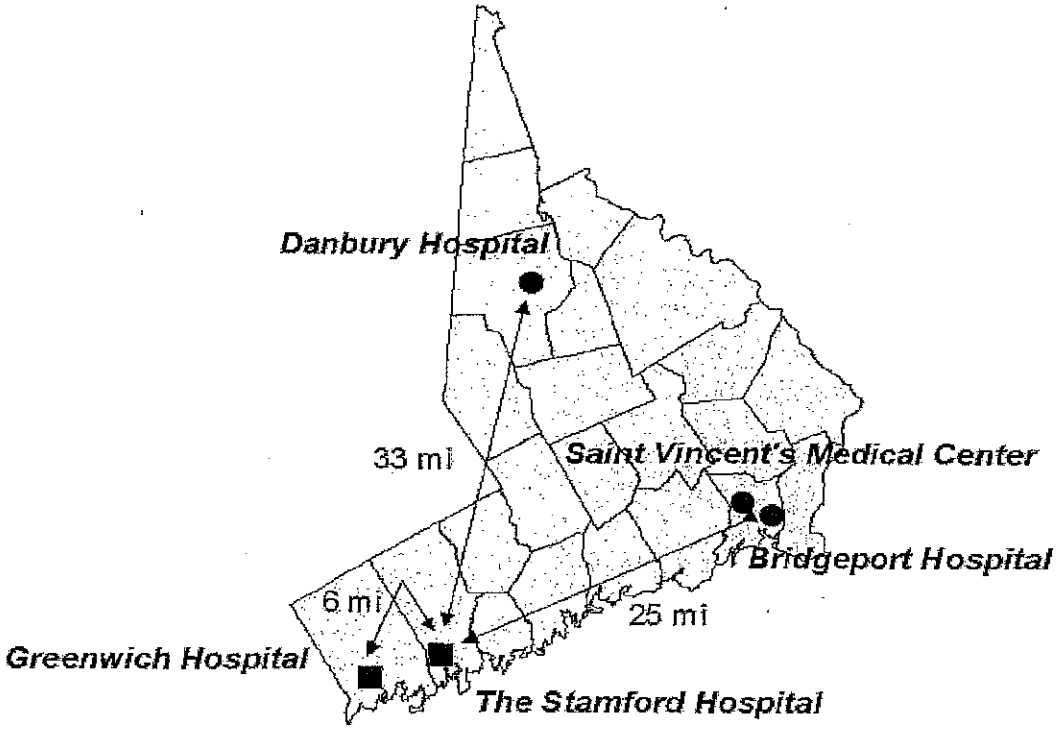
Towns	Primary	Secondary	Total Service Area
	Darien Stamford	Greenwich New Canaan Norwalk Weston Westport Wilton	Darien Greenwich New Canaan Norwalk Stamford Weston Westport Wilton
TSH's Share of Service Area's Inpatient Cardiac Catheterizations	57.4%	4.2%	26.1%
Service Area's share of TSH's Inpatient Cardiac Catheterizations	84.6%	8.7%	93.3%

(Source: Cardiac catheterization volume from *OHCA's Acute Care Hospital Inpatient Discharge Database. Service Area from Certificate of Need Application August 15, 2005, page 22)*

[c] Primary (Emergent) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure performed in a catheterization laboratory whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a previously diagnosed blockage in the heart. An expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow. Non-ST Segment elevation MI (NSTEMI or high-risk) patients consist of 80% of all MIs and are considered for angioplasty on an elective basis within 72 hours. Performance of elective angioplasty without cardiac surgery back up is not recommended by the American College of Cardiology or the American Heart Association.

8. Providers of interventional cardiac services in the Hospital's total service area ("TSA") are as follows

Map 1: Area Providers of Interventional Cardiac Services



Danbury Hospital began performing open heart surgery in January 2005.
Greenwich Hospital began performing Primary PCI in February 2005.
Stamford Hospital began performing Primary PCI in August 2005.

(Connecticut Acute Care Hospital Inpatient Discharge Database and Travel Distances from Yahoo Maps)

9. The Applicants based the need for the proposed Elective PCI and OHS program on the following:
   - Improved accessibility for patients;
   - Improved continuity of care;
   - Historical/Existing cardiac volume;
   - Adopting a standard of care that exists in the other large urban area; and
   - Improved quality of cardiac services.

   (Certificate of Need Application, August 15, 2005, pages 2-55)

10. TSH stated that the establishment of a full-service cardiac program in Stamford will provide timely access and local availability of these services in keeping with trends that have been already established nationally.
    (Prefiled Testimony of Kathleen Silard, Senior Vice President for Operations at TSH, September 19, 2005)

11. TSH's cardiac catheterization volume for FYs 2000 through 2005 are as follows:

Table 2: TSH's Historical Cardiac Catheterization Volume, FYs 2002 – 2005 1st Two Quarters

CT Service Area	2002	2003	2004	2005
Inpatient	354	352	296	147
Outpatient	321	283	332	-
Total	**675**	**635**	**628**	**147**

(Inpatient catheterization figures from OHCA's Acute Care Hospital Inpatient Discharge Database and outpatient volume from August 15, 2005, Responses to OHCA Completeness Letter, pages 1-2)

12. The following is a table of the average annual historical and projected Total PCI volumes (Primary & Elective) in TSH's service area:

Table 3: Average Annual Historical and Projected Total PCI Volumes in TSH's Service Area, FYs 2002 – 2005

	FYs 2002–2005 1st Two Quarters		Year One		Year Two		Year Three	
TSH Service Area	**Average PCIs**	**Adult Use Rate**	**Market Share (%)**	**Projected PCIs**	**Market Share (%)**	**Projected PCIs**	**Market Share (%)**	**Projected PCIs**
Primary	277	2.55	78%	216	83.5%	231	83.4%	231
Secondary	418	2.48	6.8%	28	11.0%	46	20.3%	85
Total Service Area	695	2.51	36.3%	244	40.6%	276	45.7%	316
Connecticut	**8,024**	**2.98**	-	-	-	-	-	-

Note: "Adult" refers to those 15 years and older. Adult use rate per 1,000 population.
Projected PCI volumes were calculated by applying the applicant's projected capture rate to the current PCI volume in the service area. For example, in Year One in the primary service area: 277 (average volume) * .78 (market share) = 216 PCIs.
(OHCA Acute Care Hospital Inpatient Discharge Database; MA, NY, and RI Hospital Discharge Databases; Census 2000 for population figures, and August 15, 2005 CON Application, *pages 45& 23)*

13. The following table is the annual average historical and projected OHS for TSH in the proposed service area for FYs 2002-2005:

Table 4: Historical and Projected, Average Annual OHS Volumes in TSH's Service Area, FYs 2002–2005

	FYs 2000 – 2005 1st Two Quarters		Year One		Year Two		Year Three	
TSH Service Area	**Average OHS**	**Adult Use Rate**	**Market Share (%)**	**Projected OHS**	**Market Share (%)**	**Projected OHS**	**Market Share (%)**	**Projected OHS**
Primary	112	1.03	78.1%	88	83.5%	94	83.5%	94
Secondary	213	1.27	6.7%	14	10.9%	23	20.3%	43
Total Service Area	325	1.17	32.9%	102	38.8%	117	45.7%	137
Connecticut	**4,640**	**1.72**	-	-	-	-	-	-

Note: FY 2005 is First two quarters only.
"Adult" refers to those 15 years and older. Adult use rate per 1,000 population
Projected OHS volumes were calculated by applying the Applicant's projected capture rate to the current PCI volume in the service area. For example, in Year One in the primary service area: 112 (average volume) * .781 (market share) = 88 open-heart surgeries.
(OHCA Acute Care Hospital Inpatient Discharge Database; MA, NY, and RI Hospital Discharge Databases; Census 2000 for population figures; and August 15, 2005, CON Application, pages 46&23).

14. TSH projects the following number of elective PCIs procedures and OHS for its service area.

Table 5: Projected Cardiac Volume for TSH's Service Area

Service	FY 2007	FY 2008	FY 2009
Angioplasties (Elective only)	193	324	417
Open-heart surgeries	86	150	197

Note: TSH based the projected volumes on historical utilization and population data. The use-rates utilized are based on Claritas data. OHCA can not verify any of the above claimed data. *(Responses to the Interrogatories, September 28, 2005, Updated Financial Attachment and CON Application)*

15. The 2001 American College of Cardiology ("ACC") and the American Heart Association ("AHA") Guidelines for Percutaneous Coronary Intervention ("PCI") recommend that PCI be performed by higher volume operators (>75 cases/year) with advanced technical skills (e.g. subspecialty certification) at institutions with fully equipped interventional laboratories and experienced support staff. This setting will most often be in a high-volume center (>400 cases/year) associated with an on-site cardiovascular surgical program. Therefore, PCI is best done by high-volume operators in high-volume institutions. *(JACC, 2001, Vol. 37, No.8, page 2239)*

16. The ACC/AHA Guidelines for CABG Surgery (1999) state the following:
    - Studies suggest that survival after CABG is negatively affected when carried out in institutions that perform fewer than a threshold number of cases annually. Similar conclusions have been drawn regarding individual surgeon volumes.
    - The ACC/AHA are supportive of a posture of close monitoring of institutions or individuals that perform <100 cases annually.

17. TSH states that it will utilize the existing guidelines published by the ACC and AHA as a basis for the development of standards for the proposed services, as specified in **Attachment I.** *(Certificate of Need Application, August 15, 2005, page 11)*

18. The Guidelines for Standards in Cardiac Surgery by the Advisory Council for Cardiothoracic Surgery ("ACCS") and the American College of Surgeons ("ACS") (1996) state the following:
    - An annual volume of at least 100 to 125 open-heart procedures per hospital is necessary from a quality standpoint and there is a greater variation in adjusted mortality rates for teams doing lower volumes of procedures as compared with those doing a high volume.
    - At least 200 procedures per year as previously recommended in the 1975 report of the Inter-Society Commission on Heart Disease Resources are necessary in order for a program to function efficiently.
    - A team approach with a minimum of two qualified cardiac surgeons is recommended to provide adequate and continuous perioperative care as well as assistance in the operating room.

19. Dr. Steven F. Horowitz testified to the following at the public hearing:
    - TSH can sustain a full-service cardiac program due to the increase in the size of the minority population.
    - Numerous studies have confirmed that the cardiovascular risk profile for both Hispanics and African Americans has been worsening in recent years as obesity and diabetes continue to rise exponentially within these populations.
      (Prefiled Testimony of Steven F. Horowitz, M.D. Chief of Cardiology at TSH, September 19, 2005)

20. Kathleen Silard testified to the following at the public hearing:
    - TSH has examined the significant disparity in utilization rates for PCI and OHS that exists for African Americans in TSH service area as well as other regions of the state when compared to the Caucasian population. TSH has seen how some of the major precursors of heart disease, such as diabetes and obesity, can disproportionately effect minority populations as well as the economically disadvantaged.
    - One of the primary goals of TSH's proposed program will be to address and hopefully eradicate some of those disparities by improving access to PCI and OHS to these high-risk groups.
      (Prefiled Testimony of Kathleen Silard, Senior Vice President for Operations at TSH, September 19, 2005)

21. The demographic characteristics by Race for TSH's TSA are as follows:

Table 6: TSH Demographics by Race

Service Area	Caucasian	African American	Native American	Asian	Other	Total
Primary	73.6%	13.2%	0.2%	4.6%	8.4%	100%
Secondary	85.7%	6.6%	0.1%	3.5%	4.1%	100%
Total Service Area	81.0%	9.2%	0.2%	3.9%	5.7	100%
Connecticut	81.6%	9.1%	0.3%	2.4%	6.6%	100%

Source: Census 2000.

22. The demographic characteristics by Hispanic ethnicity for the proposed TSA:

Table 7: Hispanic Ethnicity of TSH Service Areas

Service Area	Hispanic or Latino	Non-Hispanic	Total
Primary	14.7%	85.3%	**100%**
Secondary	8.4%	91.6%	**100%**
Total Service Area	10.8%	89.2%	**100%**
Connecticut	**9.4%**	**90.6%**	**100%**

Source: Census 2000.

23. The AMI discharges for the TSH TSA are as follows:

Table 8: Share of AMI by Race and Hispanic Ethnicity, FYs 2002 – 2005 (First 2 Quarters)

Service Area	Caucasian	African American	Hispanic	Asian	Native American	Other	Total
Primary	84.7%	7.0%	4.2%	0.1%	0.0%	4.0%	**100%**
Secondary	85.1%	7.1%	3.4%	1.0%	0.1%	3.3%	**100%**
Total Service Area	84.9%	7.0%	3.7%	0.6%	0.1%	3.6%	**100%**
Connecticut	**87.1%**	**4.7%**	**4.0%**	**0.3%**	**0.1%**	**3.8%**	**100%**

(Discharges from OHCA Acute Care Hospital Inpatient Discharge Database and MA, NY, and RI Hospital Discharge Databases. "White," "Black," "Asian," "Native American," and "Other" are non-Hispanic categories.)

24. NYPH has one of the largest cardiac surgery and cardiac catheterization[d] programs in New York State with its physicians performing over 3,000 PCIs and close to 2,000 OHS in calendar year 2004. *(Prefiled Testimony of Arthur A. Klein, M.D., September 19, 2005)*

[d] Diagnostic Cardiac Catheterization is a diagnostic procedure in which a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to the heart to measure electrical activity, blood pressure, and locate blockages.

25. Dr. Steven Horowitz, testified on behalf of TSH to the following:
    - Diabetes is a leading cause of hospitalization among Connecticut's African American and Hispanic populations which are 3.8 and 2.2 times more likely to be hospitalized directly due to the disease as compared to the Caucasian Connecticut residents.
    - The percent difference for the African American utilization rates in the TSH's TSA versus those statewide is nearly 26% and 62% for PCI and cardiac surgery respectively. The same numbers skyrocket to 41% and 95% when the focus is placed solely on the City of Stamford.
    - TSH can target the African American and Hispanic population and relieve some of these barriers to access through the comprehensive preventive and medical outreach program.

    (Prefiled Testimony of Steven F. Horowitz, M.D., Chief of Cardiology Department at TSH, September 19, 2005)

26. Dr. Arthur Klein testified to the following at the public hearing:
    - NYPH and NYPHS have developed a number of strong and effective partnerships with affiliated hospitals to elevate the scope of and quality of cardiac care in the tri-state region.
    - NYPHS assists in the operation of nine (9) diagnostic cardiac catheterization programs through out the tri-state area, four elective angioplasty programs and one primary angioplasty program.
    - In this proposal, the cardiac surgery professional services will be provided exclusively by full-time faculty of the Division of Cardiothoracic Surgery, Department of Surgery of Columbia College of Physicians and Surgeons.
    - Oversight of elective angioplasty shall be through a joint committee co-chaired by Drs. Moses and Stone, senior faculty from Columbia University's Division of Cardiology and Stamford Hospital's cardiology leadership.

    (Prefiled Testimony of Arthur A. Klein, M.D., September 19, 2005)

27. Dr. Eric A. Rose testified at the public hearing that Columbia University Department of Surgery's professional expertise in cardiothoracic research, its strategic network of partnerships and its vast clinical experience will help support TSH in their cardiac health services. *(Prefiled Testimony of Eric A. Rose, M.D., Chairman for the Dept. of Surgery at NYP/C, September 19, 2005)*

28. TSH submitted a signed Draft Agreement with NYPHS. NYPHS' role is defined as follows:
    - Arrange consultative assistance to the Hospital in the following areas:
        - Preparation of the CON Application;
        - Clinical training of nursing and technical staff;
        - Development of the Hospital's standards of care, risk stratification criteria and operational policies;
        - Development of clinical guidelines and protocols;
        - Collection and analysis of quality data for clinical outcomes and performance monitoring;
        - Recruiting procedures; and

- Adoption by the Hospital of policies, procedures and protocols, including developing practice guidelines and requirements related to the proposed program.

- Recommend CPC standards and/or the standards of NYPHS-affiliated Connecticut institutions for physician, nursing and technical staff protocols to foster a high-quality credentialing program; and
- Advise the Hospital with respect to quality assurance and utilization management functions related to the proposed program.

(Completeness Responses, August 15, 2005, Draft Agreement between the Applicants, Exhibit 4, page 4)

29. TSH proposes to provide elective PCI utilizing five (5) interventional cardiologists, who are currently providing primary PCI services at TSH. *(Certificate of Need Application, August 15, 2005, page 11)*

30. The PCI volumes for the proposed interventionalists for FYs 2002-2005 1st two quarters are as follows:

Table 9: Volume of Proposed Program Interventionalists (FYs 2002 – FY 2005 1st Two Quarters)

Physician	Hospital Affiliation	Office/Home	Average Annual PTCA Volume
Alcan[1]	St. Vincent's & TSH	Norwalk	347
Jumper[2]	St. Vincent's & TSH	Valhalla, NY	119[3]
Charney	NY Presbyterian, Greenwich, & TSH	New Rochelle	X[4]
Messinger	NY Presbyterian, Greenwich, & TSH	New Rochelle	X[4]
Stone	NY Presbyterian, TSH (pending)	Greenwich	-

[1]Member of Cardiology Associates of Fairfield County
[2]In training
[3]Dr. Jumper performed 57 in FY 2004 and 122 in the first two quarters of FY 2005.
[4] TSH reported volume (FYs 2003 & 2004 – NYP physicians not specifically identified)
Physician C: 156 & 145 and Physician D: 108 & 126
(OHCA Acute Care Hospital Inpatient Discharge Database and CON Application, August 15, 2005, page 11&58 and Completeness Responses, August 15, 2005, page 8)

31. TSH stated that three additional cardiac interventionalists, Drs. Portnay, Lorenz and Corvaja will be added to the proposed program to perform PCIs at TSH. *(CON Application, August 15, 2005, pages 11&58 and Completeness Responses, August 15, 2005, page 8)*

32. TSH proposes to staff the proposed OHS program with two (2) board-certified cardiac surgeons, who will practice full-time at TSH and be credentialed at both TSH and at NYP/C. These two surgeons will be recruited through the formation of a three (3) person committee which will include as its members, Dr. Craig Smith, Dr. Mehmet Oz and Dr. Eric Rose, Chair of the Surgery Department at NYP/C. *(Certificate of Need Application, August 15, 2005, page 11)*

33. The average annual PCI and OHS volumes in TSH's TSA by hospital provider for FYs 2000-2005 (1st two quarters) are as follows:

Table 10: Average Annual PCI and Open-Heart Surgery Volumes by Provider in TSH's TSA by Provider, (FYs 2002 – 2005 1st Two Quarters)

	PCIs			Open-Heart Surgeries		
Hospital	Procedures	Market Share	Area Volume as Share of Total Provider Volume (%)	Procedures	Market Share	Area Volume as Share of Total Provider Volume (%)
Bridgeport	154	22.2%	12.3%	75	23.1%	24.3%
Danbury	0	0.0%	-	0	0.0%	-
Greenwich	1*	0.1%	100%	-	0.0%	-
Hartford	0	0.0%	-	0	0.0%	-
John Dempsey	1	0.1%	0.2%	0	0.0%	-
Saint Francis	0	0.0%	-	1	.3%	.1%
Saint Raphael's	4	0.5%	0.4%	3	.9%	.4%
Saint Vincent's	392	56.4%	34.9%	119	36.6%	39.7%
Yale	78	11.2%	4.8%	57	17.5%	6.4%
Out of State	65	9.3%	-	70	21.6%	-
Totals	**695**	**100%**	-	**325**	**100%**	-

*Greenwich Hospital began providing primary PCI in February 2005.
(OHCA Acute Care Hospital Inpatient Discharge Database and MA, NY, and RI Hospital Discharge Databases)

34. Danbury Hospital, along with Waterbury Hospital and St. Mary's Hospital (one program, two sites in Waterbury) were authorized by OHCA to offer full-service cardiac programs in 2003. *(Certificate of Need Applications, Final Decision Docket Numbers 03-30167 & 03-30143, both dated July 23, 2005)*

35. St. Vincent's Medical Center ("SVMC") testified to the following:
    a. Angioplasty volume is flat nationally and has begun to decline in Connecticut.
    b. If TSH proposal is approved, St. Vincent's Medical Center would not be able to achieve both institutional and surgeon specific minimum volumes for OHS and would put the quality of St. Vincent's Medical Center at significant risk.
    c. SVMC performed 1,097 PCIs and 283 OHS in FY 2005.
    d. The overall risk adjusted mortality rate at SVMC is 1.3%.
    e. Other than volume, SVMC measures quality through independent third party companies (to whom they report data to).
    (Prefiled Testimony of Jose Missri, M.D. St. Vincent's Medical Center, September 28, 2005 and Public Hearing Testimony, October 6&27, 2005)

36. Bridgeport Hospital ("BH"), as part of Yale-New Haven Health Heart Institute, testified to the following:
    a. BH performed under 1,200 PCIs and under 250 OHS in FY 2005.
    b. BH could not specify their overall risk adjusted mortality rate, BH simply stated that it was under 2.0%.
    c. Other than volume, BH measures quality through independent third party companies (to whom they report data to).

d. If the proposed CON was to be approved, this would not impact the physician coverage at BH.
(Prefiled Testimony of Stuart .Zarich, M.D., Bridgeport Hospital, September 28, 2005 and Public Hearing Testimony, October 6&27, 2005)

37. Yale-New Haven Hospital ("YNHH"), as part of Yale-New Haven Health Heart Institute, testified to the following:
    a. There is a statewide decline in the number of OHS cases,
    b. There is a flattening of PCI volumes,
    c. Proliferation of full-service cardiac program will place additional stress on the state's staffing infrastructure,
    d. Additional cardiac programs will not improve mortality rates,
    e. The residents of Fairfield County have a wide range of options for their full-service cardiac care needs,
    f. There is a direct correlation between physician and institutional case volumes and quality outcomes, and
    g. In FY 2004, YNHH had 64 PCI discharges (4.3% of YNHH's total PCI) and 52 OHS discharges (6.2% of YNHH's total OHS) from the Stamford service area.
    (Prefiled Testimony of Kyle Kramer, Executive Director of the Yale-New Haven Health Heart Institute, September 28, 2005 and Public Hearing Testimony, October 6&27, 2005)

38. In order to implement the proposed project, TSH will require a series of facility renovations. The renovations will include an expansion of surgical facilities on Level 2 of TSH's North building to allow for the creation of two new, state-of–the-art operating rooms that will be the primary operating suites for the proposed program as well as enlarged perioperative and other surgical support areas.
(Certificate of Need Application, August 15, 2005, page 13)

Financial Feasibility of the Proposal and its Impact on the Hospital's Rates and Financial Condition

Impact of the Proposal on the Interests of Consumers and Payers of Health Care Services

Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines

39. The proposal has a total expenditure cost of $5,404,425 which consists of the following:

Table 11: Total Capital Expenditure

Description	Cost
Medical Equipment	3,109,345
Construction/Renovation	1,590,065
Project Contingency	704,925
Total Capital Expenditure	**$5,404,425**

(Certificate of Need, August 15, 2005, page 63)

40. The proposal will be financed from the TSH's equity through operations. *(Certificate of Need, August 15, 2005, page 64)*

41. TSH will pay NYPHS a fee for expenses related to training and oversight of TSH's proposed program. This arrangement will be finalized if the proposal is approved by OHCA. *(Arthur S. Klein, Chief Operating Officer of NYPHS, Public Hearing Testimony, October 6&27, 2005)*

42. TSH projects incremental to the project losses from operations for the first two years of operation for FYs 2007 and 2008 of ($1,940,000) and ($294,000), respectively. This is due to program start up. However, TSH is projecting incremental gains from operation of $1,082,000 for the third year of operation, FY 2009. *(Responses to the OHCA Completeness Letter, August 15, 2005, Updated Financial Attachment)*

43. TSH is projecting a gain from operations with the CON project of $10,137,000, $12,327,000 and $14,365,000, for FYs 2007, 2008 and 2009. *(Responses to the OHCA Completeness Letter, August 15, 2005, Updated Financial Attachment)*

44. TSH proposes to hire 26, 34 and 38 Full Time Equivalent employees for FYs 2007, 2008 and 2009, respectively. *(Responses to the OHCA Completeness Letter, August 15, 2005, Updated Financial Attachment)*

45. There is no State Health Plan in existence at this time. *(Certificate of Need Application, August 15, 2005, page 14)*

46. TSH has adduced evidence that this proposal is consistent with TSH's long-range plan. *(Certificate of Need Application, August 15, 2005, page 14)*

47. TSH has improved productivity and contained costs by participating in group purchasing, energy conservation, reengineering and through application of technology. *(Certificate of Need Application, August 15, 2005, page 59)*

48. TSH stated that this proposal will help enhance the existing academic affiliation with Columbia University College of Physicians and Surgeons. *(Certificate of Need Application, August 15, 2005, pages 59&60)*

49. TSH stated that the patient physician mix of TSH is unique as the cardiac patient care is fully integrated across all medical disciplines and is managed through a state-of-the-art multi-modality data management system. *(Certificate of Need Application, August 15, 2005, page 60)*

50. TSH's rates are sufficient to cover the proposed capital expenditure and operating costs associated with this proposal. *(Responses to Interrogatories, September 28, 2005, Updated Financial Attachment)*

Rationale

The Office of Health Care Access ("OHCA") approaches community and regional need for proposed services on a case-by-case basis. Certificate of Need ("CON") applications for cardiac services do not lend themselves to general applicability due to the variety and complexity of factors, which may affect any given proposal; e.g., the characteristics of the population to be served, the nature of the existing services, the specific services proposed to be offered, the current utilization of services, and the financial feasibility of the proposed service. In considering this application, OHCA determined that TSH's current cardiac utilization, population served, quality of providers and physicians and geographic accessibility were significant factors in determining need.

The Stamford Hospital ("TSH") and New York Presbyterian Healthcare System, Inc. ("NYPHS") (collectively known as "Applicants"), propose to expand the cardiac services delivered at TSH to include elective angioplasty services and open heart surgery. The Applicants based the need for the elective PCI and open heart surgery programs on improved accessibility for patients, improved continuity of care, historical and existing cardiac volume, adopting a standard of care that exists in the other large urban areas and improved quality of care.

TSH's primary and secondary service area ("TSA") consists of eight (8) towns. There are no providers of elective PCI or OHS in TSH's TSA. The Hospital's service area is comprised of a higher proportion of African American and Hispanic population when compared to the rest of the state overall. The primary service area has experienced higher adult per capita rates of AMI discharges for African American and Hispanic as compared to the state as a whole. In addition, there appears to be a disparity in the utilization rates for PCI and OHS for Hispanics and African Americans in the service area when compared to the Caucasian population. This proposed cardiac program will enhance the access for the African American and Hispanic population in TSH's TSA. OHCA concludes that the Applicants proposal will provide the residents of lower Fairfield County with improved access to the full continuum of cardiac care.

TSH's historical cardiac catheterizations volumes for FYs 2002, 2003, 2004, and 2005 (1st 2 quarters) were 675, 635, 628 and 147, respectively. OHCA determined that TSH could potentially perform a minimum of 244 annual total PCIs (primary & elective) and 102 OHS cases on residents of TSH's TSA in the first full year of operation of the proposal based upon historical catheterization volume and its market share. This volume increases to 276 total PCI procedures and 117 OHS cases for the second year of operation, and 316 total PCI procedures and 137 OHS cases for the third of operation. Based on historical inpatient diagnostic cardiac catheterization volume and market share, the proposed full-service cardiac program at TSH would exceed institutional minimum volumes recommended by the ACC/AHA for PCI (200) and the American College of Surgeons–Advisory Council for Cardiothoracic Surgery for open-heart surgery (100–125 surgeries per year).

The proposal involves offering of elective Percutaneous Coronary Intervention ("PCI") through the use of five (5) interventional cardiologists, who are currently providing primary PCI services at TSH. TSH also proposes to provide OHS utilizing two (2) surgeons will be recruited from outside of Connecticut, through the formation of a three (3) person committee comprised of TSH and Columbia physicians. Therefore this program will not impact coverage at any of the existing cardiac programs in Connecticut. In addition, OHCA concludes that even though the PCI and OHS volumes may decline at the existing providers, the PCI and OHS volumes will not fall below the institutional minimum volumes recommended by ACC/AHA for PCI and American College of Surgeons-Advisory Council for Cardiothoracic Surgery for OHS.

TSH's proposal will increase the availability of quality PCI and OHS services for residents of TSH's TSA. The proposed elective PCI and OHS program will be developed in collaboration with NYPHS. NYPHS will provide or arrange for TSH consulting in the areas of clinical training for staff, development of TSH's standards of care, development of clinical guidelines, collection and analysis of data and recruiting procedures. NYPHS expects the initial training to continue over an eighteen month period. NYPHS will also advise TSH with respect to quality assurances and utilization management and provide assistance to TSH concerning the adoption of policies, procedures and protocols, including developing practice guidelines and program requirements. This proposal will improve the quality of care and continuity of TSH's cardiac services.

Finally, the CON proposal is financially feasible. The proposal has a total capital expenditure of $5,404,425, which consists $3,109,345 for medical equipment, $1,590,065 for construction/renovations and $704,925 for contingency costs. TSH proposes to fund the proposed total capital expenditure through TSH's equity, specifically through operations. TSH will pay NYPHS a fee for expenses related to training and oversight of TSH's proposed program; however, the details have not yet been finalized. TSH projects incremental losses from project operations for the first two years of operation of ($1,940,000), and ($294,000), respectively. However, TSH is projecting an incremental gain from operation of $1,082,000 by the third year of operation. Further, TSH is projecting gains from total Hospital operations with the CON project of $10,137,000, $12,327,000 and $14,365,000 for the first three years of operations. The projected utilization and financials of this proposal appear to be reasonable, financially feasible and cost-effective and will not adversely impact the interests of consumers and payers of such services.

TSH's proposed elective angioplasty and open heart surgery program is differentiated from other cardiac-related proposals in the following ways. TSH currently operates a high volume diagnostic cardiac catheterization program and recently initiated a primary angioplasty program. The Hospital's service area is comprised of a higher proportion of African American and Hispanic population than the rest of the state. The implementation of the proposed program should address some of the disparities in utilization of cardiac services by this population. Additionally, the proposed program is not expected to impact the physician coverage at any of the existing cardiac programs in Connecticut because the interventionalists are already on staff at TSH and the cardiac surgeons will be

recruited from out of state. TSH's strong collaborative relationship with the NYPHS will enhance the accessibility of high quality, community-based medical services offered by TSH. TSH will utilize the resources of NYPHS to further enhance provision of quality care including access to the expertise, information, and consultative support of a nationally recognized academic healthcare center renowned for the diagnosis and treatment of cardiac disease. Finally, implementation of TSH's proposal will bring appropriate access to high quality cardiac services to the residents of the proposal's TSA. In summary, the proposal will result in enhanced cardiac services in the Stamford region.

Order

NOW, THEREFORE, the Office of Health Care Access ("OHCA") and The Stamford Hospital ("TSH") and New York Presbyterian Healthcare System, Inc. ("NYPHS") (together referred to as "Applicants") hereby stipulate and agree to the terms of settlement with respect to the Applicants' request to establish elective angioplasty and open heart surgery program to be located at Stamford Hospital at a total capital expenditure of $5,404,425, as follows:

1. The Applicants' request for a CON to establish an elective angioplasty and open-heart surgery program to be located at TSH, a total capital expenditure of $5,404,425, is hereby approved.

2. TSH shall only commence operation of the OHS program at The Stamford Hospital initially. Once the number of OHS procedures exceeds 125, the Hospital may commence operation of the elective angioplasty program. Prior to commencement of the angioplasty services, TSH is required to provide OHCA evidence that it has performed the required 125 OHS.

3. TSH will have at least two cardiac surgeons as part of this proposal, who are in the process of being recruited and shall be identified prior to the beginning of the OHS program. The surgeons must be fully credentialed and have the following qualifications:
   - Board-Certified in cardiac surgery
   - Maintains a Connecticut license and admitting privileges at the Hospital
   - Has performed OHS procedures at a cardiac surgical center that meets or exceeds the annual ACCS/ACS minimum institutional volume standard for cardiac surgery for the past 2 years
   - TSH shall provide the Curriculum Vitae ("CV") of the cardiac surgeons prior to commencement of the OHS program. TSH shall demonstrate that the cardiac surgeons satisfy all requirements specified above. The OHS program shall not commence operation until OHCA acknowledges receipt of the CV and that it complies with this Order.

4. TSH shall provide the CVs of each of the cardiac operating room nurses, Board-certified cardiac anesthesiologists, intensivists and perfusionists for the authorized OHS program prior to commencement of the OHS program. Fifty percent (50%) of each of the core OR staff mentioned above must be trained in OHS prior to commencement of the OHS program. The OHS program shall not commence operation until OHCA acknowledges receipt of the CVs and that they comply with this Order.

5. TSH shall not exceed the approved total capital expenditure of $5,404,425. In the event TSH learns of potential cost increases or expects final project costs will exceed those approved, the Hospital shall file with OHCA a request for approval of

the revised CON project budget. The source of funding for the project will be The Stamford Hospital's operations and owner equity.

6. TSH shall complete and submit to OHCA on a quarterly basis the data elements in the Connecticut Cardiac Data Registry (**Attachment II**). Data should be submitted to OHCA on a computer disk in either an excel workbook or comma-delimited text file in a format specified by OHCA. The most current version of the Connecticut Cardiac Data Registry includes, but may not be limited to, the elements listed in **Attachment II**. Data must be reported to OHCA thirty (30) calendar days following the end of the quarter. Fiscal Year quarters end December 31st, March 31st, June 30th, and September 30th. Upon receipt, OHCA will check the data's conformance to the required specifications and within ten (10) business days notify TSH in writing of its evaluation. If OHCA finds questionable material, TSH will have fifteen (15) business days from notification by OHCA to submit a revised dataset for evaluation. All patient-level data submitted to OHCA to satisfy this requirement will be subject to the laws and regulations of the state of Connecticut and the Office of Health Care Access regarding its collection, use and confidentiality. If TSH does not submit the data elements in the Connecticut Cardiac Data Registry on a quarterly basis, the programs may be terminated. In the event of such a termination, TSH shall file a CON for reinstitution of the programs.

7. TSH shall submit on an annual basis to OHCA the following reports which must be reported to OHCA thirty (30) calendar days following the end the year, for the first three (3) years of operation:
   a. A report of all elective PCIs and OHS performed each year by ethnicity and race, in a format to be specified.
   b. A report which illustrates that this CON proposal helped relieve the barriers to access through comprehensive preventive and medical out-reach programs for the African American and Hispanic population within TSH's TSA.

8. If TSH does not perform 125 OHS procedures within twelve months of the initiation of the OHS program, TSH shall submit monthly reports of OHS arrayed by physician to OHCA until such time as these volumes are met by TSH. If these volumes are not met for a period of two consecutive 12-month periods, TSH's OHS program shall be terminated. In the event of such a termination, TSH shall file a CON for reinstitution of the OHS program.

9. If TSH does not perform 200 elective PCIs within twelve months of the initiation of the PCI program, TSH shall submit monthly reports of elective PCIs arrayed by physician to OHCA until such time as these volumes are met by TSH.

10. TSH shall participate in the Society of Thoracic Surgeons Database (STS-DB) database and the ACC National Cardiovascular Database Registry (ACC-NCDR) and report all data including the optional follow-up section. TSH shall provide OHCA quarterly data reports from STS-DB and ACC-NCDR. Data must be

reported to OHCA thirty (30) calendar days subsequent to TSH receiving the reports from the STS and ACC. TSH is required to comply with the STS and ACC/AHA criteria and standards. If TSH determines not to participate in the STS-DB or ACC-NCDR, TSH shall notify OHCA immediately, and continue to comply with the STS and ACC/AHA criteria and standards set forth in Attachment III.

11. TSH shall provide OHCA with a copy of a dated and signed Consulting Services Agreement with NYPHS or its Affiliates prior to commencement of operation of the OHS program. This contract shall be renewed annually for a period of three years.

12. OHCA and TSH agree that this Agreed Settlement represents a final agreement between OHCA and TSH with respect to this request. The signing of this Agreed Settlement resolves all objections, claims and disputes, which may have been raised by the Hospital with regard to Docket Number 04-30374.

13. This authorization for the OHS program shall expire on December 31, 2008. Should the TSH's open-heart surgery program not commence operation by that date, TSH must seek further approval from OHCA to complete the project beyond that date.

14. This Agreed Settlement is an order of the Office of Health Care Access with all the rights and obligations attendant thereto, and the Office of Health Care Access may enforce this Agreed Settlement pursuant to the provisions of Sections 19a-642 and 19a-653 of the Connecticut General Statutes at TSH's expense, if TSH fails to comply with its terms.

January 4, 2006

Brian G. Grissler
Duly Authorized Agent for
The Stamford Hospital

December 28, 2005

Arthur A. Klein, M.D.
Duly Authorized Agent for
New York Presbyterian Health System, Inc.

The above Agreed Settlement is hereby accepted and so ordered by the Office of Health Care Access on January 4, 2006.

January 4, 2006

Cristine A. Vogel
Commissioner & Presiding Officer

CAV:sl

ATTACHMENT III

Table 1A: Inpatient cardiac catheterization discharges by provider, FFYs 2002-2010

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	FFY 06-10 (5-yr) % Change	FFY 08-10 (3-yr) % Change	FFY 09-10 (1-yr) % Change
Backus	156	210	200	170	116	53	106	135	115	-1%	8%	-15%
Bridgeport	1,148	1,185	1,274	1,129	902	809	817	632	626	-31%	-23%	-1%
CT Children's								10	5	n/a	n/a	-50%
Danbury	263	299	260	327	748	533	475	452	418	-44%	-12%	-8%
Dempsey	519	564	633	640	487	439	480	419	462	-5%	-4%	10%
Greenwich	100	42	35	106	167	158	163	177	166	-1%	2%	-6%
Hartford	2,546	2,405	2,241	2,128	2,135	2,032	2,008	1,833	1,892	-11%	-6%	3%
Hospital of Central CT	448	465	409	411	436	401	319	344	269	-38%	-16%	-22%
Lawrence & Memorial	420	473	466	393	414	303	337	440	503	21%	49%	14%
Middlesex	28	169	168	150	182	142	161	138	138	-24%	-14%	0%
New Milford	0	0	0	22	37	38	65	37	0	-100%	-100%	-100%
Norwalk	247	203	195	182	128	67	77	104	126	-2%	64%	21%
Rockville	0	79	99	24	4	3	0	0	0	-100%	n/a	n/a
St. Francis	2,742	2,802	2,800	2,656	2,421	2,543	2,431	2,292	2,206	-9%	-9%	-4%
St. Mary's	291	299	260	307	519	469	455	480	469	-10%	3%	-2%
St. Raphael	1,744	1,878	1,833	1,496	1,383	1,200	1,113	1,062	1,098	-21%	-1%	3%
St. Vincent's	1,276	1,259	1,324	1,432	1,554	1,540	1,562	1,375	1,267	-18%	-19%	-8%
Stamford	354	352	296	299	311	297	293	358	321	3%	10%	-10%
Waterbury	451	477	367	412	658	622	611	675	608	-8%	0%	-10%
Yale	2,549	2,587	2,330	2,200	2,021	1,939	1,954	2,135	2,129	5%	9%	0%
Total	**15,282**	**15,748**	**15,190**	**14,484**	**14,623**	**13,588**	**13,427**	**13,098**	**12,818**	**-12%**	**-5%**	**-2%**

***Source**: CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database.*

ICD-9-CM Procedure Codes: 37.21-37.23

Please note: unduplicated counts utilizing all procedure codes

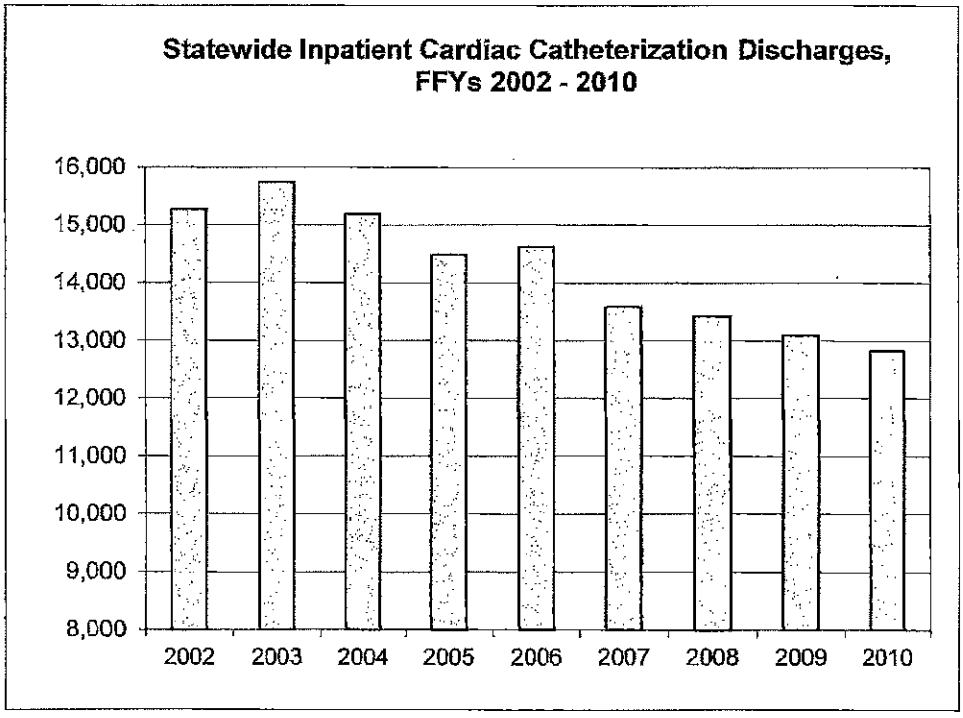


Table 2A: PCI discharges by provider, FFYs 2002-2010

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	FFY 06-10 (5-yr) % Change	FFY 08-10 (3-yr) % Change	FFY 09-10 (1-yr) % Change
Bridgeport	1,191	1,249	1,288	1,052	692	560	580	428	379	-45%	-35%	-11%
CT Children's								2	0	n/a	n/a	n/a
Danbury	0	0	0	0	453	409	330	326	277	-39%	-16%	-15%
Dempsey	452	464	453	519	401	353	376	334	368	-8%	-2%	10%
Greenwich	0	0	0	20	38	32	40	40	32	-16%	-20%	-20%
Hartford	1,312	1,483	1,321	1,282	1,246	1,206	1,093	1,031	1,122	-10%	3%	9%
Hospital of Central CT	0	0	0	26	61	70	60	74	69	13%	15%	-7%
Lawrence & Memorial	0	0	0	0	41	-	29	74	74	80%	155%	0%
New Milford	0	0	0	0	0	6	11	11	0	n/a	-100%	-100%
Norwalk								14	57	n/a	n/a	307%
St. Francis	1,192	1,253	1,349	1,223	1,170	1,188	1,171	1,232	1,030	-12%	-12%	-16%
St. Mary's	0	0	0	59	297	246	251	255	291	-2%	16%	14%
St. Raphael	715	970	924	708	680	632	595	534	523	-23%	-12%	-2%
St. Vincent's	1,063	1,035	1,085	1,150	1,181	1,101	1,124	958	925	-22%	-18%	-3%
Stamford	0	0	0	9	39	34	45	159	151	287%	236%	-5%
Waterbury	0	0	0	61	347	373	325	361	361	4%	11%	0%
Yale	1,635	1,715	1,460	1,297	1,218	1,131	1,186	1,352	1,469	21%	24%	9%
Total	**7,560**	**8,169**	**7,880**	**7,406**	**7,864**	**7,341**	**7,216**	**7,185**	**7,128**	**-9%**	**-1%**	**-1%**

Source: CT Department of Public Health Office of Health Care Access inpatient Acute Care Hospital Database

ICD-9-CM Procedure Codes: .66, 36.01, 36.02, 36.05, 36.06 and 36.07

Please note: unduplicated counts utilizing all procedure codes

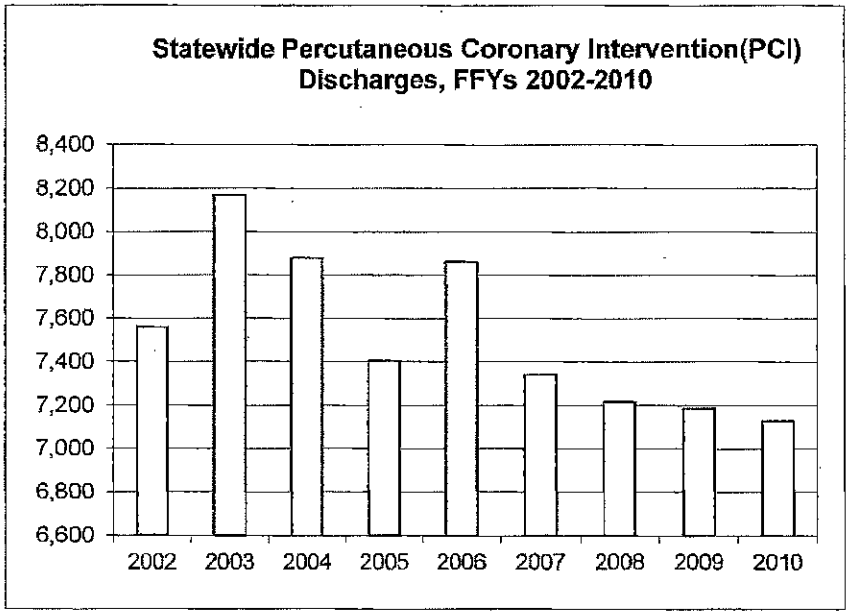


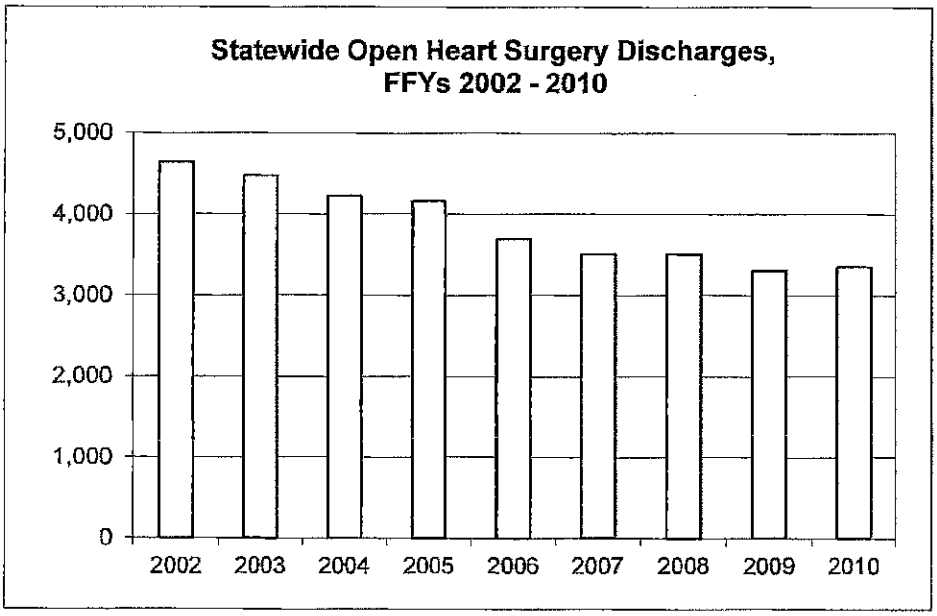
Table 3A: Open heart surgery discharges by provider, FFYs 2002-2010

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	FFY 06-10 (5-yr)% Change	FFY 08-10 (3-yr)% Change	FFY 09-10 (1-yr) % Change
Bridgeport	345	313	268	263	175	194	106	96	136	-22%	28%	42%
CT Children's								6	4	n/a	n/a	na
Danbury	0	0	0	114	177	121	162	148	174	-2%	7%	-9%
Dempsey	115	134	121	174	97	70	84	56	58	-40%	-31%	-33%
Hartford	901	844	756	726	742	685	671	652	695	-6%	4%	-3%
St. Francis	1,239	1,299	1,311	1,188	998	990	912	845	820	-18%	-10%	-7%
St. Mary's	0	0	0	19	72	100	85	114	112	56%	32%	34%
St. Raphael	761	687	617	510	353	342	321	299	318	-10%	-1%	-7%
St. Vincent's	310	296	293	291	259	232	257	219	195	-25%	-24%	-15%
Stamford	0	0	0	0	0	0	75	73	46	n/a	-39%	-3%
Waterbury	0	0	0	20	117	110	134	110	98	-16%	-27%	-18%
Yale	973	905	860	861	704	664	698	691	697	-1%	0%	-1%
Total	**4,644**	**4,478**	**4,226**	**4,166**	**3,694**	**3,508**	**3,505**	**3,309**	**3,353**	**-9%**	**-4%**	**-6%**

Source: *CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database.*

ICD-9-CM Procedure Codes: 35.10-35.28 and 36.10-36.19

Please note: unduplicated counts utilizing all procedure codes



ATTACHMENT IV

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GUIDELINES FOR STANDARDS IN CARDIAC SURGERY

The following statement is an updated version of guidelines that were first published by the American College of Surgeons in 1991. The revised statement was developed by the Advisory Council for Cardiothoracic Surgery and approved by the College's Board of Regents in October 1996.

Preamble

This report provides guidelines to be used by hospital executives and appropriate medical staff only. It places no value judgment on existing successful programs or on the treatment of individual patients.

While current standards of practice form the basis of this report, it is recognized that large programs in cardiac surgery grow from smaller ones. Hospitals and their staffs should exercise their own discretion in approving programs based on local need and the responsibility for achieving a good standard of practice.

While attention is directed primarily to open-heart surgery, the proposed standards should apply to closed-heart operations as well as to operations on the great vessels within the chest.

In borderline situations, in which the number of open-heart operations does not meet the established guidelines, the American College of Surgeons recommends the use of peer review.

Professional team

Specification of the qualifications for cardiac surgeons in an established practice is beyond the scope of these guidelines. Surgeons practicing cardiac surgery should be certified or awaiting certification by the American Board of Thoracic Surgery or its Canadian equivalent within five years after completion of an approved residency program in cardiac surgery. It is recommended that hospital committees for staff accreditation exercise their judgments for privileges based on the nature of the cardiothoracic residency or postresidency experiences of the applicant.

A team approach with a minimum of two qualified cardiac surgeons is recommended to provide adequate and continuous perioperative care as well as assistance in the OR. It is recognized that, depending on the particular setting and situation, the assistant on a particular case may vary in experience and qualification.

Hospital operative volume–Adult cardiac surgery

The 1975 report of the Inter-Society Commission on Heart Disease Resources recommended that cardiac surgical programs in a *hospital* should perform at least 200 procedures annually. This recommendation was based on the premise of a hospital dedicating 1 operating room to cardiac surgery and functioning at 80 percent capacity (4 cases per week x 52 weeks = 200 per year). While there are no presently available data linking an *individual surgeon's* patient volume and hospital mortality rate, there are data to suggest that an annual volume of at least 100 to 125 open heart procedures (including coronary artery bypass procedures, valve replacements, and other operations requiring the use of cardiopulmonary bypass) per *hospital* is necessary from a quality standpoint and that there is a greater variation in adjusted mortality rates for teams doing lower volumes of procedures as compared with those doing a high volume. While 100 to 125 cases per year per *hospital* appears sufficient from a quality standpoint, it is likely that considerably more, and at least 200 procedures per year as previously recommended, are necessary in order for a program to function efficiently.

Congenital heart surgery

Surgery for congenital heart disease, especially in infants, requires a setting that readily meets the complex and special needs

of this group of patients. These requirements include a cardiac surgeon experienced in the operative and perioperative management of such patients. There should be a pediatric cardiologist, an anesthesia team, perfusionists, intensive care nurses, and appropriate intensive care facilities for the treatment of infants and children. At a hospital where congenital heart operations are performed, a total of 100 congenital heart operations (both open and closed, not including neonatal ductus ligations) should be done. The occasional management of an infant or child with congenital heart disease by an otherwise busy and well-functioning adult cardiac surgical team is strongly discouraged.

Hospital facilities and personnel

It is urged that hospital committees for staff accreditation use peer review to determine that adequate standards of practice are maintained in terms of case frequency and results. A registry for the recording of cardiac surgical results is mandatory.

The complex operating room environment required by cardiac surgery in terms of equipment and instruments requires constant improvement in technique and proper indoctrination of personnel. Such educational programs should be under the direction of a clearly designated individual with particular interest and skill in cardiac surgery. Operating room nurses and technicians specializing in cardiac surgery are important. It should be mandatory that operating room nurses and technicians be assigned to cardiac surgery sufficiently often to develop and maintain the skills required for proficient performance in this area.

Anesthesia for cardiac surgical patients encompasses a variety of special problems. To ensure technical competence, frequent changing of the anesthesiologists assigned to cardiac surgery should be avoided.

The operation of a heart-lung machine should be performed by a specially trained nurse or technician under the supervision of the operating surgeon. A perfusionist certified by the American Board of Cardiovascular Perfusion is recommended. Perfusionists who are not certified should have at least two years of experience under supervision in an active clinical program in open-heart surgery and have a thorough background in operating room sterile techniques, perfusion physiology, the use of monitoring equipment, and a general understanding of commonly performed cardiac surgical procedures. The primary responsibility for determining the capability of the perfusionist remains with the cardiac surgeon.

Cardiac surgeons must be primarily responsible for the postoperative care of their patients, including that provided in the intensive care unit. Portions of that care may be shared with others, such as nurses and other physicians. However, only the cardiac surgeon is fully cognizant of all aspects of a given patient's condition and retains the responsibility for the continuity of care, which includes the preoperative status, the operative management, and the postoperative care.

Intensive care nursing of cardiac surgical patients is recognized as a true specialty involving skills in dealing with cardiac and respiratory emergencies. Assignment to cardiac surgical patients should be sufficiently often to maintain competence in this area of nursing. The surgeon should participate in the supervision of cardiac intensive care unit nurses.

The operating room, intensive care unit, and other facilities must conform to standards mandated by the Joint Commission on Accreditation of Health Care Organizations.

The nature of cardiac surgery makes it mandatory that diagnostic facilities be available to the surgical team. A proper cardiac catheterization laboratory must be available for hemodynamic and cine' angiographic studies. This laboratory should be under the direction of a qualified specialist and be accessible for preoperative elective studies, postoperative elective studies, and emergency procedures on a 24-hour basis.

Standard laboratory studies should be available on a 24-hour basis, including blood-gas analysis.

A blood bank facility with full resources under the direction of qualified specialists in this field is mandatory.

An intensive care facility must be available for all patients following cardiac surgery, and in some instances, for patients who are severely ill, preoperatively. This should be a limited-access area that is off limits to nonparticipating personnel and should have facilities for the adequate isolation of septic patients.

Patient follow-up

Proper patient follow-up is an integral part of surgical treatment. An effective follow-up system for patients having open-heart surgery is the responsibility of the surgical team. The team should be able to demonstrate that it has an adequate follow-up system and that patients are seen as often as necessary during the immediate postdischarge period and, subsequently, are followed up at appropriate intervals.

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Guidelines

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sponsor hospitals and OEMS the ability to begin to collect EMS data, creating the potential in the near future to begin to analyze the data and create best practices to elevate the quality of care and delivery of Emergency Medical Services to the residents and visitors of Connecticut.

In late 2008/early 2009 the AHA formed a "STEMI stakeholders group" comprised of three sub-committees (pre-hospital, timely transfers and education) intended to develop and promulgate best practice related to ST segment myocardial infarction (STEMI). The group had a varied composition including physicians (EMS/ED, cardiology, and interventional cardiology), nurses, pre-hospital providers and health care administrators/regulators. This group drafted a document outlining recommendations to improve care in relation to pre-hospital triage of STEMI patients, timely transfers of patients between facilities and issues of education for pre-hospital providers. A "STEMI Protocol" was also drafted that was intended to offer state-wide guidance for best practice regarding patients experiencing chest pain and subsequently diagnosed with a STEMI by pre-hospital EKG (including bypass for more timely cardiac catheterization).

The "STEMI Protocol" was reviewed by the CT EMS Medical Advisory Committee (CEMSMAC) beginning in 2010. In 2011, after a significant amount of thoughtful work by the CEMSMAC, a revised version of the document entitled "CT EMS STEMI Guideline" was completed and submitted to the Commissioner of Public Health for review; it was approved in January 2012.

OHCA would encourage the adherence of the "CT EMS STEMI Guideline." The foremost goal is for authorized EMS personnel to obtain a 12-lead electrocardiogram in the field for all patients suspected of myocardial infarction, thereby increasing the likelihood for percutaneous coronary intervention (PCI) within 90 minutes of first medical contact. Please see link below for the complete "CT EMS STEMI Guideline" document:

http://www.ct.gov/dph/lib/dph/ems/pdf/stemi_patients.pdf

CARDIAC SERVICES

Heart disease is the leading cause of death for both men and women in the United States.[53] In 2010, coronary heart disease alone was projected to cost the United States approximately $108.9 billion in health care services, medications, and lost productivity.[54] In Connecticut, cardiovascular disease (CVD) is also a significant public health concern and contributor of resident deaths. In fact, about one third of Connecticut resident deaths are due to CVD; coronary heart disease (48%), cerebrovascular disease (15%) also known as stroke and heart failure (8%) account form the majority of CVD deaths.[55]

Existing Connecticut statute requires CON authorization for the establishment of cardiac services, including inpatient and outpatient cardiac catheterization, interventional cardiology and cardiovascular surgery. According to OHCA's Policies and Procedures, "interventional cardiology" is defined as non-

surgical procedures performed in the cardiac catheterization laboratory for the treatment of coronary artery and peripheral vascular disease. Procedures include, but are not limited to, angioplasty, valvuloplasty, cardiac ablation, coronary thrombectomy, and congenital heart defect correction. Only those procedures authorized pursuant to CON may be performed by a health care facility or provider. Multiple cardiac services may be authorized under one CON decision. A facility that is authorized to provide open heart surgery is also authorized to provide the full range of cardiac procedures mentioned above.

CARDIAC CATHETERIZATION

Cardiac catheterization is defined as a medical procedure requiring the passage of a catheter into one or more cardiac chambers of the left and right heart, with or without coronary arteriograms, for the purpose of diagnosing congenital or acquired cardiovascular disease, or for determining measurement of blood pressure flow.

ANGIOPLASTY/PERCUTANEOUS CORONARY INTERVENTION

Primary (emergent) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a previously diagnosed blockage in the heart. An expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow

Elective (scheduled) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure performed in a catheterization lab whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a previously diagnosed blockage in the heart. An expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow.

PCI and Elective PCI are often combined with the permanent placement of a small wire mesh tube called a stent to help prop the artery open and decrease the chance of it narrowing again. Some stents are coated with medication to help keep the artery open (drug-eluting stents), while others are not (bare-metal stents).

OPEN HEART SURGERY

Open heart surgery refers to a therapeutic operative procedure performed on the heart and/or its coronary arteries in order to correct anomalous conditions (for example, coronary artery bypass surgery, heart valve replacement), often using a heart-lung by-pass machine to perform the functions of circulation during surgery.

Authorization for Connecticut hospitals to perform elective catheter-based interventions for coronary artery disease has been limited in the past to hospitals with the ability to perform cardiac surgery onsite. However, increasing operator experience, improvements in surgical technique and major advances in technology and pharmacology have contributed to a progressive trend to allow PCI without on-site surgical backup. New evidence gives support to the positive effects that these medical advances have contributed to the significant reduction in emergency surgery following PCI[56]. Elective PCI without on-site surgical backup was, until recently, recommended as class III (not recommended, potentially harmful). However, an important change occurred in 2011, when the ACCF-AHA-SCAI PCI guidelines were modified to a class IIb (Level of evidence B) recommendation. CPORT-E trial findings conclude that patients have no greater risk of death or complications when they have Elective PCI at a hospital without cardiac surgery backup. However, similar to the 2007 SCAI Expert Consensus document, the revised guidelines also recommend stringent criteria for such programs. Connecticut hospitals seeking authorization to initiate an Elective PCI program without on-site cardiac surgery capabilities will be required to meet the SCAI conditions required in guidelines as well as demonstrate clear public need for the program.

DESCRIPTION OF DATA SOURCES

The primary source to be used for Acute Care utilization will be the CT Office of Health Care Access Acute Care Hospital Inpatient Discharge Database.

MAP OF CURRENT SERVICE LOCATIONS

Table 3.10: Adult Cardiac Services in Connecticut[57]

Hospital	Cardiac Cath	Primary PCI	Elective PCI	Open Heart
William. W. Backus	X			
Bridgeport Hospital	X	X	X	X
Danbury Hospital	X	X	X	X
John Dempsey Hospital	X	X	X	X
Greenwich Hospital	X	X		
Hartford Hospital	X	X	X	X
Lawrence & Memorial Hospital	X	X		
Middlesex Hospital	X			
Hospital of Central CT	X	X		
Norwalk Hospital	X	X		
Rockville General[1]	X			
St. Francis Hospital	X	X	X	X
HCGW (Saint Mary/Waterbury)	X	X	X	X

Hospital of Saint Raphael	X	X	X	X
St. Vincent's Medical Center	X	X	X	X
Stamford Hospital	X	X	X	X
Yale-New Haven Hospital	X	X	X	X

[1]Although allowed to provide the service, the hospital has not provided the cardiac services.
Source: CT DPH-OHCA Acute Care Hospital Service Line Survey, 2012

STANDARDS/GUIDELINES

Connecticut General Statutes Section 19a-638 specifies that at CON is required for: the establishment of cardiac services, including inpatient and outpatient cardiac catheterization, interventional cardiology and cardiovascular surgery.

The Office of Health Care Access has historically utilized Professional Societies and Organizations held to be the experts for establishing standards and guidelines for cardiac care and will continue to make appropriate use of their recommendations in the future review and determination of CON applications. Examples of expert sources to be used in determining standards and guidelines include: the American College of Cardiology, the American Heart Association and the Advisory Council for Cardiothoracic Surgery.

PERCUTANEOUS CORONARY INTERVENTION (PCI)

Primary PCI

1. Based on ACC and AHA, Primary PCI for STEMI should be performed by experienced operators who perform more than 75 elective PCIs per year and, ideally, at least 11 PCI procedures for STEMI per year. Ideally, these procedures should be performed in institutions that perform more than 400 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year.
2. A report by the American College of Cardiology/American Heart Association Task Force on practice guidelines, referring to Class II b, suggests that Primary PCI for patients with STEMI might be considered in hospitals without on-site cardiac surgery provided that appropriate planning for program development has been accomplished and includes: appropriately experienced physician operators (more than 75 total PCIs and, ideally, at least 11 primary PCIs per year for STEMI); an experienced catheterization team on a 24 hours per day; a 7 day per week call schedule; a well-equipped catheterization lab with digital imaging equipment; a full array of interventional equipment; intra-aortic balloon pump capability; and a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital with appropriate hemodynamic support capability for transfer. Primary PCI should be limited to patients with STEMI or MI with new or presumably new LBBB on ECG and should be performed in a timely fashion (goal of balloon inflation within 90 minutes of presentation) by persons skilled in the procedure (at least 75 PCIs per year) and at hospitals that perform a minimum of 36 Primary PCI procedures per year. (Level of Evidence: B - Limited populations evaluated. Data derived from a single randomized trial or nonrandomized studies).

Elective PCI

1. Elective/urgent PCI should be performed by operators with an acceptable annual volume (>75 procedures) at high volume centers (> 400 procedures) with on-site cardiac surgery (Level of Evidence: C)
2. Elective/urgent PCI should be performed by operators and institutions whose current risk-adjusted outcome statistics are comparable to those reported in contemporary national data registries, (Level of Evidence: C)
3. It is reasonable that low volume operators (< 75 PCI procedures per year) perform elective/urgent PCI at high volume centers (> 400 PCI procedures per year) with on-site cardiac surgery. Ideally, operators with an annual procedure volume of fewer than 75 procedures per year should only work at institutions with an activity level of more than 600 procedures per year. Operators who perform fewer than 75 procedures per year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume of at least 150 procedures per year. (Level of Evidence C)
4. It is not recommended that elective/urgent PCI be performed by low volume operators (< 75 PCI procedures per year) at low volume centers (200 to 400 procedures per year) with or without on-site cardiac surgery. An institution with a volume of fewer than 200 procedures per year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer this service. (Level of Evidence: C)
5. The 2005 PCI Guideline does not establish an explicit minimum hospital volume threshold for elective PCI; there are multiple references in the context of operator and institutional competency to "centers" performing 200 – 400 elective PCI procedures per year.
6. The 2011 PCI Guideline states that operator and hospital volume recommendations have been carried over from the ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention.

   a. PCI in Hospitals without On-Site Surgical Back-up is in the Class IIb category.

      Class II b: Elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection (Level of Evidence: B)

      Any hospital considering elective PCI without on-site-cardiac surgery must meet the criteria set forth in the 2011 ACCF/ANA/SCAI PCI Guideline, Section 4.8., PCI in Hospitals Without On-Site Surgical Backup: Recommendations (see link below):

      http://content.onlinejacc.org/cgi/reprint/58/24/e44.pdf

      Any hospital not meeting the 2011 ACCF/ANA/SCAI PCI Guideline criteria will be considered to be in Class III.

Class III–Harm: Primary and elective PCI should not be performed in hospitals without on-site cardiac surgery capabilities without a proven plan for rapid transport to a surgery operating room in a nearby hospital or without appropriate hemodynamic support capability for transfer. (Level of Evidence: C)

Quality and Performance Considerations for PCI Programs

Based on the 2011 American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions Guidelines for Percutaneous Coronary Intervention:

1. Every PCI program should operate a quality improvement program that routinely:
   a) reviews quality and outcomes of the entire program;
   b) reviews results of individual operators;
   c) includes risk adjustment;
   d) provides peer review of difficult or complicated cases; and
   e) performs random case reviews (Level of Evidence: C)
2. Every PCI program should participate in a regional or national PCI registry for the purpose of benchmarking its outcomes against national norms. (Level of Evidence: C)

PCI quality and performance considerations are defined by attributes related to structure, processes, and risk adjusted outcomes. Structural elements include, for example, staffing, equipment, supplies, operator and institutional volumes, and the availability of electronic medical records. Processes include strategies for the appropriate patient, protocols for pre- and post-procedural care, appropriate procedural execution and management of complications, and participation in databases and registries for benchmarking program and individual operator performance. The end result of these structures and processes of care are risk-adjusted outcomes, and when available, are more reliable measures of quality than the institutional and individual operator volumes.[58]

CARDIAC SURGERY/OPEN HEART SURGERY[59]

1. Guidelines for Standards in Cardiac Surgery developed by the Advisory Council for Cardiothoracic Surgery and approved by the American College of Surgeons' Board of Regents in October 1996 – Bulletin of the American College of Surgeons, Vol. 82, No. 2, February 1997
   a. An annual volume of at least 100 to 125 open heart procedures per hospital is necessary from a quality standpoint and there is a greater variation in adjusted mortality rates for teams doing lower volumes as compared with those doing a high volume.
   b. At least 200 procedures per year are necessary in order for a program to function efficiently
   c. A team approach with a minimum of 2 qualified cardiac surgeons is recommended to provide adequate and continuous perioperative care as well as assistance in the OR.
2. The following conditions must be met to initiate a new OHS program:

a. The annual caseload of other programs w/in the proposed PSA shall not drop below 350 procedures.
b. Epidemiological evidence of conditions for which OHS is appropriate w/in the PSA or demonstrates a significant unmet need in the PSA for these procedures.
c. Existing program(s) in the service area are performing at least 350 open heart surgeries annually.
d. Evidence demonstrating the performance of a minimum of 200 open heart surgeries annually within the first three years of the start of the new Open Heart Surgery program.

CARDIAC UTILIZATION

Based on hospital discharge data, inpatient cardiac care is declining both in patient volume and overall patient days (see Table 4.7 and Chart 4.3). From FY 2008 to FY 2011, Cardiac Care-Medical discharges dropped 6%, while the corresponding patient days declined by 3%. During the same time period, Cardiac Care-Surgical care declined even more significantly, with both discharges (11%) and patient days (8%) falling.

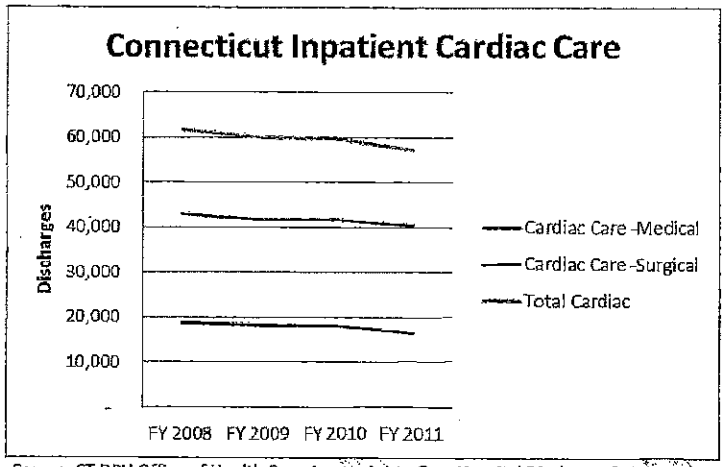
Table 3.11: Statewide Cardiac Inpatient Data

Discharges	FY 2008	FY 2009	FY 2010	FY 2011	chg 08-11	chg 10-11
Cardiac Care -Medical	43,072	41,747	41,795	40,542	-6%	-3%
Cardiac Care -Surgical	18,681	18,299	18,104	16,710	-11%	-8%
Total Cardiac	**61,753**	**60,046**	**59,899**	**57,252**	**-7%**	**-4%**

Patient Days	FY 2008	FY 2009	FY 2010	FY 2011	chg 08-11	chg 10-11
Cardiac Care -Medical	159,087	156,890	155,239	153,817	-3%	-1%
Cardiac Care -Surgical	95,344	93,054	90,455	87,361	-8%	-3%
Total Cardiac	**254,431**	**249,944**	**245,694**	**241,178**	**-5%**	**-2%**

Source: CT DPH Office of Health Care Access Acute Care Hospital Discharge Database

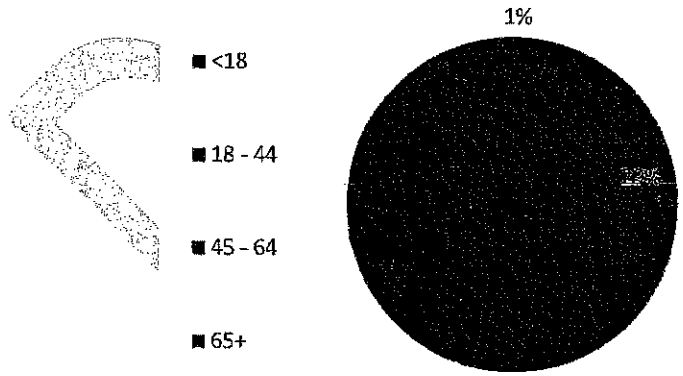
Chart 3.4: Connecticut Inpatient Cardiac Care



Source: CT DPH Office of Health Care Access Acute Care Hospital Discharge Database

Cardiac discharges are highly prevalent among the elderly. As seen in Chart 4.3, sixty-four percent of inpatient cardiac discharges in FY 2011 were for patients age 65 and older.

Chart 3.5: Cardiac Discharges by Age (FY 2011)



Source: CT DPH Office of Health Care Access Acute Care Hospital Discharge Database

DISCUSSION OF UNMET NEED AND GAPS IN SERVICES, CAPACITY ISSUES, ETC.

The tables below provide an initial step toward the identification of potential areas of unmet need for cardiac care in the state. The tables below provide information that compares the number of residents from a given region that received treatment for cardiac medical services or surgery in a given year (patient demand). This patient demand is compared to the overall volume of cardiac patients served by hospitals in the same region. If hospital volumes are lower than patient demand in the region, it may indicate the need for additional capacity and warrants additional study to examine patient migration patterns to confirm or refute this assertion.

Table 3.12: Bed Need for Inpatient Cardiac Services

				Discharges				Patient Days			
Hospitals	DEMHS Region	Service		2007	2008	2009	2010	2007	2008	2009	2010
Bridgeport, Norwalk, Greenwich, Stamford, St Vincent's	1	Medical	Demand	7,589	7,249	7,242	7,069	29,191	28,479	27,882	27,702
			Served	8,642	8,345	8,412	8,239	32,392	32,069	31,436	31,124
			Surplus (-) or Deficit (+)	(1,053)	(1,096)	(1,170)	(1,170)	(3,201)	(3,590)	(3,554)	(3,422)
		Surgical	Demand	3,418	3,340	3,031	2,926	17,810	16,340	15,777	14,429
			Served	3,850	3,728	3,263	3,205	19,693	17,724	16,198	15,181
			Surplus (-) or Deficit (+)	(432)	(388)	(232)	(279)	(1,883)	(1,384)	(421)	(752)
				Discharges				Patient Days			
Hospitals	DEMHS Region	Service		2007	2008	2009	2010	2007	2008	2009	2010
Yale, Griffin, Milford, St Raphael, MidState	2	Medical	Demand	10,202	10,250	9,967	10,664	36,304	37,646	36,740	38,336
			Served	10,000	9,936	9,745	10,539	35,660	37,066	36,198	38,379
			Surplus (-) or Deficit (+)	202	314	222	125	644	580	542	(41)
		Surgical	Demand	4,243	4,119	4,088	4,176	21,406	21,045	20,583	20,451
			Served	5,117	5,118	5,323	5,441	25,969	26,043	26,558	25,675
			Surplus (-) or Deficit (+)	(874)	(999)	(1,235)	(1,265)	(4,563)	(4,998)	(5,975)	(5,224)
				Discharges				Patient Days			
Hospitals	DEMHS Region	Service		2007	2008	2009	2010	2007	2008	2009	2010
Dempsey, Saint Francis, Bristol, HOCCT, Manchester, Hartford, CTCMC, Middlesex, Rockville, Johnson	3	Medical	Demand	12,700	12,162	11,646	10,991	45,821	47,067	46,730	44,209
			Served	14,235	13,846	13,164	12,561	51,503	53,644	53,461	50,397
			Surplus (-) or Deficit (+)	(1,535)	(1,684)	(1,518)	(1,570)	(5,682)	(6,577)	(6,731)	(6,188)
		Surgical	Demand	5,902	5,599	5,600	6,357	33,547	29,771	30,034	28,483
			Served	7,704	7,280	7,172	6,951	43,656	39,799	39,143	38,204
			Surplus (-) or Deficit (+)	(1,802)	(1,681)	(1,572)	(1,594)	(10,109)	(10,028)	(9,109)	(9,721)
				Discharges				Patient Days			
Hospitals	DEMHS Region	Service		2007	2008	2009	2010	2007	2008	2009	2010
Backus, L&M, Day Kimball, Windham	4	Medical	Demand	5,252	5,773	5,422	5,451	17,289	19,042	18,559	17,806
			Served	4,772	5,187	4,904	4,926	14,885	16,203	15,676	15,085
			Surplus (-) or Deficit (+)	480	586	518	525	2,404	2,839	2,883	2,721
		Surgical	Demand	1,948	2,051	1,980	2,120	10,852	10,340	9,556	10,658
			Served	382	426	396	414	2,227	1,982	1,923	2,052
			Surplus (-) or Deficit (+)	1,566	1,625	1,584	1,706	8,625	8,358	7,633	8,606

Hospitals	DEMHS Region	Service		Discharges				Patient Days			
				2007	2008	2009	2010	2007	2008	2009	2010
Danbury, New Milford, Hungerford, Sharon, St Mary's, Waterbury	5	Medical	Demand	6,454	6,026	5,884	5,864	22,071	21,794	21,988	21,740
			Served	6,183	5,758	5,522	5,539	20,718	20,114	20,119	20,254
			Surplus (-) or Deficit (+)	271	268	362	325	1,353	1,680	1,869	1,486
		Surgical	Demand	3,001	2,864	2,901	2,811	14,999	14,367	13,705	12,906
			Served	2,164	2,129	2,145	2,093	10,302	9,796	9,232	9,343
			Surplus (-) or Deficit (+)	837	735	756	718	4,697	4,571	4,473	3,563

Hospitals		Service		Discharges				Patient Days			
				2007	2008	2009	2010	2007	2008	2009	2010
Distributed among several hospitals	Out of State, Unk Address	Medical	Demand	1,635	1,612	1,586	1,765	4,862	5,068	4,891	5,444
			Served								
			Surplus (-) or Deficit (+)								
		Surgical	Demand	705	708	699	714	3,433	3,481	3,399	3,528
			Served								
			Surplus (-) or Deficit (+)								

RECOMMENDATIONS

1. Examine volume as indicator of quality, as well as other indicators, by examining institutional and operator performance.
2. Continue to review and update Connecticut's cardiac guidelines to reflect updated information and recommendations provided by Professional Societies and Organizations with expert knowledge of cardiac care.

CANCER TREATMENT

Oncology is the branch of medicine concerned with the study and treatment of cancer, including screening, diagnosis, therapy, follow-up and palliative care. It includes various sub specialties such as radiation oncology (medical use of high-energy radiation to kill malignant cells), surgical oncology, and pediatric oncology. Chemotherapy, most generally the treatment of disease by chemicals, can be used for a range of diseases but most frequently refers to antineoplastic drugs to treat cancer.

In Connecticut, there is no unique licensure category for cancer treatment. The Commission on Cancer (CoC), a consortium of professional organizations dedicated to improving cancer patients' lives, administers an accreditation program that encourages hospitals, treatment centers, and other facilities to improve the quality of patient care by focusing on prevention, early diagnosis, pretreatment evaluation, staging, optimal treatment, rehabilitation, surveillance for recurrent disease, support services, and end-of-life care. A broad range of available medical services combined with a multidisciplinary team approach has resulted in 80 percent of all newly diagnosed cancer patients in the US being treated in CoC-accredited cancer programs.[60] According to the CT Cancer Partnership, 67% of acute care hospitals in Connecticut are ACoS accredited.[61].

ATTACHMENT V

From: Nancy Rosenthal
To: "Jennifer Groves"; Karen Banoff; Marc Kosak; Nancy Hamson; Ahn, Jean; Capozzalo, Gayle
Subject: Fwd: PCI without surgery on site
Date: Friday, July 13, 2012 12:34:06 PM

Sent from my iPhone

Begin forwarded message:

From: Nancy Rosenthal <argrjrnr@optonline.net>
Date: July 13, 2012 12:33:06 PM EDT
To: Nancy Rosenthal <Nancy.Rosenthal@greenwichhospital.org>
Subject: Fwd: PCI without surgery on site

Sent from my iPhone

Begin forwarded message:

From: "Anna D. Colello" <adc05@health.state.ny.us>
Date: July 13, 2012 12:11:20 PM EDT
To: JONATHAN ROSENTHAL <argrjrnr@optonline.net>
Subject: RE: PCI without surgery on site

I do not know

Anna

<graycol.gif> JONATHAN ROSENTHAL ---07/13/2012 11:55:06 AM---
Because I heard they were unsuccessful in getting regulatory approval. Why did St. John's withdraw its application.

JONATHAN ROSENTHAL <argrjrnr@optonline.net> <ecblank.gif> <ecblank.gif>
To
07/13/2012 11:55 AM adc05@health.state.ny.us
<ecblank.gif> <ecblank.gif>
cc
<ecblank.gif> <ecblank.gif>
Subject
RE: PCI without surgery on site

<ecblank.gif> <ecblank.gif>

Because I heard they were unsuccessful in getting regulatory

approval. Why did St. John's withdraw its application.

On Fri, Jul 13, 2012 at 11:51 AM, Anna D. Colello wrote:

They have not been denied privileges. Why did you think so?

St John's Riverside withdrew its application in April 2012.
Sound Shore requested more time and their application remains open.

Anna Colello, Esq.
Director, Regulatory Compliance/OHSM
Cardiac Services Program
One University Place, Suite 218
Rensselaer, New York 12144
Phone: 518-402-4091
Fax: 518-402-6992

Inactive hide details for JONATHAN ROSENTHAL --- 07/13/2012 11:42:56 AM---Anna, Could you tell me when and why St. Johns Riversi JONATHAN ROSENTHAL --- 07/13/2012 11:42:56 AM---Anna, Could you tell me when and why St. Johns Riverside and Sound Shore Hospitals were denied angioplasty privileges?

JONATHAN ROSENTHAL <argrlrnr@optonline.net>
07/13/2012 11:42 AM

To

adc05@health.state.ny.us

cc

Subject

RE: PCI without surgery on site

Anna,

Could you tell me when and why St. Johns Riverside and Sound Shore Hospitals were denied angioplasty privileges?

Nancy

On Fri, Jul 13, 2012 at 11:37 AM, Anna D. Colello wrote:

This is in response to your query regarding the number of hospitals which perform elective angioplasty (PCI - percutaneous coronary intervention) without surgery on site. Section 405.29 of the Department of Health regulations specify that hospitals wishing to perform PCI must perform both primary (emergency) and elective. These regulations were promulgated in November 2009. Prior to that time there was a waiver process which

allowed first primary and later elective procedures to be approved for centers without surgery on site. One center (Bronx Lebanon Hospital) was approved for primary under the waiver system which has not yet requested approval for elective. No new center would be permitted to do just primary because of the regulations.

The centers which perform PCI without surgery on site are:
Unity Health System (Wilson Hospital)
South Nassau Communities Hospital
Faxton-St Luke's Healthcare (St Luke's Division)
Orange Regional Medical Center
St Luke's Cornwall Hospital
St Catherine of Siena Medical Center
Glens Falls Hospital
White Plains Hospital
Brookdale Hospital Medical Center
Long Island College Hospital
Lutheran Medical Center
City Hospital at Elmhurst
Jamaica Hospital Medical Center
St Barnabas
Good Samaritan Hospital on Long Island received approval as a surgery center but has not opened its surgery center so remains PCi w/o surgery at this time
Brookhaven Hospital was very recently approved to do PCI (but do not believe it has opened for PCI) It previously was diagnostic only.

Southside Hospital was approved as a surgery center in 2011

Anna Colello, Esq.
Director, Regulatory Compliance/OHSM
Cardiac Services Program
One University Place, Suite 218
Rensselaer, New York 12144
Phone: 518-402-4091
Fax: 518-402-6992

****

This message originates from Yale New Haven Health System. The information contained in this message may be privileged and confidential. If you are the intended recipient, you must maintain this message in a secure and confidential manner. If you are not the intended recipient, please notify the sender immediately and destroy this message. Thank you.

****

Dr. Christopher Howes

I would like to make some comments regarding certain aspects of Dr. William Gray's testimony including some content from the 2011 ACCF/AHA/SCAI Guidelines for Angioplasty and the 2012 ACCF/SCAI Expert Consensus Document Update.

- Dr. Gray highlighted certain content from the above referenced documents, but neglected to mention other content which clearly is consistent with the proposed program at Greenwich Hospital.

  The 2012 ACCF/SCAI Expert Consensus Document Update states on page 5 of the publication that:

  > "It is generally believed that elective and primary PCI are permissible in sites without cardiovascular surgery, if there is strict adherence to national guidelines. In particular, there must be a documented working relationship with a larger facility with cardiovascular surgical services and an emergency transportation system operative."

  As our CON application clearly says, the proposed elective angioplasty program would be a satellite of the YNHHVC, which is a full service cardiac facility. There is already an emergency transportation system in operation that includes both land and air. Consistent with the 2011 ACCF/AHA/SCAI Guidelines for Angioplasty, our ambulance provider has committed to respond to requests within 20 minutes (see Attachment I). The 2012 ACCF/SCAI Expert Consensus Document Update also stresses (page 5) that a QA/QI system be operative and active, operate 24/7 if emergency angioplasty is provided and participate in a national registry such as the ACC's National Cardiovascular Data Registry. The current emergency angioplasty program at Greenwich Hospital meets all of these recommendations and the proposed elective angioplasty program will as well.

The change in the 2011 ACCF/AHA/SCAI guidelines for elective angioplasty without onsite cardiac surgery from a Class III to a Class IIb is significant. Dr. Gray states this change is only "incremental", but my opinion is to move from a Class III which indicates harm to a Class IIb which states such a program might be considered as long as there is appropriate program development and rigorous criteria for proper patient selection is beyond "incremental". OHCA has recognized this significant change and incorporated in their Cardiac Services section of the new State Health Plan (draft form) the following statement:

> "...an important change occurred in 2011, when the ACCF-AHA-SCAI PCI guidelines were modified to a class IIb (Level of evidence B) recommendation".

- Dr. Gray discusses the results of the CPORT-E study recently published in the New England Journal of Medicine and suggests that our CON application included the position that elective angioplasty without onsite cardiac surgery is preferred over sites with onsite surgery. Our application never included any such suggestion. But the CPORT-E study, along with others noted in Dr. Cabin's prefiled testimony, and the shift from a Class III to a Class IIb assignment by the ACCF/AHA/SCAI Angioplasty Guidelines all support the reasonableness of offering elective angioplasty without onsite cardiac surgery as long as number of criteria are met which we have already addressed in our CON application. Dr. Gray's skepticism and criticism of angioplasty without onsite cardiac surgery is puzzling given his institution's (NYP) support of White Plains Hospital's program as well as support of a similar program by another NYP affiliate, Holy Name Hospital in Teaneck, New Jersey.

- Dr. Gray also highlights the statement in the 2011 ACCF/AHA/SCAI Guidelines which discusses competition with another angioplasty program in the same geographic area, particularly an established program with surgical back-up and that such competition MAY not be in the best interests of the community. The data we included in our prefiled testimony clearly shows that Greenwich and Stamford Hospitals are overwhelmingly serving residents of different communities. I would go so far as to say that we do not compete in the area of cardiology, despite our close geography. Our medical staff in

cardiovascular services does not overlap to any measurable degree and referral patterns to the interventional cardiologists are different. We have offered emergency angioplasty for approximately 8 years and despite the entrance of Stamford Hospital's program, we have maintained our emergency and elective transfer volume because patients want their care from Greenwich Hospital and the YNHHVC. In this case, a program at Greenwich Hospital IS in the best interest of the community because the Greenwich Hospital community has demonstrated that is where they want their care.

- Dr. Gray states that if the program at Greenwich Hospital is approved there is a risk that Stamford and Greenwich Hospital's angioplasty programs may perform less than 200 PCIs per year. For the reasons I have outlined above, we do not believe our program will impact Stamford's program due to the lack of patient and physician crossover. It is worthy to note that since the opening of White Plains Hospital's program, Stamford Hospital has not seen any decline in their angioplasty volume. According to Stamford Hospital's Petition, Stamford Hospital "...is on track to perform 277 PCIs in FY 2012" which represents a 25% increase from its 2011 volume as noted on Dr. Kiely's testimony page 32 (PCR data). Clearly, the presence of the White Plains Hospital program, which is located only 15 miles from Stamford Hospital and performed as many as 290 PCIs last year, has not had any impact on Stamford Hospital's angioplasty volumes.

- I must comment on Dr. Gray's suggestion that approval of the proposed program at Greenwich Hospital would in some way encourage physicians to feel "...pressure to refer patients for procedures to keep institutional volumes up. Occurrences like these will only drive up healthcare costs for payers and patients." Dr. Gray is suggesting that physicians may send a patient for an unnecessary procedure just to increase institutional volumes. This may be the practice at New York Presbyterian, but I can assure you that this is NOT the practice of YNHHVC physicians nor would it ever be condoned or permitted.

- Finally, I would like to put on the record that the State of New York regulations cited in Dr. Gray's testimony have no relevance in this CON application. Those regulations apply only to New York hospitals. Although they are irrelevant to this proceeding, it is interesting to note in New York State, hospitals seeking to perform angioplasty without onsite cardiac surgery must perform BOTH primary and elective (refer to Attachment V of Marna Borgstrom's rebuttal testimony). I suspect New York State incorporated this requirement because they recognize the benefits to patients by ensuring access to both types of angioplasty and the positive impact on institutional volumes.

Nelson Pride in Service AMBULANCE ACCESS Ambulance Service CONNECTICUT HANDIVAN

208 Quinnipiac Ave North Haven, CT 06473

July12,2012

To whom it may concern,

Nelson /Access Ambulance and Connecticut Handivan has the privilege of serving Greenwich hospital for patient transportation at ALS and BLS level care as well as wheelchair transportation.

We also staff a critical care Ambulance at Greenwich hospital to facilitate transport for any Advanced Life Support patients. The Paramedic units are equipped with ventilators and Greenwich hospital compatible IV pumps.

It will be our commitment to have an ALS ambulance on scene for pick up within the twenty (20) minute time frame of the call for all Catheterization Lab patient needed transfers to other hospitals.

We appreciate the opportunity to service Greenwich Hospital for all patient transportation, we look forward to servicing the patient's needs as a new innovative procedural department opens.

Denise Markavich
Director of Operations EMT-P AHA-I
Nelson/ Access Ambulance
Connecticut Handi-Van

PROCEDURAL MOTIONS

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS DIVISION

IN RE: ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM AT GREENWICH HOSPITAL	DOCKET NO. 12-31748-CON
	JULY 16, 2012

GREENWICH HOSPITAL AND YALE-NEW HAVEN HOSPITAL'S OBJECTION TO THE STAMFORD HOSPITAL'S PETITION FOR INTERVENOR STATUS & MOTION TO STRIKE TESTIMONY

Greenwich Hospital ("Greenwich") and Yale-New Haven Hospital ("YNHH") (collectively "Applicants"), Applicants in the above-referenced matter, hereby object to the Petition for Intervenor Status With Full Procedural Rights filed by The Stamford Hospital ("TSH"), on July 12, 2012 ("Petition"). Specifically, Applicants object to TSH's request that it be allowed to submit "rebuttal testimony" in connection with the public hearing scheduled for July 17, 2012. "Rebuttal testimony" is a privilege that OHCA typically reserves for applicants, who are customarily given the last word on the record in their own applications. In addition, Applicants move to strike all references in the testimony and exhibits to the elective angioplasty CON application filed by Lawrence & Memorial Hospital ("L&M Application"). The L&M Application has not yet been deemed complete by OHCA and, as such, it is not considered an official CON request. Moreover, because OHCA evaluates and

decides each CON application on its own merits, the arguments advanced by L&M in an unrelated CON request are irrelevant to this proceeding.

TSH Is Not Entitled To Submit Rebuttal Testimony

In its Petition, TSH "seeks permission to offer rebuttal testimony" and claims that it will demonstrate the deficiencies in Applicants' proposal through "evidence … presented in rebuttal." Petition, pp. 8 & 9. As TSH and its counsel are aware, intervenors in a contested case are not usually given the right to submit written rebuttal evidence prior to the public hearing. As an intervenor (should OHCA grant TSH this status), TSH was required to pre-file any and all testimony that it intends to present at the hearing by June 12, 2012 at noon. TSH has had access to a copy of Applicants' initial CON submission since it was filed on February 14, 2012, and has had ample time to consider and prepare its opposition. Applicants, on the other hand, will have had access to TSH's 388-page opposition document for a mere 5 days before the hearing and did not have benefit of reviewing this document prior to submitting their own testimony (which was also due at noon on June 12th). It is for this reason that Applicants are allowed an opportunity to submit a written rebuttal. Also, it is Applicants' burden of proving their case in chief for this CON request, and it is fair that they be given the last word in written submissions.

Moreover, if OHCA grants TSH full procedural rights, TSH will have an opportunity to rebut any information contained in Applicants' pre-hearing submissions through cross-examination of Applicants' witnesses. In addition, as TSH and its counsel surely know, "rebuttal" points are often raised without objection during oral hearing presentations and in response to questions posed by OHCA and the parties. For these reasons, Applicants request that TSH be denied the right to submit

or introduce, at or before the hearing, any additional written testimony or evidence beyond what was included in their June 12th filing.

All References to the L&M Elective Angioplasty CON Application Should be Stricken from the Record

TSH has included in its Petition, as well as in the testimonies of Drs. Sharon Kiely and William Gray, numerous references to the CON application submitted by L&M to establish an elective angioplasty program in New London. Reference is made in the text of the Petition at pages 6-7. Dr. Kiely mentions the L&M project in her testimony (pp. 10-11, 12) and, incredibly, attaches the 56-page CON application in that matter as an exhibit (pp. 53-109). Dr. Gray also mentions the L&M proposal in his testimony at pages 7 and 10 (page 10 makes reference to the CON application for elective angioplasty being filed by The Hospital of Central Connecticut as well).

As a threshold matter, OHCA should not consider the L&M Application because it has not yet been deemed complete. OHCA is still in the process of its completeness review and until L&M responds to any questions from the agency, the CON application remains incomplete and does not constitute an official CON request.

TSH's argument for including the L&M Application is simple – that L&M presents a better case for the addition of elective angioplasty without onsite surgery than Greenwich. However, none of what TSH proposes to say about the L&M Application is relevant to the matter before OHCA. Other than the relationships that both programs have with the Yale New Haven Heart and Vascular Center ("YNHHVC"), the proposals are entirely different. As TSH aptly points out, the programs operate at opposite ends of the state serving distinct patient populations. Allowing this type of

testimony into the record opens the door for future applicants to claim relevance of similar proposals at hospitals and facilities that are nowhere near their own.

OHCA has been clear in its policy that each CON request is evaluated on its own merits and that applications do not lend themselves to general applicability. The fact that TSH has included the L&M Application in its opposition submission is inappropriate. It is a not-so-veiled attempt by TSH to convince OHCA that it should approve only one YNHHVC satellite elective angioplasty program without onsite surgery – the one that is 90 miles away from Stamford. TSH has an obvious self-interest in defeating Applicants' proposal, which is clearly needed and which will undoubtedly improve the quality and accessibility of angioplasty services for area residents. TSH should not be allowed to distract from the real issues before this agency by testifying and cross-examining Applicants' witnesses on a CON that has no relevance to the pending application. For these reasons, Applicants request that all references to the L&M Application be stricken from the record.

WHEREFORE, for the foregoing reasons Applicants request that their Objection to TSH's Petition for Intervenor Status be sustained and their Motion to Strike be granted.

Respectfully Submitted,

GREENWICH HOSPITAL
YALE-NEW HAVEN HOSPITAL

By: _____

JENNIFER L. GROVES, ESQ.
Updike, Kelly & Spellacy, P.C.
265 Church Street
One Century Tower
New Haven, CT 06510
Tel: (203) 786-8300
Fax (203) 772-2037

CERTIFICATION

I hereby certify that a copy of the foregoing has been sent via facsimile and first class mail, postage prepaid, this 16th of July, 2012 to the following:

Stephen M. Cowherd
Jeffers Cowherd
5 Walls Drive
Fairfield, CT 06824

Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS DIVISION

IN RE: ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM AT GREENWICH HOSPITAL	DOCKET NO. 12-31748-CON
	JULY 16, 2012

GREENWICH HOSPITAL AND YALE-NEW HAVEN HOSPITAL'S OBJECTION TO THE ADMINISTRATIVE NOTICE OF DOCKET NO. 08-31210-CON

Greenwich Hospital ("Greenwich") and Yale-New Haven Hospital ("YNHH") (collectively "Applicants"), Applicants in the above-referenced matter, hereby object to OHCA's decision (see Exhibit A attached) to take administrative notice of the entire record of Applicants' previous CON request for permission to establish an elective angioplasty program in Greenwich (Docket No. 08-31210-CON) (the "2008 Docket"). Applicants object to the inclusions of the 2008 Docket in the record of this matter on the grounds that (i) it is the written policy of OHCA to evaluate every CON proposal on a case-by-case basis and decide each application on its own merits; and (ii) the current application is fundamentally different than the 2008 Docket and the inclusion of outdated and irrelevant information from that docket will only serve to confuse the issues before OHCA in this proceeding.

While OHCA has the authority to take administrative notice of judicially cognizable facts, including prior orders and decisions, it has long been the policy of the agency not to take notice of prior dockets in their entirety for purposes of a hearing on a CON request. Participants in a hearing will often ask the agency to take notice of prior dockets involving their opponents so that they can cross-examine for inconsistencies. Applicants sometimes also ask OHCA to take

administrative notice of the dockets of similar proposals for purposes of comparison. OHCA's response has typically been to deny the requests for administrative notice on the grounds that each CON is unique (while giving latitude to cross-examine witnesses on select parts of relevant dockets that are included in pre-hearing submissions) – meaning prior dockets, whether they involve the same parties or the same or similar services, are irrelevant to the analysis of a CON proposal. The preamble to virtually every CON decision since 2005 includes a caveat stating that CONs do not lend themselves to general applicability and that every case is reviewed and judged on its merits.

Applicants are concerned that by taking administrative notice of the 2008 Docket, and by possibly allowing The Stamford Hospital to cross-examine Applicants' witnesses on prior submissions, the issues before OHCA will become confused and the current application will not be decided on its own merits. Much of the information contained within the 2008 Docket has changed and is no longer relevant to Applicants' elective angioplasty proposal. This includes, but is not limited to, changes in the structure of the proposed affiliation arrangement; changes to the ACCF/AHA/SCAI Guidelines recommendations for elective angioplasty without onsite surgical backup; revised need methodology; and changes in the treatment of border hospitals by OHCA for state health planning purposes. In addition, the CON laws themselves have changed since the 2008 Docket was decided and the statutory decision criteria that governed that application are not applicable to this CON request.

For these reasons, Applicants respectfully request that OHCA reconsider its decision to take administrative notice of the 2008 Docket. In the alternative, if the 2008 Docket remains a part of the record in this matter, Applicants request that any cross-examination be limited to information relevant to the 2012 elective angioplasty proposal. Applicants further request that

any information from that docket be given appropriately limited weight and consideration. This will afford Applicants' the fairest possible resolution of the current CON request.

WHEREFORE, Applicants respectfully request that their Objection to the Administrative Notice of Docket No. 08-31210-CON be granted.

Respectfully Submitted,

GREENWICH HOSPITAL
YALE-NEW HAVEN HOSPITAL

By: _____

JENNIFER L. GROVES, ESQ.
Updike, Kelly & Spellacy, P.C.
265 Church Street
One Century Tower
New Haven, CT 06510
Tel: (203) 786-8300
Fax (203) 772-2037

CERTIFICATION

I hereby certify that a copy of the foregoing has been sent via facsimile and first class mail, postage prepaid, this 16th of July, 2012 to the following:

Stephen M. Cowherd
Jeffers Cowherd
5 Walls Drive
Fairfield, CT 06824

Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.

EXHIBIT A

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
Office of Health Care Access

March 15, 2012 VIA FAX & EMAIL ONLY

Ms. Jean Ahn
System Director
Yale-New Haven Hospital
Planning & Business Development Office
20 York Street (Howe 3)
New Haven, CT 06504

RE: Certificate of Need Application; Docket Number: 12-31748-CON
Yale-New Haven Hospital and Greenwich Hospital
Proposal to Establish and Operate an Elective Angioplasty
Program without Onsite Surgical Backup at Greenwich Hospital

Dear Ms. Ahn:

On February 14, 2012, the Office of Health Care Access ("OHCA") received your initial Certificate of Need ("CON") application filing on behalf of Yale-New Haven Hospital ("YNHH") and Greenwich Hospital ("Hospital") (collectively the "Applicants") for the establishment and operation of an elective angioplasty program without onsite surgical backup at the Hospital.

Note: Please be advised, administrative notice is being taken of the entire record of the prior CON application in this matter, as identified under Docket Number: 08-31210-CON. A copy of the Final Table of the Record from the aforementioned record has been attached as Exhibit I, identifying all the individual exhibits included in the record.

OHCA has reviewed the CON application and requests the following additional information pursuant to General Statutes §19a-639a(c):

Clear Public Need - pages 15 through 29

1. With respect to the state map presented on page 18 of the CON application, please provide a map legend and notes of a legible size as the application's presentation is difficult to discern.

2. With respect to the table entitled "Number of Patients Discharged Directly from GH to Another Institution for Elective Angioplasty" on page 19 of the CON application, please address the following:

   a. Identify the distance in miles and travel time between Greenwich Hospital and each of the other six hospitals to which Greenwich Hospital transfered patients requiring elective angioplasty over the last four and a quarter fiscal year period.

   b. Describe the existing physician referral patterns that have resulted in 232 patients needing elective angioplasty, not being able to access this service and being transferred to other Connecticut hospitals; 235 to Yale-New Haven Hospital and 2 to Stamford Hospital over four and a quarter fiscal year period.

3. The Applicants point out that: "... transferring patients to another facility creates an unnecessary stressful and uncomfortable situation for patients and family." Further "transferring to another facility is an increased stress for the patients and their families with regard to transportation. For some, in Greenwich Hospital's greater service area, transportation outside the service area is problematic." This being the case, why is Yale-New Haven Hospital the institution of choice when transferring a patient requiring elective angioplasty, as Stamford Hospital presents a much closer Connecticut alternative hospital site?

4. With respect to the table entitled Population Projections- Greenwich Hospital Service Area on page 27 of the CON application, please provide two tables in the same format, the first depicting the population projections for the state of Connecticut and the second depicting the population projections for the state of New York.

5. Please address the following questions regarding existing providers of elective angioplasty closest to the Hospital and its service area:

   a. Please identify all providers that currently offer Elective Angioplasty.
   b. Identify the existing providers that currently offer elective angioplasty with on-site surgical backup.
   c. What impact will this proposal have on these exiting providers financially and on their elective PCI utilization?

6. Provide a copy of the Hospital's protocols related to the proposed elective angioplasty without cardiac surgery backup. Additionally, explain any protocols that will be specific to this program.

2011 ACCF/AHA/SCAI Guidelines for Percutaneous Coronary Intervention-pages 140-230

7. In regard to the Attachment VI: 2011 ACCF/AHA/SCAI Guidelines for Percutaneous Coronary Intervention, please address the following questions:

a. How does the Hospital meet each of the criteria listed in Class IIa, IIb, III and tables 5 & 6?

b. How does the Hospital plan to meet the guidelines regarding the rapid transport to a cardiac surgery operating room in a nearby hospital and without hemodynamic support to transfer?

c. How do ACCF/AHA/SCAI guidelines define "nearby" hospital/operating room?

d. How does the Hospital's transport agreement with YNHH (where majority of the patients have been transferred in the past) relate to or meet the guidelines?

e. The Hospital's median time to immediate PCI for STEMI patients is 67.0 minutes. As reported in the ACC-NCDR report (Attachment XI of the CON application) all hospitals in the 90th percentile have a median time to immediate PCI for STEMI patients of 50.4 minutes. How does Hospital's median time relate to the ACCF/AHA/SCAI guidelines published in November 2011?

8. The Applicants state on page 15, that the Hospital "must address the cost-effectiveness of angioplasty services." Please address how this goal of the Applicants is consistent with the statement in Class III, which states that desires for personal or institutional financial gain…are not appropriate consideration(s) for initiation of a PCI program without on-site cardiac surgery.

9. The guidelines state that "[c]ompetition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interests of the community." Please address your proposal in relation to this statement while taking into consideration the existing providers of elective angioplasty in the Hospital's service area (and geographic) (in CT and NY).

10. Considering that the Hospital does not have access to a helicopter, explain how it expects to meet the protocols related to emergency transportation to a cardiac facility with a cardiac surgery program. In particular, discuss the Hospital's transfer agreement with its affiliate YNHH in this matter.

In responding to the questions contained in this letter, please repeat each question before providing your response. **Paginate and date** your response (i.e., each page in its entirety). Information filed after the initial CON application submission (i.e. completeness response letter, prefile testimony, late file submissions and the like) must be numbered sequentially from the Applicant's document preceding it. Please reference "Docket Number: 12-31748-CON." Submit one (1) original and five (5) hard copies of your response. In addition, please submit a scanned copy of your response including all attachments on CD in an Adobe format (.pdf) and in an MS Word format.

If you have any questions concerning this letter, please feel free to contact me or Steven W. Lazarus at (860) 418-7001.

Sincerely,

Jack A. Huber

Jack A. Huber
Health Care Analyst

Exhibit I

FINAL

TABLE OF THE RECORD

APPLICANTS: **Greenwich Hospital and Yale-New Haven Hospital**

DOCKET NUMBER: **08-31210-CON**

PUBLIC HEARING: **February 24, 2009 at 9:00 a.m.**

PLACE: **410 Capitol Avenue, Third Floor Hearing Room**
Hartford, Connecticut

EXHIBIT	DESCRIPTION
A	Letter from Greenwich Hospital and Yale-New Haven Hospital ("Applicants") dated July 25, 2008, enclosing Letter of Intent forms to establish and operate an elective angioplasty program at Greenwich Hospital, received by the Office of Health Care Access ("OHCA") on July 25, 2008.
B	OHCA's request for legal notification in the *Greenwich Times* and the *New Haven Register* and notification to Applicants of receipt of the Letter of Intent in the matter of the CON application under Docket Number 08-31210, dated July 30, 2008.
C	OHCA's letter to the Applicants dated S4eptember 12, 2008, enclosing the Certificate of Need ("CON") application forms under Docket Number 08-31210.
D	Various emails between the Applicants and OHCA beginning September 12, 2008 through November 5, 2008 in the matter of the CON application under Docket Number 08-31210.
E	Email between the Applicants and OHCA dated November 6, 2008 in the matter of the CON application under Docket Number 08-31210.
F	Letter from the Applicants dated November 21, 2008, enclosing the CON application under Docket Number 08-31210, received by OHCA on November 21, 2008.
G	OHCA's letter to the Applicants dated December 8, 2008, requesting additional information and/or clarification in the matter of the CON application under Docket Number 08-31210.

H	Applicants' responses to OHCA's letter of December 8, 2008 dated January 23, 2009, in the matter of the CON application under Docket Number 08-31210, received by OHCA on January 23, 2009.
I	OHCA's request for legal notification in the *Greenwich Times* and the *New Haven Register* and OHCA's Notice to the Applicants of the public hearing scheduled for February 24, 2009, in the matter of the CON application under Docket Number 08-31210, dated February 6, 2009.
J	OHCA's letter to the Applicants dated February 11, 2009, requesting prefile testimony and interrogatories in the matter of the CON application under Docket Number 08-31210.
K	OHCA's email to the Applicants dated February 18, 2009 confirming the hearing scheduled for February 24, 2009 in the matter of the CON application under DN 08-31210.
L	Letter from the Applicants enclosing Prefile Testimony and responses to interrogatories dated February 19, 2009 in the matter of the CON application under Docket Number 08-31210, received by OHCA on February 19, 2009.
M	Petition of The Stamford Hospital dated February 19, 2009, requesting party status or intervenor status with full procedural rights as well as prefile testimonies and a notice of appearance of Jeffers and Ireland in the matter of the CON application under Docket Number 08-31210, received by OHCA on February 19, 2009.
N	Email from The Stamford Hospital to OHCA dated February 20, 2009 attaching their request for status, prefile testimony and exhibits in the matter of the CON application under Docket Number 08-31210, received by OHCA on February 20, 2009.
O	Email from OHCA to the Applicants dated February 20, 2009 forwarding the email OHCA received from The Stamford Hospital in the matter of the CON application under Docket Number 08-31210.
P	Facsimile letter from Wiggin and Dana LLP to OHCA dated February 20, 2009 noticing their appearance on behalf of the Applicants in the matter of the CON application under Docket Number 08-31210, received by OHCA on February 20, 2009.
Q	Facsimile letter from the Applicants to OHCA dated February 23, 2009 requesting a continuance or rescheduling of the hearing in the matter of the CON application under Docket Number 08-31210, receive by OHCA on February 23, 2009.
R	Facsimile letter from Jeffers & Ireland to OHCA dated February 22, 2009 opposing the request by the Applicants to continue or reschedule the hearing in the matter of the CON application under Docket Number 08-31210, received by OHCA on February 23, 2009.

S	Facsimile letter from the Applicants to OHCA dated February 23, 2009 objecting to the request by The Stamford Hospital for party status in the matter of the CON application under Docket Number 08-31210, received by OHCA on February 23, 2009.
T	Facsimile letter from the Applicants to OHCA dated February 23, 2009 responding to The Stamford Hospital's objection to the Applicants request for continuance or rescheduling of the hearing in the matter of the CON application under Docket Number 08-31210, received by OHCA on February 23, 2009.
U	Letter from OHCA to the Applicants dated February 23, 2009 denying their request for continuance or rescheduling of the hearing in the matter of the CON application under Docket Number 08-31210.
V	Email from Jeffers & Ireland to OHCA dated February 23, 2009 responding to Applicants letter for request of continuance in the matter of the CON application under Docket Number 08-31210, received by OHCA on February 23, 2009.
W	OHCA's Ruling on the Petition of The Stamford Hospital to be granted intervenor status in the matter of the CON application under Docket Number 08-31210, dated February 23, 2009.

Where Applicable faxes will be used as originals.

Administrative Notice is taken of the following items:

1. Greenwich Hospital, Docket Number 07-027AR, FY 2007 Annual Reporting.
2. Yale-New Haven Hospital Docket Number 07-016AR, FY 2007 Annual Reporting
3. OHCA's Administrative Folder containing Agenda, Table of the Record etc. in the matter of the CON application under Docket Number:08-31210

Late Files requested by OHCA at the Hearing on February 24, 2009:

1. Information regarding New York's elective angioplasty.

Late File from the Applicant dated March 9, 2009, received by OHCA on March 10, 2009 in the matter of the CON application under Docket Number: 08-31210.

E-mail from OHCA to the Intervenor dated March 13, 2009 confirming due date Of March 17, 2009 for responses to the Applicants late file.

Intervenors responses dated March16, 2009 received by OHCA on March 17, 2009 in the matter of the CON application under Docket Number: 08-31210.

Email from the Applicant to OHCA confirming their response date to the Intervenors response of March 20, 2009 in the matter of the CON application under Docket Number: 08-31210.

Applicants response to the intervenors responses dated March 20, 2009 in the matter of the CON application under Docket Number 08-31210, received by OHCA on March 20, 2009 (email, faxed and hardcopy received on the same day).

Letter from the Intervenor dated March 23, 2009 responding to Applicants letter dated march 20, 2009 in the matter of the CON application under Docket Number: 08-31210, received by OHCA (fax on March 23, 2009 and hardcopy on March 24, 2009)

Letter from White Plains Hospital dated March 16, 2009 in the matter of the CON application under Docket Number: 08-31210, received by OHCA on March 23, 2009

OHCA's letter dated March 26, 2009 to all parties closing the public hearing in the matter of the CON application under Docket Number: 08-31210.

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS DIVISION

IN RE: ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM AT GREENWICH HOSPITAL	DOCKET NO. 12-31748-CON
	JULY 16, 2012

GREENWICH HOSPITAL AND YALE-NEW HAVEN HOSPITAL'S MOTION TO DISQUALIFY COUNSEL FOR THE STAMFORD HOSPITAL

Greenwich Hospital ("Greenwich") and Yale-New Haven Hospital ("YNHH") (collectively "Applicants"), Applicants in the above-referenced matter, hereby move to disqualify Stephen M. Cowherd and the law firm of Jeffers Cowherd (collectively "Cowherd") from representing The Stamford Hospital ("TSH") at the public hearing on this matter scheduled for July 17, 2012[1], should the Department of Public Health Office of Health Care Access Division ("OHCA") grant TSH status in this proceeding.[2] This Motion to Disqualify is based upon the potential ethical conflict of interest that arises from Cowherd having served as a paid consultant for OHCA in connection with YNHH's CON application for the acquisition of the Hospital of St. Raphael (Docket No. 12-31747-CON) (the "YNHH/HSR Proceeding").

[1] Applicants understand that if OHCA grants this Motion to Disqualify Cowherd, a continuance of the hearing may be required so that TSH can secure alternate counsel.

[2] TSH filed a Petition For Intervenor Status With Full Procedural Rights and prefiled the testimony of several witnesses on July 12, 2012.

Factual Background

This docket concerns a request by Applicants for permission to add elective angioplasty to the suite of cardiac services available at Greenwich Hospital ("Greenwich Elective Angioplasty Program"). Greenwich and YNHH are both members of the Yale New Haven Health System ("YNHHS") and Greenwich serves as a satellite of the Yale New Haven Heart and Vascular Center ("YNHHVC"). Notice of this CON was published in the Greenwich Time on December 1, 2 and 3, 2011, and the CON Application was filed with OHCA on February 14, 2012.

On February 9, 2012, Applicant YNHH and the Hospital of St. Raphael ("HSR") filed their CON Application for the change of ownership of HSR. Soon thereafter, OHCA retained Cowherd to serve as a paid consultant with respect to the YNHH/HSR CON. According to the Jeffers Cowherd website, Attorney Cowherd's practice focuses on healthcare and administrative law, including but not limited to, work before OHCA in connection with CON matters. He represents a variety of providers, including acute care hospitals. Notably, Cowherd has represented TSH for many years. He represented TSH in 2009, when the hospital opposed Applicants' last request for permission to establish an elective angioplasty program at Greenwich (Docket No. 08-31210-CON). This representation occurred prior to Cowherd's retention by OHCA as a consultant in connection with the YNHH/HSR Proceeding.

Cowherd was one of several attorneys that OHCA considered for the YNHH/HSR engagement and he was hired over the objection of YNHH. YNHH objected to Cowherd's involvement based on the fact that he represents TSH, which competes with and has been aggressive in opposing projects proposed by Greenwich and YNHH. At the time Cowherd agreed to consult with OHCA on the YNHH/HSR Proceeding, he was aware of the Greenwich

Elective Angioplasty Program filing (which had been noticed in December of 2011) and he knew or should have known, based on past experience, that his client TSH would oppose the CON request.

Cowherd's involvement in the YNHH/HSR Proceeding afforded him unique and unprecedented access to OHCA staff in connection with their evaluation of a CON and formulation of an Agreed Settlement. He reviewed documents and provided advice to staff, the specifics of which cannot be known by Applicants given that they were not involved in the discussions. Moreover, Cowherd was privy to confidential information, not otherwise available to the public, in the discharge of his duties as advisor to OHCA. It is our understanding that Cowherd reviewed "draft" documents from the agency, which are not discoverable under the Connecticut Freedom of Information Act ("CT FOIA"), and had conversations with senior OHCA staff regarding the substance of the agency's completeness review. Cowherd also reviewed information regarding OHCA's statewide facilities planning process, which has yet to be finalized and which presumably had some relevance to OHCA's review of the YNHH/HSR CON.

Argument

Cowherd should be disqualified as counsel in this matter based on the prohibitions set forth in Rule 1.11(c) of the Connecticut Rules of Professional Conduct (see Exhibit A attached). Rule 1.11(c) provides, in pertinent part, as follows:

> [A] lawyer having information that the lawyer knows is confidential government information about a person acquired when the lawyer was a public officer or employee, may not represent a private client whose interests are adverse to that person in a matter in which the information could be used to the material disadvantage of that person. As used in this Rule, "confidential government information" means information that has been obtained under governmental authority and which ... the government is prohibited by law from disclosing to the public or has a legal privilege not to disclose and which is not otherwise available to the public.

According to its commentary, Rule 1.11 is intended to prevent attorneys who have worked with the government from obtaining an unfair advantage over their clients' adversaries as a result of information learned during the attorneys' service.

Here, Cowherd's relationship with OHCA in connection with the YNHH/HSR CON, while characterized as that of consultant, was akin to that of a staff attorney employed by the agency. In fact, Applicants' understanding is that he was hired because the agency was short-staffed, due in part to the recent departure of its in-house counsel. To the best of Applicants' knowledge, Cowherd was asked to review the CON submissions, assist in formulating completeness questions and advise OHCA regarding the application's conformance with the agency's statutes and statewide facilities planning objectives, much like the former OHCA staff attorney would have done. Cowherd's position with OHCA, however titled, gives his client an unfair advantage over Applicants in this matter.

In addition, it is clear that Cowherd was privy to "confidential government information" during his service, which OHCA has the right to withhold from the public. As previously noted, confidential government information is information that has been obtained under governmental authority and which the government is prohibited by law from disclosing to the public or has a legal privilege not to disclose and which is not otherwise available to the public (see Rule 1.11). Cowherd had access to, and reviewed and provided comment on, initial drafts of the completeness questions issued to YNHH and HSR, which in final form had a far more "legal" tone than questions typically issued by OHCA staff (see Exhibit B attached). It is unclear whether Cowherd had access to initial drafts of the Agreed Settlement as well. These preliminary agency documents are not available to the public, including YNHH and HSR, but rather are protected from disclosure by the CT FOIA exemption found in Section 1-210(b)(1) of

the Connecticut General Statutes. Section 1-210(b)(1) provides that an agency need not disclose to the public any "[p]reliminary drafts or notes provided the public agency has determined that the public interest in withholding such documents clearly outweighs the public interest in disclosure." It has been the policy of OHCA not to disclose to the public drafts of documents, including completeness letters and decisions, which ultimately make their way into the administrative record in final form.

Moreover, Cowherd may have had access to certain documents associated with the YNHH/HSR Proceeding that were not made available to the public by agreement between the agency and the parties. These documents included several independent consulting reports obtained by the hospitals and an un-redacted version of the Asset Purchase Agreement for the transaction. OHCA staff may also have shared with Cowherd their thought processes regarding CON decision-making in general, resolution of the YNHH/HSR application specifically, and YNHHS system and service-line development. None of this information is available to the general public or to applicants and counsel who practice before the agency. This information may also be considered "confidential government information" under Rule 1.11.

Now, less than three weeks after the YNHH/HSR transaction was approved by OHCA via Agreed Settlement, Cowherd seeks to represent TSH, a competitor of Greenwich and YNHH, in opposing their CON request for an elective angioplasty satellite. However, Rule 1.11 expressly prohibits a lawyer in Cowherd's position from "represent[ing] a private client whose interests are adverse to that person in a matter in which the information could be used to the material disadvantage of that person." Here, the "private client" is TSH and "that person" is YNHH, an Applicant in this matter along with its sister hospital Greenwich. The "information" at issue could include specific facts regarding YNHH and YNHHS services (including cardiac

services), as well as general OHCA priorities for system development and CONs, any of which could conceivably be used to oppose the current application. Cowherd has filed a lengthy and detailed opposition to the Greenwich Elective Angioplasty Program on behalf of TSH. Applicants have no assurance that Cowherd has not used and will not use, either intentionally or unintentionally, confidential information that he obtained by virtue of his consulting arrangement with OHCA to the material disadvantage of YNHH and Greenwich in this proceeding. As previously noted, Rule 1.11 seeks to avoid just this type of "unfair advantage" resulting from the use of inside information obtained during an attorney's government service.

Furthermore, Canon 9 of the ABA Model Code of Professional Responsibility states that an attorney shall strive to avoid "not only professional impropriety but also the appearance of impropriety" (see Exhibit C attached). The fact that Cowherd agreed to serve as a consultant to OHCA in the YNHH/HSR Proceeding, knowing full well that his client, TSH, would soon be opposing a YNHH CON request for an elective angioplasty satellite in Greenwich, gives at the very least the appearance of impropriety. Applicants and the public are left wondering whether and to what extent Cowherd has gained inside knowledge about OHCA and YNHHS that he will use for the benefit of TSH and to the material disadvantage of Applicants.

Conclusion

The Hearing Officer has the authority to make such orders as will aid in the just resolution of a contested case. Reg., Conn State Agencies, Section 19a-9-29(g). Cowherd cannot separate the information he learned serving as a consultant to OHCA in a YNHH matter from his representation of TSH in opposition to this Greenwich/YNHH CON request.

Accordingly, the interests of justice require that Stephen M. Cowherd and the law firm of Jeffers Cowherd be disqualified from representing TSH in this proceeding.[3]

WHEREFORE, Applicants respectfully request that their Motion to Disqualify Stephen M. Cowherd and the law firm of Jeffers Cowherd be granted.

Respectfully Submitted,

GREENWICH HOSPITAL
YALE-NEW HAVEN HOSPITAL

By: _____

JENNIFER L. GROVES, ESQ.
Updike, Kelly & Spellacy, P.C.
265 Church Street
One Century Tower
New Haven, CT 06510
Tel: (203) 786-8300
Fax (203) 772-2037

[3] Jeffers Cowherd cannot continue to represent TSH through other attorneys because Attorney Cowherd was not timely screened from any participation in this matter (see Exhibit A).

CERTIFICATION

I hereby certify that a copy of the foregoing has been sent via facsimile and first class mail, postage prepaid, this 16th of July, 2012 to the following:

Stephen M. Cowherd
Jeffers Cowherd
5 Walls Drive
Fairfield, CT 06824

Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.

EXHIBIT A

Principles of Imputed Disqualification. The rule of imputed disqualification stated in subsection (a) gives effect to the principle of loyalty to the client as it applies to lawyers who practice in a law firm. Such situations can be considered from the premise that a firm of lawyers is essentially one lawyer for purposes of the rules governing loyalty to the client, or from the premise that each lawyer is vicariously bound by the obligation of loyalty owed by each lawyer with whom the lawyer is associated. Subsection (a) operates only among the lawyers currently associated in a firm. When a lawyer moves from one firm to another, the situation is governed by Rules 1.9 (b) and 1.10 (b).

The Rule in subsection (a) does not prohibit representation where neither questions of client loyalty nor protection of confidential information are presented. Where one lawyer in a firm could not effectively represent a given client because of strong political beliefs, for example, but that lawyer will do no work on the case and the personal beliefs of the lawyer will not materially limit the representation by others in the firm, the firm should not be disqualified. On the other hand, if an opposing party in a case were owned by a lawyer in the law firm, and others in the firm would be materially limited in pursuing the matter because of loyalty to that lawyer, the personal disqualification of the lawyer would be imputed to all others in the firm.

The Rule in subsection (a) also does not prohibit representation by others in the law firm where the person prohibited from involvement in a matter is a nonlawyer, such as a paralegal or legal secretary. Nor does subsection (a) prohibit representation if the lawyer is prohibited from acting because of events before the person became a lawyer, for example, work that the person did while a law student. Such persons, however, must be screened from any personal participation in the matter to avoid communication to others in the firm of confidential information that both the nonlawyers and the firm have a legal duty to protect. See Rules 1.0 (k) and 5.3.

Rule 1.10 (b) operates to permit a law firm, under certain circumstances, to represent a person with interests directly adverse to those of a client represented by a lawyer who formerly was associated with the firm. The Rule applies regardless of when the formerly associated lawyer represented the client. However, the law firm may not represent a person with interests adverse to those of a present client of the firm, which would violate Rule 1.7. Moreover, the firm may not represent the person where the matter is the same or substantially related to that in which the formerly associated lawyer represented the client and any other lawyer currently in the firm has material information protected by Rules 1.6 and 1.9 (c).

Rule 1.10 (c) removes imputation with the informed consent of the affected client or former client under the conditions stated in Rule 1.7. The conditions stated in Rule 1.7 require the lawyer to determine that the representation is not prohibited by Rule 1.7 (b) and that each affected client or former client has given informed consent to the representation, confirmed in writing. In some cases, the risk may be so severe that the conflict may not be cured by client consent. For a discussion of the effectiveness of client waivers of conflicts that might arise in the future, see Rule 1.7 and its Commentary. For a definition of informed consent, see Rule 1.0 (f).

Where a lawyer has joined a private firm after having represented the government, imputation is governed by Rule 1.11 (b) and (c), not this Rule. Under Rule 1.11 (d), where a lawyer represents the government after having served clients in private practice, nongovernmental employment or in another government agency, former-client conflicts are not imputed to government lawyers associated with the individually disqualified lawyer.

Where a lawyer is prohibited from engaging in certain transactions under Rule 1.8, subsection (k) of that Rule, and not this Rule, determines whether that prohibition also applies to other lawyers associated in a firm with the personally prohibited lawyer.

Rule 1.11. Special Conflicts of Interest for Former and Current Government Officers and Employees

(Amended June 26, 2006, to take effect Jan. 1, 2007.)

(a) Except as law may otherwise expressly permit, a lawyer who has formerly served as a public officer or employee of the government:

(1) is subject to Rule 1.9 (c); and

(2) shall not otherwise represent a client in connection with a matter in which the lawyer participated personally and substantially as a public officer or employee, unless the appropriate government agency gives its informed consent, confirmed in writing, to the representation.

(b) When a lawyer is disqualified from representation under subsection (a), no lawyer in a firm with which that lawyer is associated may knowingly undertake or continue representation in such a matter unless:

(1) The disqualified lawyer is timely screened from any participation in the matter and is apportioned no part of the fee therefrom; and

(2) Written notice is promptly given to the appropriate government agency to enable it to ascertain compliance with the provisions of this Rule.

(c) Except as law may otherwise expressly permit, a lawyer having information that the lawyer knows is confidential government information about a person acquired when the lawyer was a public officer or employee, may not represent a private client whose interests are adverse to that person in a matter in which the information could be used to the material disadvantage of that person. As used in this Rule, the term "confidential government information" means information that has been obtained under governmental authority and which, at the time this Rule is applied, the government is prohibited by law from disclosing to the public or has a legal privilege not to disclose and which is not otherwise available to the public. A firm with which that lawyer is associated may undertake or continue representation in the matter only if the disqualified lawyer is timely screened from any participation in the matter and is apportioned no part of the fee therefrom.

(d) Except as law may otherwise expressly permit, a lawyer currently serving as a public officer or employee:

(1) Is subject to Rules 1.7 and 1.9; and

(2) Shall not:

(i) Participate in a matter in which the lawyer participated personally and substantially while in

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private practice or nongovernmental employment, unless the appropriate government agency gives its informed consent, confirmed in writing; or

(ii) Negotiate for private employment with any person who is involved as a party or as lawyer for a party in a matter in which the lawyer is participating personally and substantially; except that a lawyer serving as a law clerk to a judge, other adjudicative officer or arbitrator may negotiate for private employment as permitted by Rule 1.12 (b) and subject to the conditions stated in Rule 1.12 (b).

(e) As used in this Rule, the term "matter" includes:

(1) Any judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, investigation, charge, accusation, arrest or other particular matter involving a specific party or parties, and

(2) Any other matter covered by the conflict of interest rules of the appropriate government agency.

(P.B. 1978-1997; Rule 1.11.) (Amended June 26, 2006, to take effect Jan. 1, 2007.)

COMMENTARY: A lawyer who has served or is currently serving as a public officer or employee is personally subject to the Rules of Professional Conduct, including the prohibition against concurrent conflicts of interest stated in Rule 1.7. In addition, such a lawyer may be subject to statutes and government regulations regarding conflict of interest. Such statutes and regulations may circumscribe the extent to which the government agency may give consent under this Rule. See Rule 1.0 (f) for the definition of informed consent.

Subsections (a) (1), (a) (2) and (d) (1) restate the obligations of an individual lawyer who has served or is currently serving as an officer or employee of the government toward a former government or private client. Rule 1.10 is not applicable to the conflicts of interest addressed by this Rule. Rather, subsection (b) sets forth a special imputation rule for former government lawyers that provides for screening and notice. Because of the special problems raised by imputation within a government agency, subsection (d) does not impute the conflicts of a lawyer currently serving as an officer or employee of the government to other associated government officers or employees, although ordinarily it will be prudent to screen such lawyers.

Subsections (a) (2) and (d) (2) apply regardless of whether a lawyer is adverse to a former client and are thus designed not only to protect the former client, but also to prevent a lawyer from exploiting public office for the advantage of another client. For example, a lawyer who has pursued a claim on behalf of the government may not pursue the same claim on behalf of a later private client after the lawyer has left government service, except when authorized to do so by the government agency under subsection (a). Similarly, a lawyer who has pursued a claim on behalf of a private client may not pursue the claim on behalf of the government, except when authorized to do so by subsection (d). As with subsections (a) (1) and (d) (1), Rule 1.10 is not applicable to the conflicts of interest addressed by these subsections.

This Rule represents a balancing of interests. On the one hand, where the successive clients are a government agency and another client, public or private, the risk exists that power or discretion vested in that agency might be used for the special benefit of the other client. A lawyer should not be in a position where benefit to the other client might affect performance of the lawyer's professional functions on behalf of the government. Also, unfair advantage could accrue to the other client by reason of access to confidential government information about the client's adversary, obtainable only through the lawyer's government service. On the other hand, the rules governing lawyers presently or formerly employed by a government agency should not be so restrictive as to inhibit transfer of employment to and from the government. The government has a legitimate need to attract qualified lawyers as well as to maintain high ethical standards. Thus, a former government lawyer is disqualified only from particular matters in which the lawyer participated personally and substantially. The provisions for screening and waiver in subsection (b) are necessary to prevent the disqualification rule from imposing too severe a deterrent against entering public service. The limitation of disqualification in subsections (a) (2) and (d) (2) to matters involving a specific party or parties, rather than extending disqualification to all substantive issues on which the lawyer worked, serves a similar function.

When a lawyer has been employed by one government agency and then moves to a second government agency, it may be appropriate to treat that second agency as another client for purposes of this Rule, as when a lawyer is employed by a city and subsequently is employed by a federal agency. However, because the conflict of interest is governed by subsection (d), the latter agency is not required to screen the lawyer as subsection (b) requires a law firm to do. The question of whether two government agencies should be regarded as the same or different clients for conflict of interest purposes is beyond the scope of these Rules. See Commentary to Rule 1.13.

Subsections (b) and (c) contemplate a screening arrangement. See Rule 1.0 (l) (requirements for screening procedures). These subsections do not prohibit a lawyer from receiving a salary or partnership share established by prior independent agreement, but that lawyer may not receive compensation directly relating the lawyer's compensation to the fee in the matter in which the lawyer is disqualified.

Notice, including a description of the screened lawyer's prior representation and of the screening procedures employed, generally should be given as soon as practicable after the need for screening becomes apparent.

Subsection (c) operates only when the lawyer in question has knowledge of the information, which means actual knowledge; it does not operate with respect to information that merely could be imputed to the lawyer.

Subsections (a) and (d) do not prohibit a lawyer from jointly representing a private party and a government agency when doing so is permitted by Rule 1.7 and is not otherwise prohibited by law.

For purposes of subsection (e) of this Rule, a "matter" may continue in another form. In determining whether two particular matters are the same, the lawyer should consider the extent to which the matters involve the same basic facts, the same or related parties, and the time elapsed.

Rule 1.12. Former Judge, Arbitrator, Mediator or Other Third-Party Neutral

(Amended June 26, 2006, to take effect Jan. 1, 2007.)

(a) Except as stated in subsection (d), a lawyer shall not represent anyone in connection with a matter in which the lawyer participated personally as a judge or other adjudicative officer or law clerk

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EXHIBIT B

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH
Office of Health Care Access

March 8, 2012 VIA FAX ONLY

Ms. Jean Ahn
System Director
Yale-New Haven Hospital
20 York Street (Howe 3)
New Haven, CT 06504

Ms. Terrie Estes
Director of Planning and Business Development
Saint Raphael Healthcare System &
Hospital of Saint Raphael
1450 Chapel Street
New Haven, CT 06511

RE: Certificate of Need Application; Docket Number: 12-31747-CON
Proposal for Yale-New Haven Hospital's Acquisition of the Saint Raphael Healthcare System Inc. and Hospital of Saint Raphael

Dear Ms. Ahn and Ms. Estes,

On February 9, 2012, the Office of Health Care Access ("OHCA") received your initial Certificate of Need ("CON") application for Yale-New Haven Hospital's ("YNHH") acquisition of the Saint Raphael Healthcare System Inc. ("SRHS"), including the Hospital of Saint Raphael ("HSR").

OHCA has reviewed the CON application and requests additional information pursuant to General Statutes § 19a-639a(c):

Project Description and Need: Change of Ownership or Control – pages 20 through 25

1. Please describe the following:

   a. SHRHS' ownership and control of Saint Regis Health Center, Inc. d/b/a Sister Virginie Grimes Center;
   b. HSR's ownership and control of Connecticut CK Leasing, LLC;
   c. DePaul Health Services Corporation, Inc.'s ownership and control of Saint Raphael Dialysis Center Partnership; and
   d. The businesses engaged in by Connecticut CK Leasing, LLC and Saint Raphael Dialysis Center Partnership and any services they provide to inpatients or outpatients of HSR.

2. On page 21, applicants state that HSR provides "a number of community based programs" and outlines some of these programs in a list.

   Please indicate whether each of these programs is expected to continue following the acquisition. In addition, please provide information regarding all other HSR community based programs and indicate whether each of these additional programs will continue following the acquisition. If any program will be terminated as a result of or directly following the acquisition, describe the reason for such termination, how the decision was made and how the need will be met.

3. On page 22, applicants state that "[d]espite many efforts to mitigate financial losses, HSR recognized that without outside assistance and investment, it could not survive long term as a standalone entity."

   Please describe in detail the efforts HSR has taken to mitigate financial losses and provide detailed evidence supporting the conclusion that HSR could not survive as a standalone entity.

4. Applicants indicate, on page 24, that, "absent the proposed acquisition of HSR, YNHH will have to construct a 5th bed tower..." and further indicate that such tower is estimated to cost approximately $400 million and take nearly five years to complete.

   Please describe:

   a. The number and types of beds (by service category) that were estimated to be contained in the tower.
   b. How the cost and timeline estimates for the tower were determined.

5. Also on page 24, applicants state that "YNHH will make significant investments in the HSR campus to improve its facilities and technological capabilities."

   Please address the following:

   a. Describe, in detail, the nature of the facility improvements that will be made.
   b. Describe, in detail, the nature of the technological improvements that will be made.
   c. Describe how decisions will be made regarding these facility and technological improvements.
   d. Provide an estimated completion date for the improvements described in subsections (a) and (b), respectively.

6. Also on page 24, applicants state that "HSR's long term debt will be extinguished and resources will be provided to address the current Church plan pension shortfall."

   Please provide the following:

   a. The amount of long term debt that HSR currently carries and the amount that will be extinguished;
   b. The amount of the current Church plan pension shortfall and the amount that the shortfall will be reduced; and
   c. The source of the funds that will be used to make the payments described in subsections (a) and (b).

7. Please address the following:

   a. How are the current 421 operational beds at HSR allocated between medical/surgical, pediatric, obstetric, rehabilitation and psychiatric services.
   b. Would YNHH's acquisition of HSR result in any change to the current allocation of beds on the HSR campus.
   c. What would be necessary to make all of HSR's 511 licensed beds operational (up from the current 421 operational beds).
   d. Beyond the current 421 operational beds at HSR, how many additional beds could be phased into operation before the end of FY 2015, what would the likely phasing schedule be and what would be necessary to achieve this.
   e. From 10/08 to the month of applicants' completeness response, what has been the average monthly census for HSR based on both total beds and medical/surgical beds (please provide this data in chart and table form similar to that found on pps. 15-17 of YNHH's CON Application to Increase the Hospital's Licensed Bed Count by 70 under Docket No. 12-31745-CON).
   f. Assuming YNHH is licensed at 1,407 general hospital beds post-acquisition of HSR, and based on the projected inpatient utilization of both campuses, when would YNHH expect to exceed an 80% occupancy level based on average monthly census projections (please provide evidence of all assumptions and calculations on which such projection is based, and a chart of YNHH's bed need for each year until the 80% threshold is reached).
   g. Provide the same information as requested in subsection (f) above, but restrict the projection to when 80% occupancy of the combined medical/surgical beds on both campuses would be exceeded.
   h. Assuming YNHH is licensed at 1,477 general hospital beds post-acquisition of HSR, and based on the projected inpatient utilization of both campuses, when would YNHH expect to exceed an 80% occupancy level based on average monthly census projections (please provide evidence of all assumptions and calculations on which such projection is based).
   i. Provide the same information as requested in subsection (h) above, but restrict the projection to when 80% occupancy of the combined medical/surgical beds on both campuses would be exceeded.

8. On pages 24 and 25, applicants indicate that they engaged Deloitte "to identify cost savings which could be achieved through the acquisition" and that these cost savings are expected to exceed a half of a billion dollars over the next five years.

   Please provide:

   a. A copy of the Deloitte report;
   b. The applicants' cost savings plan; and
   c. An explanation of how applicants foresee that the savings will reduce costs of health care services for patients served by YNHH if the CON application is granted.

9. On page 25, applicants state that "[b]oth HSR and YNHH have focused on maintaining access and improving the quality of care despite the ever-present financial challenges of the industry."

   Please explain, in detail, HSR's efforts to maintain access and improve quality of care since 10/08.

10. Please describe, in detail, how the acquisition of HSR by YNHH will affect the following:

    a. Teaching and residency programs currently located at HSR and YNHH;
    b. Research and clinical trials conducted at HSR and YNHH;
    c. Emergency department services currently located at HSR and YNHH;
    d. Charity care and financial assistance programs currently operating at HSR and YNHH; and
    e. The rates currently charged for hospital services at HSR and YNNH.

Determination of Need by HSR – pages 26 through 27

11. Please describe, in detail, the steps that HSR took to address its financial situation. In addition, provide detailed evidence for the conclusion that HSR will be unable to achieve financial stability in the future. Please include information regarding the following cost saving efforts in the discussion:

    a. Aggressive negotiations with managed care organizations;
    b. Productivity enhancements;
    c. Supply chain cost reductions;
    d. Adjustments to fringe benefits; and
    e. Postponement of essential renovations and equipment purchases.

12. On page 26, applicants indicate that in early 2010, the SRHS Board's Ad Hoc Strategy Committee "began to explore and evaluate options to ensure continuation of the mission of Saint Raphael's and the Sisters into the future."

    Please provide evidence of the Committee's exploration and evaluation of options. Include information regarding the other options besides integration with YNHH that were explored.

13. Provide any reports prepared by Navigant Consulting relating to the analysis of health systems that it performed for HSR.

14. Provide a copy of the letter of intent signed by YNHH and HSR in March 2011.

Benefits to HSR – pages 27 through 29

15. On page 27, applicants state that HSR identified YNHH as its optimal partner for a number of reasons outlined in the application. Please address the following:

    a. Describe any clinical staff/clinical positions at HSR that would not be retained after the acquisition.
    b. Explain what Centers of Excellence would be created and located at the HSR campus.
    c. How will the HSR campus be held out/identified to the public post-acquisition by YNHH?

16. On pages 28 and 29, applicants state that "[i]n the first five years, YNHH plans to invest $129.5 million" in the HSR campus for a variety of purposes. Please address the following:

    a. Is the $129.5 million investment separate and distinct from the $160 million being paid by Buyer pursuant to Section 2.3 of the Asset Purchase Agreement set forth at Attachment III to the CON application?
    b. List the deferred capital purchases and projects on the HSR campus the investment will address.
    c. List the investments in clinical service infrastructure that will be made on the HSR campus.
    d. Explain when YNHH would expect the existing information technology systems on the HSR campus to be integrated with YNHH's and when the implementation of the Epic electronic medical record system would be completed on the HSR campus.

17. Describe, in detail, the "new, integrated organization [that] will preserve clinical services and ensure HSR's charitable assets for future generations" referenced on page 29. Please also provide the following information regarding the Charitable Funds defined at Section 5.5 of the Asset Purchase Agreement:

    a. What amount of Charitable Funds, if any, will be transferred to Buyer or Buyer's Affiliate as part of the Purchased Assets and how will they be used for the benefit of the Facilities?
    b. What amount of Charitable Funds that cannot be transferred to Buyer or Buyer's Affiliate as part of the Purchased Assets will be used by Sellers at or for the benefit of the Facilities and how will they be used?
    c. What amount of Charitable Funds shall be used by Sellers to fund activities mutually agreed upon by the parties that benefit the delivery of health care services consistent with the Directives in the greater New Haven area and how will they be used?

Determination of Need by YNHH – pages 29 through 35

18. On page 32 in Graphs I and II, respectively, applicants provided information on YNHH's occupancy based on the midnight census and the contact census for all services and for medical/surgical beds as compared to total beds and 80% occupancy levels. Please provide HSR's occupancy based on its census data from FY 2011 to FY 2012 (year to date) in the same format.

19. YNHH recently submitted a CON application to add 70 beds which will be temporarily located in its East Pavilion. Assuming that CON is granted, please explain what will happen to these 70 beds if the CON application for the acquisition of HSR is not approved and, alternatively, if the CON application for the acquisition of HSR is approved.

20. Please provide a copy of YNHH's long range financial plan showing the need for an additional 74 beds by 2016 even if 70 additional beds are added pursuant to Docket No. 12-31745-CON.

21. Please provide copies of the inpatient volume projections submitted to the Connecticut Attorney General and the Federal Trade Commission.

22. Please provide evidence of YNHH's decision-making process regarding the location of the new bed tower that has been contemplated as part of its long range financial planning efforts.

Benefits to YNHH – pages 35 through 40

23. On page 35, applicants state that "[t]he opportunity to avoid duplicative investments and focus on key strategies, such as primary care development, will enhance access to services for patients in the region."

    Please describe the discussions HSR and YNHH have had surrounding the development of primary care and the avoidance of duplication of services.

24. On page 36, applicants state that "discussions have been held with the State of Connecticut Attorney General and the Federal Trade Commission to initiate governmental approval of the transaction."

    Please describe the status of those discussions and provide a timeline for when decisions from the Attorney General's Office and the Federal Trade Commission might be expected if they have not already been rendered.

25. On page 37, applicants state that they "have worked to identify a number of options to achieve cost savings and work flow efficiencies."

    Please describe these cost savings and work flow efficiencies.

    a. Please provide additional detail regarding which subspecialties will be, or are likely to be consolidated, on one campus (indicating which campus) and include the reasoning behind each decision.
    b. What subspecialties will be, or are likely to be, offered on both campuses? Explain how these service lines were selected.

26. On page 37, applicants state that "Deloitte has estimated cost savings from clinical and business operational integrations of at least $300 million over five years."

    Please provide information that describes these cost savings in detail, including a breakdown of the approximate amount of money saved by each measure.

27. Please describe how the acquisition will improve efficiency, access to health care and quality for the area's growing elderly population.

28. Please provide an unredacted copy of the Asset Purchase Agreement and all exhibits thereto.

Quality Measures – pages 40 through 43

29. To the extent not already provided, please describe the $85 million in facility upgrades that YNHH plans to undertake on the HSR campus and the estimated amounts that will be spent in each year.

30. To the extent not already provided, please describe the type of routine capital expenditures that will amount to $25 million in expenditures over the next five years and the estimated amounts that will be spent in each year.

31. When will the EPIC installation at YNHH be complete? If the acquisition is approved, how long after Closing is it estimated that EPIC installation at HSR would begin?

Proposed Capital Expenditures/Costs and Patient Population Mix – pages 45 through 52

32. Please describe what makes up the $60,248,000 in the "Other Non-Construction (Other Asset Purchases)" line of the proposed capital expenditure chart on page 45.

33. On page 45, applicants state that specific capital costs for HSR's assets equal $147,879,000. Please provide information on how much of the remaining $12,021,000 in capital expense is being allocated to the purchase of DePaul Health Services Corporation, Inc.'s ownership interest in the Saint Raphael Magnetic Resonance Center (SRMRC).

34. Please summarize any analyses or reports from Barclays Capital, other underwriters or YNHH's financial advisors regarding YNHH's credit rating and ability to obtain the $160 million in bond financing necessary to complete the proposed acquisition.

35. On page 49, with respect to the assumptions for patient population mix, please explain why volumes for HSR are assumed to be flat through the projection period.

Financial Attachments I & II – pages 50-52 and Attachments VII and VIII

36. On page 231 (Attachment I for YNHH), please explain, in detail, the underlying assumptions for the increases in bad debt and interest expense connected with the HSR acquisition?

37. On page 234 (Attachment I for HSR), please explain, in detail, the underlying assumptions for inpatient discharges dropping in FY 2012 and remaining flat throughout the projection period without the YNHH affiliation taking place.

38. On page 234 (Attachment I for HSR), please explain, in detail, the underlying assumptions for outpatient visits increasing in FY 2012 and remaining flat throughout the projection period without the YNHH affiliation taking place.

39. On page 238, please explain the basis for the net negative adjustment to hospital inpatient and outpatient revenue due to health care reform.

40. On pages 50-51, please explain in more detail how YNHH intends to establish budget neutral agreements "with new payment terms that will not result in an adverse financial impact to the managed care payers or the self-funded employers they represent" if the affiliation occurs. Please also explain whether YNHH would be able to negotiate similar budget neutral agreements if the affiliation with HSR did not occur and how the affiliation impacts YNHH's ability to negotiate with managed care plans as well as other private health insurers.

MRI CON Questions and Responses – Appendix I

41. On page 246, applicants state that inpatient "scan volume is projected to increase in proportion to an expected increase in the average daily census (ADC) at the Saint Raphael campus following the acquisition by YNHH ... ADC is projected to increase by 40 in FY 2012, 60 in FY 2014 and 85 in FY 2015." Yet, at page 236 of the CON Application, no increase in HSR utilization is assumed. Please explain this apparent discrepancy.

42. Will there be any change in the radiologists who provide professional services interpreting the SRMRC MRI scans as a result of YNNH's acquisition of HSR?

In responding to the questions contained in this letter, please repeat each question before providing your response. Paginate and date your response. Information filed must be numbered sequentially from the applicants' document preceding it. For example, if the application concludes with page 100, your completeness response letter would begin with page 101. Please reference "Docket Number: 12-31747-CON" and submit one (1) original and five (5) hard copies of your response. In addition, please submit a scanned copy of your response, including all attachments, on CD using MS Word format or Adobe Acrobat.

Upon receipt of the responses to this letter and after incorporating the provided information into the initial submission, OHCA staff will perform a detailed review of the entire CON application. If you have any questions concerning this letter, please feel free to contact Steven W. Lazarus at OHCA at (860) 418-7012.

Sincerely,

Steven W. Lazarus
Associate Health Care Analyst

EXHIBIT C

CANON 9
A Lawyer Should Avoid Even the Appearance of Professional Impropriety

ETHICAL CONSIDERATIONS

EC 9-1 Continuation of the American concept that we are to be governed by rules of law requires that the people have faith that justice can be obtained through our legal system.[1] A lawyer should promote public confidence in our system and in the legal profession.[2]

EC 9-2 Public confidence in law and lawyers may be eroded by irresponsible or improper conduct of a lawyer. On occasion, ethical conduct of a lawyer may appear to laymen to be unethical. In order to avoid misunderstandings and hence to maintain confidence, a lawyer should fully and promptly inform his client of material developments in the matters being handled for the client. While a lawyer should guard against otherwise proper conduct that has a tendency to diminish public confidence in the legal system or in the legal profession, his duty to clients or to the public should never be subordinate merely because the full discharge of his obligation may be misunderstood or may tend to subject him or the legal profession to criticism. When explicit ethical guidance does not exist, a lawyer should determine his conduct by acting in a manner that promotes public confidence in the integrity and efficiency of the legal system and the legal profession.[3]

EC 9-3 After a lawyer leaves judicial office or other public employment, he should not accept employment in connection with any matter in which he had substantial responsibility prior to his leaving, since to accept employment would give the appearance of impropriety even if none exists.[4]

EC 9-4 Because the very essence of the legal system is to provide procedures by which matters can be presented in an impartial manner so that they may be decided solely upon the merits, any statement or suggestion by a lawyer that he can or would attempt to circumvent those procedures is detrimental to the legal system and tends to undermine public confidence in it.

EC 9-5 Separation of the funds of a client from those of his lawyer not only serves to protect the client but also avoids even the appearance of impropriety, and therefore commingling of such funds should be avoided.

EC 9-6 Every lawyer owes a solemn duty to uphold the integrity and honor of his profession; to encourage respect for the law and for the courts and the judges thereof; to observe the Code of Professional Responsibility; to act as a member of a learned profession, one dedicated to public service; to cooperate with his brother lawyers in supporting the organized bar through the devoting of his time, efforts, and financial support as his professional standing and ability reasonably permit; to conduct himself so as to reflect credit on the legal profession and to inspire the confidence, respect, and trust of his clients and of the public; and to strive to avoid not only professional impropriety but also the appearance of impropriety.[5]

EC 9-7 A lawyer has an obligation to the public to participate in collective efforts of the bar to reimburse persons who have lost money or property as a result of the misappropriation or defalcation of another lawyer, and contribution to a client's security fund is an acceptable method of meeting this obligation.[6]

DISCIPLINARY RULES

DR 9-101 Avoiding Even the Appearance of Impropriety.[1]

(A) -A lawyer shall not accept private employment in a matter upon the merits of which he has acted in a judicial capacity.[4]

(B) -A lawyer shall not accept private employment in a matter in which he had substantial responsibility while he was a public employee.[5]

(C) -A lawyer shall not state or imply that he is able to influence improperly or upon irrelevant grounds any tribunal, legislative body,[6] or public official.

DR 9-102 Preserving Identity of Funds and Property of a Client.[7]

(A) -All funds of clients paid to a lawyer or law firm, other than advances for costs and expenses, shall be deposited in one or more identifiable bank accounts maintained in the state in which the law office is situated and no funds belonging to the lawyer or law firm shall be deposited therein except as follows:

(1) -Funds reasonably sufficient to pay bank charges may be deposited therein.

(2) -Funds belonging in part to a client and in part presently or potentially to the lawyer or law firm must be deposited therein, but the portion belonging to the lawyer or law firm may be withdrawn when due unless the right of the lawyer or law firm to receive it is disputed by the client, in which event the disputed portion shall not be withdrawn until the dispute is finally resolved.

(B) -A lawyer shall:

(1 -)Promptly notify a client of the receipt of his funds, securities, or other properties.

(2) -Identify and label securities and properties of a client promptly upon receipt and place them in a safe deposit box or other place of safekeeping as soon as practicable.

(3) -Maintain complete records of all funds, securities, and other properties of a client coming into the possession of the lawyer and render appropriate accounts to his client regarding them.

(4) -Promptly pay or deliver to the client as requested by a client the funds, securities, or other properties in the possession of the lawyer which the client is entitled to receive.

NOTES

1. "Integrity is the very breath of justice. Confidence in our law, our courts, and in the administration of justice is our supreme interest. No practice must be permitted to prevail which invites towards the administration of justice a doubt or distrust of its integrity." Erwin M. Jennings Co. v. DiGenova, 107 Conn. 491, 499, 141 A. 866, 868 (1928).

2. "A lawyer should never be reluctant or too proud to answer unjustified criticism of his profession, of himself, or of his brother lawyer. He should guard the reputation of his profession and of his brother as zealously as he guards his own." Rochelle & Payne, *The Struggle for Public Understanding*, 25 Texas B.J. 109, 162 (1962).

3. *See* ABA Canons of Professional Ethics, Canon 29 (1908).

4. *See* ABA Canons of Professional Ethics, Canon 36 (1908).

5. "As said in Opinion 49, of the Committee on Professional Ethics and Grievances of the American Bar Association, page 134: 'An attorney should not only avoid impropriety but should avoid the appearance of impropriety.' " State ex rel. Nebraska State Bar Ass'n v. Richards, 165 Neb. 80, 93, 84 N.W.2d 136, 145 (1957).

"It would also be preferable that such contribution [to the campaign of a candidate for judicial office] be made to a campaign committee rather than to the candidate personally. In so doing, possible appearances of impropriety would be reduced to a minimum" *ABA Opinion* 226 (1941).

"The lawyer assumes high duties, and has imposed upon him grave responsibilities. He may be the means of much good or much mischief. Interests of vast magnitude are entrusted to him; confidence is reposed in him; life, liberty, character and property should be protected by him. He should guard, with zealous watchfulness, his own reputation, as well as that of his profession." People ex rel. Culler v. Ford, 54 Ill. 520, 522 (1870), and also quoted in State Board of Law Examiners v. Sheldon, 43 Wyo. 522, 526, 7 P.2d 226, 227 (1932).

See ABA Opinion 150 (1936).

6. Amended, February 1980; House Informational Report No. 105.

7. *Cf.* Model Code of Professional Responsibility, EC 5-6.

8. *See* ABA Canons of Professional Ethics, Canon 36 (1908).

"It is the duty of the judge to rule on questions of law and evidence in misdemeanor cases and examinations in felony cases. That duty calls for impartial and uninfluenced judgment, regardless of the effect on those immediately involved or others who may, directly or indirectly, be affected. Discharge of that duty might be greatly interfered with if the judge, in another capacity, were permitted to hold himself out to employment by those who are to be, or who may be, brought to trial in felony cases, even though he did not conduct the examination. His private interests as a lawyer in building up his clientele, his duty as such zealously to espouse the cause of his private clients and to defend against charges of crime brought by law enforcement agencies of which he is a part, might prevent, or even destroy, that unbiased judicial judgment which is so essential in the administration of justice.

"In our opinion, acceptance of a judgeship with the duties of conducting misdemeanor trials, and examinations in felony

cases to determine whether those accused should be bound over for trial in a higher court, ethically bars the judge from acting as attorney for the defendants upon such trial, whether they were examined by him or by some other judge. Such a practice would not only diminish public confidence in the administration of justice in both courts, but would produce serious conflict between the private interests of the judge as a lawyer, and of his clients, and his duties as a judge in adjudicating important phases of criminal processes in other cases. The public and private duties would be incompatible. The prestige of judicial office would be diverted to private benefit, and the judicial office would be demeaned thereby." *ABA Opinion* 242 (1942).

"A lawyer, who has previously occupied a judicial position or acted in a judicial capacity, should refrain from accepting employment in any matter involving the same facts as were involved in any specific question which he acted upon in a judicial capacity and, for the same reasons, should also refrain from accepting any employment which might reasonably appear to involve the same facts." *ABA Opinion* 49 (1931).

See ABA Opinion 110 (1934).

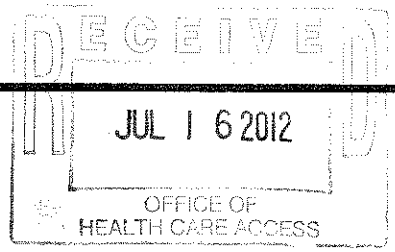
9. *See ABA Opinions* 125 (1935) and 134 (1935); *cf.* ABA CANONS OF PROFESSIONAL ETHICS, CANON 36 (1980) and *ABA Opinions* 59 (1931) and 26 (1930). *But see ABA Opinion* 37 (1931).

10. "[A statement by a governmental department or agency with regard to a lawyer resigning from its staff that includes a laudation of his legal ability] carries implications, probably not founded in fact, that the lawyer's acquaintance and previous relations with the personnel of the administrative agencies of the government place him in an advantageous position in practicing before such agencies. So to imply would not only represent what probably is untrue, but would be highly reprehensible." *ABA Opinion* 184 (1938).

11. *See* ABA CANONS OF PROFESSIONAL ETHICS, CANON 11 (1908).

"*Rule 9* . . . . A member of the State Bar shall not commingle the money or other property of a client with his own; and he shall promptly report to the client the receipt by him of all money and other property belonging to such client. Unless the client otherwise directs in writing, he shall promptly deposit his client's funds in a bank or trust company . . . in a bank account separate from his own account and clearly designated as 'Clients' Funds Account' or 'Trust Funds Account' or words of similar import. Unless the client otherwise directs in writing, securities of a client in bearer form shall be kept by the attorney in a safe deposit box at a bank or trust company . . . which safe deposit box shall be clearly designated as 'Clients' Account' or 'Trust Account' or words of similar import, and be separate from the attorney's own safe deposit box." CAL. BUSINESS AND PROFESSIONS CODE §6076 (West 1962).

"[C]ommingling is committed when a client's money is intermingled with that of his attorney and its separate identity lost so that it may be used for the attorney's personal expenses or subjected to claims of his creditors . . . . The rule against commingling was adopted to provide against the probability in some cases, the possibility in many cases, and the danger in all cases that such commingling will result in the loss of clients' money." Black v State Bar, 57 Cal. 2d 219, 225-26, 368 P.2d 118, 122, 18 Cal. Rptr. 518, 522 (1962).



Greer, Leslie

RECEIVED
JUL 16 2012
OFFICE OF
HEALTH CARE ACCESS

From: Lazarus, Steven
Sent: Monday, July 16, 2012 3:30 PM
To: Greer, Leslie
Cc: Olejarz, Barbara
Subject: FW: Docket No. 12-31748-CON
Attachments: Revised Pages to Dr. Kiely's Testimony 7-16-12 (00038125).PDF

Leslie,

Please add to the original file.

Thank you,
Steve

Steven W. Lazarus
Associate Health Care Analyst
Office of Heaalth Care Access
A Division of Department of Public Health
410 Capitol Avenue
Hartford, CT 06134
Phone (Direct): 860.418.7012
Fax (Main): 860.418.7053

From: Martone, Kim
Sent: Monday, July 16, 2012 3:26 PM
To: Lazarus, Steven; Yandow, Joanne; Veyberman, Alla
Cc: Horn, Marianne
Subject: FW: Docket No. 12-31748-CON

Kimberly R. Martone
Director of Operations
Office of Health Care Access
860-418-7029

From: Anna Mastroianni [mailto:AMastroianni@jeffers-law.com] **On Behalf Of** Stephen Cowherd
Sent: Monday, July 16, 2012 3:18 PM
To: Martone, Kim; 'dsmith@stamhealth.org'; jean.ahn@ynhh.org; jgroves@uks.com
Cc: Stephanie E. Sprague; Stephen Cowherd
Subject: Docket No. 12-31748-CON

Ms. Martone:

Please see the attached relating to docket number 12-31748-CON. Please contact us if you have any questions.

Thanks,
Anna

Anna Mastroianni
Assistant to Stephen M. Cowherd
Jeffers Cowherd P.C.
55 Walls Drive
Fairfield, CT 06824
Tel: (203) 259-7900 ext. 244
Fax: (203) 259-1070

JEFFERS
COWHERD

JEFFERS COWHERD P.C.
ATTORNEYS AT LAW

55 WALLS DRIVE
FAIRFIELD, CT 06824
203-259-7900
203-259-1070 FAX
WWW.JEFFERS-LAW.COM

STEPHEN M. COWHERD
Email: scowherd@jeffers-law.com

RECEIVED
JUL 16 2012
OFFICE OF
HEALTH CARE ACCESS

July 16, 2012

VIA ELECTRONIC MAIL

Kimberly R. Martone
Director of Operations
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: Certificate of Need Application; Docket Number: 12-31748-CON
Yale-New Haven Hospital and Greenwich Hospital to
Establish and Operate an Elective Angioplasty Program at Greenwich Hospital

Dear Kim:

Enclosed please find two corrected pages of Dr. Kiely's pre-file testimony – pages 8 and 10. Also enclosed are blacklined copies of the same showing the corrections.

Please contact the undersigned should you have any questions.

Respectfully submitted,

Stephen M. Cowherd /am

Stephen M. Cowherd

Enclosure

cc: David L. Smith, Senior Vice President, Stamford Hospital (via email)
Jean Ahn, System Director, Planning & Business Development, Yale-New Haven Hospital (via email)
Jennifer L. Groves, Esq. (via email)

FY 2009-2011 Inpatient Cardiac Catheterization Volume in Proposed Service Area

State	FY 09	FY 10	FY 11
CT Service Area*	1,000	948	808
NY Service Area**	1,443	1,355	1,353
Total	2,443	2,303	2,161

*The CT Service Area is made up of Darien, Greenwich, New Canaan, Norwalk, Stamford, Weston and Westport. (*See* Application at p. 24)
** The NY Service Area is made up of Armonk, Bedford, Bedford Hills, Harrison, Hartsdale, Katonah, Larchmont, Mamaroneck, Mount Kisco, Mount Vernon, New Rochelle, Port Chester, Round Ridge, Purchase, Scarsdale, South Salem, West Harrison, and White Plains. (*See* Application at p. 24)
Source: CT Chime and NY SPARCS database. *See* Exhibit 3.

FY 2009-2011 Inpatient Coronary Angioplasty (PCI) Volume in Proposed Services Area

State	FY 09	FY 10	FY 11
CT Service Area*	598	610	429
NY Service Area**	844	775	772
Total	1,442	1,385	1,201

*The CT Service Area is made up of Darien, Greenwich, New Canaan, Norwalk, Stamford, Weston and Westport.
** The NY Service Area is made up of Armonk, Bedford, Bedford Hills, Harrison, Hartsdale, Katonah, Larchmont, Mamaroneck, Mount Kisco, Mount Vernon, New Rochelle, Port Chester, Round Ridge, Purchase, Scarsdale, South Salem, West Harrison, and White Plains.
Source: CT Chime and NY SPARCS database. *See* Exhibit 3.

Applicants did not provide any of this data in their CON Application because they know it in no way supports their proposal. They also have not provided any credible reasons why these utilization trends will change in the future.

There also has not been any increase in Greenwich's own emergency PCI volumes that would suggest a need for an elective angioplasty program at their hospital. In the three year period before Greenwich submitted its prior application for an elective PCI program, it performed 38, 33 and 41 primary angioplasties, respectively, and in the three year period

FY 2009-2011 Inpatient Cardiac Catheterization Volume in Proposed Service Area

State	FY 09	FY 10	FY 11
CT Service Area*	1,000	948	808
NY Service Area**	1,443	1,355	1,353
Total	2,443	2,303	2,161

*The CT Service Area is made up of Darien, Greenwich, New Canaan, Norwalk, Stamford, Weston and Westport. (*See* Application at p. 24)
** The NY Service Area is made up of Armonk, Bedford, Bedford Hills, Harrison, Hartsdale, Katonah, Larchmont, Mamaroneck, Mount Kisco, Mount Vernon, New Rochelle, Port Chester, Round Ridge, Purchase, Scarsdale, South Salem, West Harrison, and White Plains. (*See* Application at p. 24)
Source: CT Chime and NY SPARCS database. *See* Exhibit 3.

FY 2009-2011 Inpatient Coronary Angioplasty (PCI) Volume in Proposed Services Area

State	FY 09	FY 10	FY 11
CT Service Area*	598	610	429
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*The CT Service Area is made up of Darien, Greenwich, New Canaan, Norwalk, Stamford, Weston and Westport.
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Source: CT Chime and NY SPARCS database. .*See* Exhibit 3.

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Document comparison by Workshare Professional on Monday, July 16, 2012 11:51:30 AM

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Style change	0
Format changed	0
Total changes	4

In considering the lack of volume growth cited above, it is also important to note that the White Plains Hospital elective angioplasty program began operating in 2010, making the field of elective PCI providers in the Applicants' proposed service area even more crowded than it was in 2009 when Applicants' previous application was denied. White Plains Hospital is located approximately ten miles to Greenwich Hospital's west. This means that if this Application is approved, three (3) elective angioplasty programs will operate within sixteen (16) miles of each other. How can that possibly make sense or be an appropriate balance of health care services? The answers are that it doesn't and it can't, especially in a time of zero volume growth.

That the Greenwich Hospital and White Plains programs will severely overlap in the proposed New York service area is borne out by the data. In FY 2011, WPH performed 165 inpatient PCIs, with 110 of these procedures performed on residents of Greenwich Hospital's New York service area. *See* Exhibit 5. Attached to my testimony as Exhibit 6 is a letter from Susan Fox, Executive Vice President of White Plains Hospital which describes that Hospital's elective angioplasty program in more detail and sets forth its position on the pending Application. This letter verifies that the Westchester County market targeted by Applicants is well served not only by WPH but by a host of other providers including the Westchester County Medical Center, Montefiore Medical Center, New York Presbyterian-Weill Cornell Medical Center, New York Presbyterian-Columbia University Medical Center, Lenox Hill Hospital and Mount Sinai Medical Center. This being the case, Applicants' certainly cannot rely on a lack of capacity in New York to establish clear public need for their proposal.

The situation in Fairfield and Westchester Counties is clearly different from the eastern part of Connecticut as presented by Lawrence & Memorial Hospital ("L&M") in its

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The situation in Fairfield and Westchester Counties is clearly different from the eastern part of Connecticut as presented by Lawrence & Memorial Hospital ("L&M") in its

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Moved from	0
Moved to	0
Style change	0
Format changed	0
Total changes	4

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JUL 16 2012
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Greer, Leslie

From: Lazarus, Steven
Sent: Monday, July 16, 2012 3:32 PM
To: Jennifer Groves (JGroves@uks.com)
Cc: Greer, Leslie; Olejarz, Barbara
Subject: FW: Docket No. 12-31748-CON
Attachments: Revised Pages to Dr. Kiely's Testimony 7-16-12 (00038125).PDF

Attorney Groves,

Attached you will find the revised pages from Dr. Kiely's Testimony received by OHCA this afternoon.

Steve

Steven W. Lazarus
Associate Health Care Analyst
Office of Heaalth Care Access
A Division of Department of Public Health
410 Capitol Avenue
Hartford, CT 06134
Phone (Direct): 860.418.7012
Fax (Main): 860.418.7053

From: Martone, Kim
Sent: Monday, July 16, 2012 3:26 PM
To: Lazarus, Steven; Yandow, Joanne; Veyberman, Alla
Cc: Horn, Marianne
Subject: FW: Docket No. 12-31748-CON

Kimberly R. Martone
Director of Operations
Office of Health Care Access
860-418-7029

From: Anna Mastroianni [mailto:AMastroianni@jeffers-law.com] **On Behalf Of** Stephen Cowherd
Sent: Monday, July 16, 2012 3:18 PM
To: Martone, Kim; 'dsmith@stamhealth.org'; jean.ahn@ynhh.org; jgroves@uks.com
Cc: Stephanie E. Sprague; Stephen Cowherd
Subject: Docket No. 12-31748-CON

Ms. Martone:

Please see the attached relating to docket number 12-31748-CON. Please contact us if you have any questions.

Thanks,
Anna

Anna Mastroianni
Assistant to Stephen M. Cowherd
Jeffers Cowherd P.C.

55 Walls Drive
Fairfield, CT 06824
Tel: (203) 259-7900 ext. 244
Fax: (203) 259-1070

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

IN THE MATTER OF:

A Certificate of Need Application by
Greenwich Hospital and Yale-New Haven Hospital
To Establish and Operate an Elective Angioplasty Program

Docket Number: 12-31748-CON
July 16, 2012

ORDERS

1. RULING ON A PETITION FILED BY THE STAMFORD HOSPITAL TO BE DESIGNATED AS AN INTERVENOR WITH FULL RIGHTS OF CROSS-EXAMINATION

On July 12, 2012, The Stamford Hospital ("Petitioner") filed *Petition of the Stamford Hospital for Intervenor Status with Full Procedural Rights*. On July 16, 2012, Greenwich Hospital and Yale-New Haven Hospital (collectively "Applicant") filed an objection to the Petitioner's petition for intervenor status and moved to strike certain testimony.

Petitioner's petition is granted, in part, and denied, in part. Pursuant to Connecticut General Statutes § 4-177a, Petitioner is granted limited intervenor status; Petitioner's motion for status with full procedural rights is denied. Petitioner shall have the rights to inspect and copy records, physical evidence, papers and documents, to introduce evidence, and to make a brief closing argument. Petitioner shall not have the right to cross-examine Applicant's witnesses. Petitioner's witnesses are subject to cross-examination by the Applicant.

Applicant's motion to strike certain testimony will be addressed at hearing.

2. RULING ON APPLICANT'S OBJECTION TO THE ADMINISTRATIVE NOTICE OF DOCKET NO. 08-31210-CON.

On July 16, 2012, Applicant filed an objection to the administrative notice of docket no. 08-31210-CON. Applicant's objection is overruled.

3. RULING ON APPLICANT'S MOTION TO DISQUALIFY COUNSEL FOR PETITIONER

On July 16, 2012, Applicant filed a motion to disqualify Attorney Stephen M. Cowherd and the law firm of Jeffers Cowherd from representing Petitioner. Applicant has failed to demonstrate the basis for disqualification. Applicant's motion is denied.

7/16/12
Date

Joanne V. Yandow
Hearing Officer

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

TABLE OF THE RECORD

APPLICANTS: **Yale-New Haven and Greenwich Hospital**

DOCKET NUMBER: **12-31748-CON**

PUBLIC HEARING: **July 17, 2012 at 9:00 a.m.**

PLACE: **410 Capitol Avenue, Third Floor Hearing Room**
Hartford, Connecticut

EXHIBIT	DESCRIPTION
A	Letter from Yale-New Haven Hospital and Greenwich Hospital ("Applicants") dated February 10, 2012, enclosing the Certificate of Need ("CON") application under Docket Number 12-31748 to establish and operate an elective angioplasty program without onsite surgical backup at Greenwich Hospital received by the Office of Health Care Access ("OHCA") on February 14, 2012. (583 pages)
B	OHCA's letter to the Applicants dated March 15, 2012 requesting additional information and/or clarification in the matter of the CON application under Docket Number 12-31748. (8 pages)
C	Applicants' responses to OHCA's letter of March 15, 2012, dated May 14, 2012, in the matter of the CON application under Docket Number 12-31748, received by OHCA on May 14, 2012. (45 pages)
D	OHCA's letter to the Applicants dated June 20, 2012 deeming the application complete in the matter of the CON application under Docket Number 12-31748. (1 page)
E	OHCA's request for legal notification in the *Greenwich Times* and OHCA's Notice to the Applicants of the public hearing scheduled for July 17, 2012, in the matter of the CON application under Docket Number 12-31748, dated July 2, 2012. (4 pages)
F	Designation letter, dated July 3, 2012, designating Attorney Joanne V. Yandow as hearing officer in the matter of the CON application under Docket Number 12-31748. (1 page)

G	OHCA's letter to the Applicants dated July 10, 2012, requesting prefile testimony and interrogatories in the matter of the CON application under Docket Number 12-31748. (3 pages)
H	Letter from the Applicants enclosing Prefile Testimony and notice of appearance of Jennifer L. Groves, Esquire on behalf of the Applicants dated July 12, 2012 in the matter of the CON application under Docket Number 12-31748, received by OHCA on July 12, 2012. (69 pages)
I	Petition of Stamford Hospital dated July 12, 2012, requesting intervenor status and included prefile testimony and notice of appearance of Stephen M. Cowherd, Esquire in the matter of the CON application under Docket Number 12-31748, received by OHCA on July 12, 2012. See Exhibit K for additional prefile. (348 pages)
J	OHCA's letter to the Applicants dated July 12, 2012 informing them that the Office is in receipt of Stamford Hospital's petition for intervenor status and any responsive document should be filed by no later than 10:00 a.m. on July 15, 2012. In the matter of the CON application under Docket Number 12-31748. (1 page)
K	Email from Stamford Hospital dated July 13, 2012 enclosing prefile testimony from Dr. Sharon Kiely and Dr. William Gray in the matter of the CON application under Docket Number 12-31748. Received by OHCA on July 13, 2012.(35 pages)
L	Email from Attorney Jennifer Groves dated July 16, 2012, enclosing Applicants' rebuttal testimony and procedural motions related to the July 17, 2010, Public Hearing.
M	Emial from Jeffers Cowherd dated July 16, 2012, enclsing reviwed pages 8 & 10 from Dr. Keily's Pre-file Testimony.
N	OHCA's Order on the Petition of Stamford to be granted intervenor status and procedural motions in the matter of the CON application under Docket Number 12-31748, dated July 16, 2012.

Administrative Notice:

1. CON Docket Number: 08-31210-CON
2. CON Docket Number:03-30148-CON
3. Declatory Ruling: 09-31433-DCR

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

TENTATIVE AGENDA

PUBLIC HEARING

Docket Number: 12-31748-CON

Yale New Haven Hospital and Greenwich Hospital

Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital

July 17, 2012, at 9:00 a.m.

I. **Convening of the Public Hearing**

II. **Applicants' Direct Testimony (15 minutes)**

III. **Intervenor's Direct Testimony (10 minutes)**

IV. **Applicants' Cross-Examine Intervenor**

V. **OHCA's Questions of the Applicants**

VI. **Public Comment**

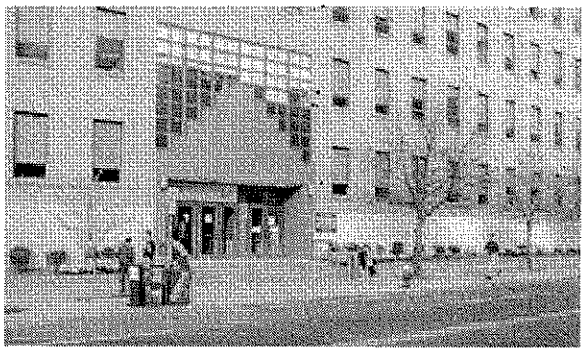
VII. **Closing Remarks**

VIII. **Public Hearing Recessed/Closed**

An Equal Opportunity Employer
410 Capitol Ave., MS#13HCA, P.O.Box 340308, Hartford, CT 06134-0308
Telephone: (860) 418-7001 Toll-Free: 1-800-797-9688
Fax: (860) 418-7053

Department of Public Health

From I-91 North or South and from East of the River:
In Hartford take I-84 westbound. Exit at Asylum Street, exit 48.
At the signal at the bottom of the ramp, make a gradual right, staying to the left of the fork in the road.
At the first light, take an immediate left onto Broad Street.
Travel on Broad Street to the light at the first four-way intersection; take a right onto Capitol Avenue. OHCA (tan brick building at 410 Capitol Avenue) is two blocks down on the right.
* Pass 410 and enter in the driveway between 410 and 450 Capitol Avenue. Turn right into the parking lot behind the building and proceed to the Security building in the lot. You will be directed to available parking.



From the West:
Take I-84 East to Capitol Avenue, Exit 48B. Bear right on the exit ramp. At the end of the ramp, turn right onto Capitol Avenue. OHCA is 3 blocks down on the right (tan brick building at 410 Capitol Avenue).

Proceed from * above.

Content Last Modified on 8/31/2004 8:13:46 AM

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PAGES SENT	6
RESULT	OK

STATE OF CONNECTICUT
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: JENNIFER GROVES

FAX: (203) 772-2037

AGENCY: UPDIKE, KELLY & SPELLACY

FROM: STEVEN LAZARUS

DATE: 7/16/12 **TIME:**

NUMBER OF PAGES: 6
(including transmittal sheet

Comments: Docket 12-31748-CON Hearing material

PLEASE PHONE IF THERE ARE ANY TRANSMISSION PROBLEMS.

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TX/RX NO	2996
RECIPIENT ADDRESS	912032591070
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ST. TIME	07/16 16:35
TIME USE	00'55
PAGES SENT	6
RESULT	OK

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: STEPHEN M. COWHERD

FAX: (203) 259-1070

AGENCY: JEFFERS COWHERD P.C.

FROM: STEVEN LAZARUS

DATE: 7/16/12 **TIME:**

NUMBER OF PAGES: 6
(including transmittal sheet

Comments: Docket 12-31748-CON Hearing material

PLEASE PHONE IF THERE ARE ANY TRANSMISSION PROBLEMS.

Olejarz, Barbara

From: Lazarus, Steven
Sent: Tuesday, July 17, 2012 7:26 AM
To: Greer, Leslie; Olejarz, Barbara
Subject: FW: TSH Procedural Motions and Rebuttal Testimony DN: 12-31748-CON
Attachments: 4 files [19 7-17-2012 07].ZIP

Please add to the record.

Thank you.

Steve

Steven W. Lazarus
Associate Health Care Analyst
Office of Heaalth Care Access
A Division of Department of Public Health
410 Capitol Avenue
Hartford, CT 06134
Phone (Direct): 860.418.7012
Fax (Main): 860.418.7053

From: Anna Mastroianni [mailto:AMastroianni@jeffers-law.com] **On Behalf Of** Stephen Cowherd
Sent: Tuesday, July 17, 2012 7:23 AM
To: Martone, Kim
Cc: Stephanie E. Sprague; Stephen Cowherd; jgroves@uks.com; jean.ahn@ynhh.org; Lazarus, Steven
Subject: TSH Procedural Motions and Rebuttal Testimony DN: 12-31748-CON

Dear Ms. Martone:

We have attached TSH's Response to Applicants' Objection to TSH's Submission of Rebuttal Testimony and Motion to Strike, TSH's Objection and Motion to Strike a Portion of Applicants' Rebuttal Testimony and TSH's rebuttal testimony for the above-referenced docket. Kindly confirm receipt by reply email. Copies of these documents are being provided simultaneously to Applicants via this email. Hard copies will be delivered to OHCA by approximately 8:30 this morning.

Best regards,

Stephen Cowherd

Anna Mastroianni
Jeffers Cowherd P.C.
55 Walls Drive
Fairfield, CT 06824
Tel: (203) 259-7900 ext. 244
Fax: (203) 259-1070

BEFORE THE OFFICE OF HEALTH CARE ACCESS DIVISION OF THE DEPARTMENT OF PUBLIC HEALTH	:	Docket No. 12-31748-CON
IN RE APPLICATION OF YALE-NEW HAVEN HOSPITAL AND GREENWICH HOSPITAL TO ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM AT GREENWICH HOSPITAL	:	July 17, 2012

INTERVENOR THE STAMFORD HOSPITAL'S OBJECTION TO AND MOTION TO STRIKE A PORTION OF REBUTTAL TESTIMONY OF MARNA BORGSTROM AND CHRISTOPHER HOWES, M.D.

Intervenor The Stamford Hospital ("TSH") hereby objects to and moves to strike portions of the pre-filed rebuttal testimony of Marna Borgstrom and Christopher Howes, M.D. submitted by Greenwich Hospital ("Greenwich") and Yale-New Haven Hospital ("YNHH") (collectively "Applicants") for the public hearing. The portions of the testimony sought to be stricken are identified on the pages of testimony attached as Exhibit A hereto. As set forth more fully below, Ms. Borgstrom's pre-filed rebuttal testimony (pages 698-701) includes extensive commentary regarding open heart surgery, which is totally irrelevant and immaterial to the pending Application. Additionally, Dr. Howes' pre-filed rebuttal testimony (pages 762-763) inappropriately quotes the State Health Plan, which at the present time is a draft not yet finalized or adopted, and includes an unwarranted caustic and insulting comment directed at New York Presbyterian Hospital. TSH, therefore, respectfully requests that OHCA strike the foregoing impermissible testimony.

Ms. Borgstrom's pre-filed rebuttal testimony (pages 698-701 and Attachments II, III and IV (pages 716-756)) includes extensive commentary and statistical data regarding inpatient open heart surgery volume, both state-wide and at TSH, which is irrelevant and immaterial to the pending application for approval to perform elective angioplasty without open heart surgery. Ms. Borgstrom's testimony about TSH's open heart surgery program is especially prejudicial because TSH will not have the opportunity to cross-examine this witness. This rebuttal testimony has no arguable relevance to the issues pending before OHCA and should be stricken in its entirety.

Dr. Howes' pre-filed rebuttal testimony (pages 762-63) is likewise objectionable for two reasons. First, Dr. Howes quotes a single sentence from the Draft State Health Plan referencing a change in the ACCF-AHA-SCAIPCI guidelines. The best evidence in this regard is the ACCF-AHA-SCAIPCI guidelines, and it is not appropriate for the Applicant's witness to refer to a plan which exists only in draft form which has not been finalized or adopted. Moreover, if OHCA determines that it is appropriate to consider the draft State Health Plan, then the draft Plan should be considered in its entirety, rather than one sentence taken out of context, as reflected in Dr. Howes' rebuttal testimony. In addition, Dr. Howes' rebuttal testimony includes a spurious remark directed at New York Presbyterian Hospital, which bears no relevance to the issues in this proceeding and is inconsistent with the professionalism and civility customarily demonstrated by witnesses who testify before OHCA.

Wherefore, for the foregoing reasons, Intervenor's objection to the rebuttal testimony should be sustained and the testimony stricken as set forth in Exhibit A hereto.

Respectfully submitted,

THE STAMFORD HOSPITAL

BY _____

Carolyn R. Linsey
Stephen M. Cowherd
Jeffers Cowherd P.C.
55 Walls Drive
Fairfield, CT 06824
Tel.: 203-259-7900
Fax: 203-259-1070
scowherd@jeffers-law.com
clinsey@jeffers-law.com
Its Attorneys

CERTIFICATE OF SERVICE

This is to certify that a true and accurate copy of the foregoing was sent by electronic mail this 17 day of July 2012 to:

Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.
265 Church Street
New Haven, CT 06510
jgroves@uks.com

Jean Ahn
System Director
Yale-New Haven Hospital
Planning & Business Development
20 York Street (Howe 3)
New Haven, CT 06504
jean.ahn@ynhh.org

Carolyn R. Linsey

EXHIBIT A

YNHHVC. Ms. Capozzalo will be in attendance at the hearing and can address her discussions with Stamford Hospital under oath.

~~YNHHVC and Greenwich Hospital fully intended to collaborate with Stamford Hospital in~~ the area of cardiac care and had sought to help strengthen Stamford's open heart surgery program, which is suffering from low volume. The presence of Yale faculty based in southwestern Connecticut communities along with the YNHHVC's clinical program support and quality improvement systems would have significantly improved Stamford Hospital's cardiac surgery program's credibility, which is at significant risk, evidenced by the fact that they performed only 80 open heart cases last year and are on track to perform approximately 50 this fiscal year based on 6 months volumes from CHIME (see Table below).

Connecticut Inpatient Volume for Open Heart Surgery by Hospital for FY 2010 - FY 2012 (6 Months)				
Hospital	FY 2010	FY 2011	FY 2012*	
Bridgeport	152	127	140	
Danbury	181	182	150	
Dempsey	67	71	72	
Hartford	793	801	702	
HSR	343	313	300	
St. Francis	867	781	734	
St. Mary's	118	100	114	
St. Vincent's	239	223	200	
Stamford	84	80	54	
Waterbury	109	102	104	
YNHH	869	800	820	
TOTAL	3,792	3,580	3,390	
Source: CHIME				
*FY 2012 annualized based on 6 months actual				

It is clear that YNHHVC acted in good faith to create a cost effective care model for cardiology services in the Stamford and Greenwich area, but it is Stamford Hospital that does not want to collaborate.

- I would also like to point out that Stamford Hospital's extremely low cardiac surgery volume does not come close to meeting professional society recommendations or OHCA's own standards as outlined in the Agreed Settlement for Stamford Hospital (DN: 04-30374-CON) (see Attachment II). Condition #8 states:

  "If TSH does not perform 125 OHS procedures within twelve months of the initiation of the OHS program, TSH shall submit monthly reports of OHS arrayed by physician to OHCA until such time as these volumes are met by TSH. If **these volumes are not met for a period of <u>two consecutive 12-month periods</u>, TSH's OHS program <u>shall be terminated</u>...**"

  We are not aware that this condition has been modified by OHCA based on a review of OHCA's website and modifications pursued by Stamford Hospital.

  According to OHCA's own data (see Attachment III) through 2010, Stamford Hospital has never come close to reaching 125 open heart surgeries in a year. In fact, it appears that its highest volume was 80 in FY 2011. As previously shown above, based on 6 months of CHIME data for 2012, they are on track to perform about 54 surgeries this year, less than half of the guidelines requirement. These low volumes have been of concern to YNHHVC physicians and we suspect have contributed to fewer referrals to their surgery program. Low surgical volume can also affect the physicians' decisions to transfer patients to Stamford for elective angioplasty, given the uncertain quality of the surgical backup available at that site. Such low surgical volumes present a significant quality concern as identified by the American College of Surgeons which published that an annual volume of 100-125 is <u>necessary</u> from a quality standpoint and this requirement has also been noted by OHCA in its draft Cardiac Services section of the new State Health Plan (see Attachment IV).

- Dr. Kiely states that OHCA should not approve Greenwich Hospital's proposed elective angioplasty program because elective angioplasty volumes are flat in Connecticut and the proposed service area. Stamford Hospital did not previously view flat or declining volumes as problematic when it pursued its full service cardiac program CON. At that time, their own cardiac catheterization volumes had been in decline as noted in OHCA's

Agreed Settlement's Findings of Fact #11 (previously referenced as Attachment II); statewide inpatient cardiac catheterization and angioplasty volumes had declined steadily between 2003 and 2005, as shown in Dr. Kiely's own testimony and open heart surgery volumes had also been declining between 2002 and 2005 as shown in the OHCA table and graph below.

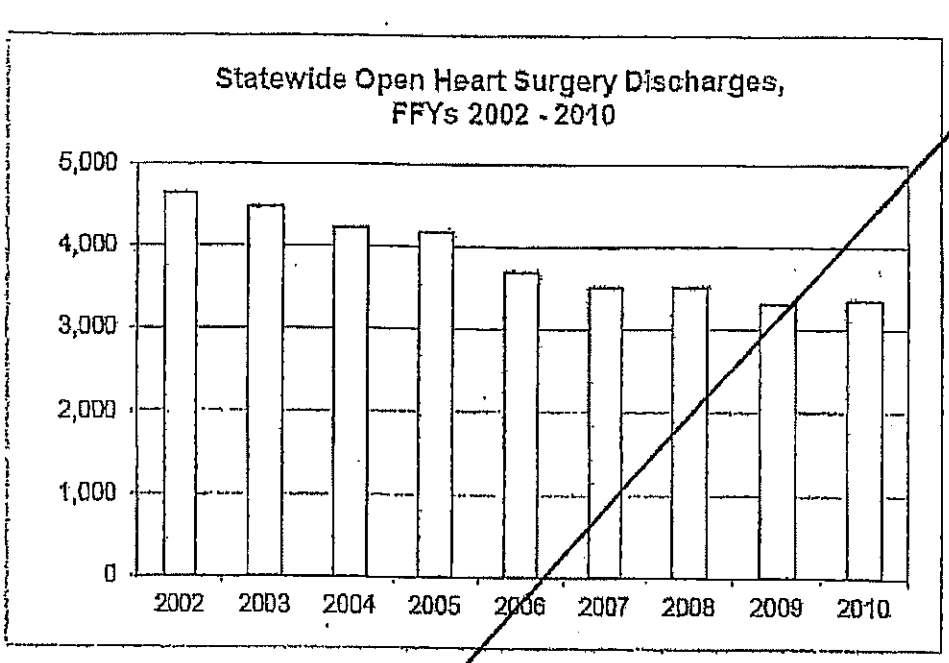
Table 3A: Open heart surgery discharges by provider, FFYs 2002-2010

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	FFY 06-10 (5-yr)% Change	FFY 08-10 (3-yr)% Change	FFY 09-10 (1-yr) % Change
Bridgeport	345	313	268	263	175	194	106	96	136	-22%	28%	42%
CT Children's								6	4	n/a	n/a	na
Danbury	0	0	0	114	177	121	162	148	174	-2%	7%	-9%
Dempsey	115	134	121	174	97	70	84	56	58	-40%	-31%	-33%
Hartford	901	844	756	726	742	685	671	652	695	-6%	4%	-3%
St. Francis	1,238	1,299	1,311	1,188	998	990	912	845	820	-18%	-10%	-7%
St. Mary's	0	0	0	19	72	100	85	114	112	56%	32%	34%
St. Raphael	761	687	617	510	353	342	321	299	318	-10%	-1%	-7%
St. Vincent's	310	296	293	291	259	232	257	219	195	-25%	-24%	-15%
Stamford	0	0	0	0	0	0	75	73	46	n/a	-39%	-3%
Waterbury	0	0	0	20	117	110	134	110	98	-16%	-27%	-19%
Yale	973	905	860	861	704	664	698	691	697	-1%	0%	-1%
Total	4,644	4,478	4,225	4,166	3,694	3,608	3,505	3,309	3,353	-9%	-4%	-8%

Source: CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database.

ICD-9-CM Procedure Codes: 35.10-35.28 and 35.10-36.19

Please note: unduplicated counts utilizing all procedure codes



All of these related and declining volumes did not seem relevant to Stamford Hospital or OHCA as a full service cardiac program was proposed and approved. Stamford Hospital expended more than $8 million dollars in capital expenses to develop their angioplasty and surgery program in a declining volume market (modified from the $5.4 million they estimated at the time of their original CON filing). They based their need on such factors as improved accessibility, continuity of care and improved quality. These are the same reasons why Greenwich Hospital seeks to offer elective angioplasty and ~~can do so without any capital expense.~~

- Dr. Kiely's testimony includes conflicting statistics and information about New York programs. First, I would like to highlight the following statement from OHCA's 2010 Declaratory Ruling, Docket Number: 09-31433-DCR, which specifically states that:

  "...OHCA only has the authority to act on behalf of the state within the parameters of its enabling statutes and its jurisdiction is limited to health care facilities located within the state. Thus, OHCA has no jurisdiction over health care facilities located in other states just as those states have no authority to regulate facilities located within Connecticut."

ATTACHMENT II

Office of Health Care Access
Certificate of Need Application

Agreed Settlement

Hospital:	The Stamford Hospital and New York Presbyterian Healthcare System, Inc.
Docket Number:	04-30374-CON
Project Title:	Establish Elective Angioplasty and Open Heart Surgery Program at The Stamford Hospital
Statutory Reference:	Sections 19a-638 & 639, Connecticut General Statutes
Filing Date:	August 15, 2005
Hearing Dates:	Public Portion: September 22, 2005 Technical Portion: October 6, 2005 and October 27, 2005
Commissioner & Presiding Officer:	Cristine A. Vogel
Agreed Settlement Date:	January 4, 2006
Default Date:	Not Applicable
OHCA Staff	Steven W. Lazarus Michael Sabados

Project Description: The Stamford Hospital ("TSH" and "Hospital") and New York Presbyterian Healthcare System, Inc. ("Applicants") propose the establishment of an elective angioplasty ("PCI") and open-heart surgery ("OHS") program, to be located at the Hospital, at a capital expenditure of $5,404,425.

Nature of Proceedings: On August 15, 2005, the Office of Health Care Access ("OHCA") received the Applicants' Certificate of Need ("CON") application seeking authorization to establish an elective angioplasty and open-heart surgery program, to be located at the Hospital, at a capital expenditure of $5,404,425. The Stamford Hospital is organized under the laws of Connecticut, and New York Presbyterian Healthcare System, Inc. is a corporation organized under the laws of the State of New York. The Hospital is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

Public hearings regarding the CON Application were held on September 22, 2005, October 6, 2005 and October 27, 2005. The Hospital was notified of the date, time, and place of the hearings and notices to the public were published prior to the hearings in *The Advocate* (Stamford) by OHCA. The hearings were conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the Connecticut General Statutes) and Sections 19a-638 and 19a-639, C.G.S.

Yale-New Haven Hospital, Bridgeport Hospital, and Greenwich Hospital collectively known as Yale-New Haven Heart Health Institute were granted Intervenor status with rights to cross-examine. St. Vincent's Medical Center was granted Intervenor status with the rights to cross-examine.

The Presiding Officer heard testimony from the general public, legislators, local officials and witnesses for the Hospital and Intervenors. In rendering this decision, the presiding officer has considered the entire record of the proceeding. OHCA's authority to review, approve, modify or deny this proposal is established by Sections 19a-638 and 19a-639, C.G.S. The provisions of these sections, as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were considered by OHCA in its review.

Findings of Fact

Clear Public Need
Impact on The Hospital's Current Utilization Statistics
Proposal's Contribution to Accessibility and Quality of Health Care Delivery in the Region

1. The Stamford Hospital ("TSH" and "Hospital") is a not-for-profit, 305-bed acute care hospital located in Stamford, Connecticut. TSH, as an affiliate member of the New York Presbyterian Healthcare System ("System"). TSH provides a comprehensive array of services including: Medicine, Surgery, Obstetrics/Gynecology, Psychiatry as well as Medical and Surgical critical care units. *(Completeness Responses, Proposed Resolution, August 15, 2005, Exhibit 3 and Certificate of Need Application, August 15, 2005, page 1-3)*

2. The New York Presbyterian Healthcare System, Inc ("NYPHS") coordinates a system of hospitals and other healthcare institutions throughout the tri-state area, including The Stamford Hospital ("TSH") and New-York Presbyterian Hospital ("NYPH"). NYPH operates New York-Presbyterian Hospital/Columbia University Medical Center ("NYP/C") in affiliation with Columbia University College of Physicians and Surgeons ("CU"). *(Certificate of Need Application, August 15, 2005, pages 2-3)*

3. TSH and NYPHS ("Applicants") propose the establishment of an elective percutaneous coronary angioplasty[a] ("PCI") and open-heart surgery[b] ("OHS") program, to be located at the Hospital. *(Certificate of Need Application, August 15, 2005, page 2)*

4. TSH's proposal is for a full-service cardiovascular services program in the lower Fairfield County. TSH is located in the region's largest population center. *(Prefiled Testimony of Brian Grissler, September 19, 2005,)*

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[a] Elective (Scheduled) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure performed in a catheterization laboratory whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a previously diagnosed blockage in the heart. An expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow.

[b] Open-heart surgery is a surgical intervention performed on the opened heart while the bloodstream is diverted through a heart-lung machine. Cardiac Surgery includes Coronary Artery Bypass Graft (CABG), Valvuloplasty, and Valve Replacement. CABG is where a vein from the chest or leg, or a prosthesis, is grafted onto either side of a blockage in the coronary artery. This reroutes blood flow around the blockage to the heart muscle. Valvuloplasty is where a balloon tipped catheter is inserted into plaque-blocked heart valves to widen and separate them through repeated balloon inflation. A Valve Replacement is a replacement of plaque-blocked heart valves with prosthetic or tissue graft.

5. On August 25, 2004, TSH received CON authorization from OHCA to perform primary[c] PCI services. *(Certificate of Need Application, August 15, 2005, page 2)*

6. The proposed program will augment existing cardiovascular services at the Hospital. The Hospital currently offers:

Primary Angioplasty	Electrocardiogram
Interventional electrophysiology (ablations)	Electrophysiology
Diagnostic cardiac catheterization	Holter monitoring
Coronary care unit	Intra-aortic balloon pump
Telemetry inpatient care	Nuclear stress testing
Cardiac imaging	Pulmonary function testing
Cardiac rehabilitation	Stress testing
Cardiac ultrasound	Tilt table testing
Cardiopulmonary testing	Vascular and thoracic surgical services

(Certificate of Need Application, August 15, 2005, pages 8-9)

7. TSH's cardiology primary and secondary service areas consist of the following Connecticut towns:

Table 1: Stamford Hospital's Proposed Service Area for this Proposal for FYs 2002 – 2005 (1st Two Quarters)

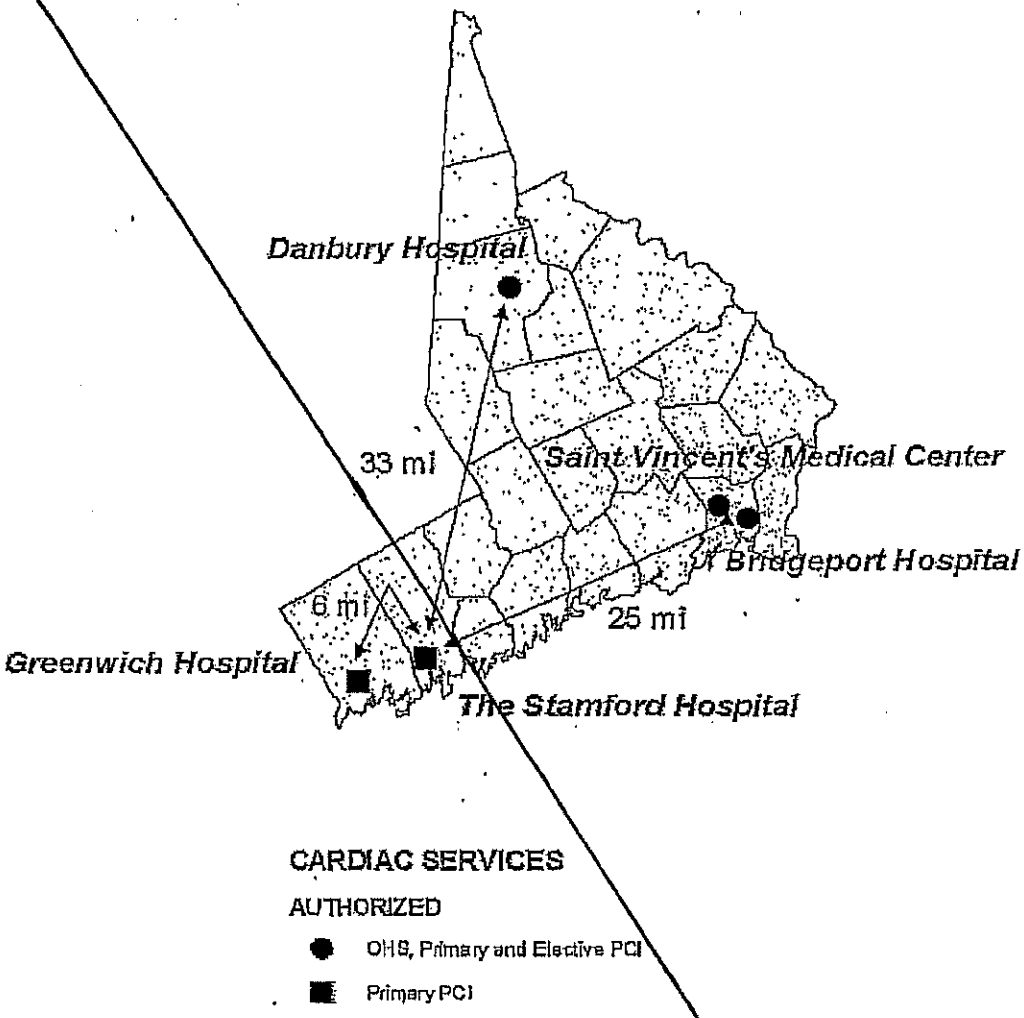
Towns	Primary	Secondary	Total Service Area
	Darien Stamford	Greenwich New Canaan Norwalk Weston Westport Wilton	Darien Greenwich New Canaan Norwalk Stamford Weston Westport Wilton
TSH's Share of Service Area's Inpatient Cardiac Catheterizations	57.4%	4.2%	26.1%
Service Area's share of TSH's Inpatient Cardiac Catheterizations	84.6%	8.7%	93.3%

(Source: Cardiac catheterization volume from *OHCA's Acute Care Hospital Inpatient Discharge Database. Service Area from Certificate of Need Application August 15, 2005, page 22)*

[c] Primary (Emergent) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure performed in a catheterization laboratory whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a previously diagnosed blockage in the heart. An expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow. Non-ST Segment elevation MI (NSTEMI or high-risk) patients consist of 80% of all MIs and are considered for angioplasty on an elective basis within 72 hours. Performance of elective angioplasty without cardiac surgery back up is not recommended by the American College of Cardiology or the American Heart Association.

8. Providers of interventional cardiac services in the Hospital's total service area ("TSA") are as follows

Map 1: Area Providers of Interventional Cardiac Services



Danbury Hospital began performing open heart surgery in January 2005.
Greenwich Hospital began performing Primary PCI in February 2005.
Stamford Hospital began performing Primary PCI in August 2005.

(Connecticut Acute Care Hospital Inpatient Discharge Database and Travel Distances from Yahoo Maps)

9. The Applicants based the need for the proposed Elective PCI and OHS program on the following:
   - Improved accessibility for patients;
   - Improved continuity of care;
   - Historical/Existing cardiac volume;
   - Adopting a standard of care that exists in the other large urban area; and
   - Improved quality of cardiac services.

   (Certificate of Need Application, August 15, 2005, pages 2-55)

10. TSH stated that the establishment of a full-service cardiac program in Stamford will provide timely access and local availability of these services in keeping with trends that have been already established nationally.
    (Prefiled Testimony of Kathleen Silard, Senior Vice President for Operations at TSH, September 19, 2005)

11. TSH's cardiac catheterization volume for FYs 2000 through 2005 are as follows:

Table 2: TSH's Historical Cardiac Catheterization Volume, FYs 2002 – 2005 1st Two Quarters

CT Service Area	2002	2003	2004	2005
Inpatient	354	352	296	147
Outpatient	321	283	332	-
Total	**675**	**635**	**628**	**147**

(Inpatient catheterization figures from OHCA's Acute Care Hospital Inpatient Discharge Database and outpatient volume from August 15, 2005, Responses to OHCA Completeness Letter, pages 1-2)

12. The following is a table of the average annual historical and projected Total PCI volumes (Primary & Elective) in TSH's service area:

Table 3: Average Annual Historical and Projected Total PCI Volumes in TSH's Service Area, FYs 2002 – 2005

	FYs 2002–2005 1st Two Quarters		Year One		Year Two		Year Three	
TSH Service Area	**Average PCIs**	**Adult Use Rate**	**Market Share (%)**	**Projected PCIs**	**Market Share (%)**	**Projected PCIs**	**Market Share (%)**	**Projected PCIs**
Primary	277	2.55	78%	216	83.5%	231	83.4%	231
Secondary	418	2.48	6.8%	28	11.0%	46	20.3%	85
Total Service Area	695	2.51	36.3%	244	40.6%	276	45.7%	316
Connecticut	8,024	2.98	-	-	-	-	-	-

Note: "Adult" refers to those 15 years and older. Adult use rate per 1,000 population.
Projected PCI volumes were calculated by applying the applicant's projected capture rate to the current PCI volume in the service area. For example, in Year One in the primary service area: 277 (average volume) * .78 (market share) = 216 PCIs.
(OHCA Acute Care Hospital Inpatient Discharge Database; MA, NY, and RI Hospital Discharge Databases; Census 2000 for population figures, and August 15, 2005 CON Application, *pages 45 & 23)*

13. The following table is the annual average historical and projected OHS for TSH in the proposed service area for FYs 2002-2005:

Table 4: Historical and Projected, Average Annual OHS Volumes in TSH's Service Area, FYs 2002–2005

	FYs 2000 – 2005 1st Two Quarters		Year One		Year Two		Year Three	
TSH Service Area	Average OHS	Adult Use Rate	Market Share (%)	Projected OHS	Market Share (%)	Projected OHS	Market Share (%)	Projected OHS
Primary	112	1.03	78.1%	88	83.5%	94	83.5%	94
Secondary	213	1.27	6.7%	14	10.9%	23	20.3%	43
Total Service Area	325	1.17	32.9%	102	38.8%	117	45.7%	137
Connecticut	4,640	1.72	-	-	-	-	-	-

Note: FY 2005 is First two quarters only.
"Adult" refers to those 15 years and older. Adult use rate per 1,000 population
Projected OHS volumes were calculated by applying the Applicant's projected capture rate to the current PCI volume in the service area. For example, in Year One in the primary service area: 112 (average volume) * .781 (market share) = 88 open-heart surgeries.
(OHCA Acute Care Hospital Inpatient Discharge Database; MA, NY, and RI Hospital Discharge Databases; Census 2000 for population figures; and August 15, 2005, CON Application, pages 46&23).

14. TSH projects the following number of elective PCIs procedures and OHS for its service area.

Table 5: Projected Cardiac Volume for TSH's Service Area

Service	FY 2007	FY 2008	FY 2009
Angioplasties (Elective only)	193	324	417
Open-heart surgeries	86	150	197

Note: TSH based the projected volumes on historical utilization and population data. The use-rates utilized are based on Claritas data. OHCA can not verify any of the above claimed data. *(Responses to the Interrogatories, September 28, 2005, Updated Financial Attachment and CON Application)*

15. The 2001 American College of Cardiology ("ACC") and the American Heart Association ("AHA") Guidelines for Percutaneous Coronary Intervention ("PCI") recommend that PCI be performed by higher volume operators (>75 cases/year) with advanced technical skills (e.g. subspecialty certification) at institutions with fully equipped interventional laboratories and experienced support staff. This setting will most often be in a high-volume center (>400 cases/year) associated with an on-site cardiovascular surgical program. Therefore, PCI is best done by high-volume operators in high-volume institutions. *(JACC, 2001, Vol. 37, No.8, page 2239)*

16. The ACC/AHA Guidelines for CABG Surgery (1999) state the following:
    - Studies suggest that survival after CABG is negatively affected when carried out in institutions that perform fewer than a threshold number of cases annually. Similar conclusions have been drawn regarding individual surgeon volumes.
    - The ACC/AHA are supportive of a posture of close monitoring of institutions or individuals that perform <100 cases annually.

17. TSH states that it will utilize the existing guidelines published by the ACC and AHA as a basis for the development of standards for the proposed services, as specified in **Attachment I.** *(Certificate of Need Application, August 15, 2005, page 11)*

18. The Guidelines for Standards in Cardiac Surgery by the Advisory Council for Cardiothoracic Surgery ("ACCS") and the American College of Surgeons ("ACS") (1996) state the following:
    - An annual volume of at least 100 to 125 open-heart procedures per hospital is necessary from a quality standpoint and there is a greater variation in adjusted mortality rates for teams doing lower volumes of procedures as compared with those doing a high volume.
    - At least 200 procedures per year as previously recommended in the 1975 report of the Inter-Society Commission on Heart Disease Resources are necessary in order for a program to function efficiently.
    - A team approach with a minimum of two qualified cardiac surgeons is recommended to provide adequate and continuous perioperative care as well as assistance in the operating room.

19. Dr. Steven F. Horowitz testified to the following at the public hearing:
    - TSH can sustain a full-service cardiac program due to the increase in the size of the minority population.
    - Numerous studies have confirmed that the cardiovascular risk profile for both Hispanics and African Americans has been worsening in recent years as obesity and diabetes continue to rise exponentially within these populations.

    (Prefiled Testimony of Steven F. Horowitz, M.D. Chief of Cardiology at TSH, September 19, 2005)

20. Kathleen Silard testified to the following at the public hearing:
    - TSH has examined the significant disparity in utilization rates for PCI and OHS that exists for African Americans in TSH service area as well as other regions of the state when compared to the Caucasian population. TSH has seen how some of the major precursors of heart disease, such as diabetes and obesity, can disproportionately effect minority populations as well as the economically disadvantaged.
    - One of the primary goals of TSH's proposed program will be to address and hopefully eradicate some of those disparities by improving access to PCI and OHS to these high-risk groups.

    (Prefiled Testimony of Kathleen Silard, Senior Vice President for Operations at TSH, September 19, 2005)

21. The demographic characteristics by Race for TSH's TSA are as follows:

Table 6: TSH Demographics by Race

Service Area	Caucasian	African American	Native American	Asian	Other	Total
Primary	73.6%	13.2%	0.2%	4.6%	8.4%	100%
Secondary	85.7%	6.6%	0.1%	3.5%	4.1%	100%
Total Service Area	81.0%	9.2%	0.2%	3.9%	5.7	100%
Connecticut	81.6%	9.1%	0.3%	2.4%	6.6%	100%

Source: Census 2000.

22. The demographic characteristics by Hispanic ethnicity for the proposed TSA:

Table 7: Hispanic Ethnicity of TSH Service Areas

Service Area	Hispanic or Latino	Non-Hispanic	Total
Primary	14.7%	85.3%	100%
Secondary	8.4%	91.6%	100%
Total Service Area	10.8%	89.2%	100%
Connecticut	9.4%	90.6%	100%

Source: Census 2000.

23. The AMI discharges for the TSH TSA are as follows:

Table 8: Share of AMI by Race and Hispanic Ethnicity, FYs 2002 – 2005 (First 2 Quarters)

Service Area	Caucasian	African American	Hispanic	Asian	Native American	Other	Total
Primary	84.7%	7.0%	4.2%	0.1%	0.0%	4.0%	100%
Secondary	85.1%	7.1%	3.4%	1.0%	0.1%	3.3%	100%
Total Service Area	84.9%	7.0%	3.7%	0.6%	0.1%	3.6%	100%
Connecticut	87.1%	4.7%	4.0%	0.3%	0.1%	3.8%	100%

(Discharges from OHCA Acute Care Hospital Inpatient Discharge Database and MA, NY, and RI Hospital Discharge Databases. "White," "Black," "Asian," "Native American," and "Other" are non-Hispanic categories.)

24. NYPH has one of the largest cardiac surgery and cardiac catheterization[d] programs in New York State with its physicians performing over 3,000 PCIs and close to 2,000 OHS in calendar year 2004. *(Prefiled Testimony of Arthur A. Klein, M.D., September 19, 2005)*

[d] Diagnostic Cardiac Catheterization is a diagnostic procedure in which a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to the heart to measure electrical activity, blood pressure, and locate blockages.

25. Dr. Steven Horowitz, testified on behalf of TSH to the following:
    - Diabetes is a leading cause of hospitalization among Connecticut's African American and Hispanic populations which are 3.8 and 2.2 times more likely to be hospitalized directly due to the disease as compared to the Caucasian Connecticut residents.
    - The percent difference for the African American utilization rates in the TSH's TSA versus those statewide is nearly 26% and 62% for PCI and cardiac surgery respectively. The same numbers skyrocket to 41% and 95% when the focus is placed solely on the City of Stamford.
    - TSH can target the African American and Hispanic population and relieve some of these barriers to access through the comprehensive preventive and medical outreach program.

    (Prefiled Testimony of Steven F. Horowitz, M.D., Chief of Cardiology Department at TSH, September 19, 2005)

26. Dr. Arthur Klein testified to the following at the public hearing:
    - NYPH and NYPHS have developed a number of strong and effective partnerships with affiliated hospitals to elevate the scope of and quality of cardiac care in the tri-state region.
    - NYPHS assists in the operation of nine (9) diagnostic cardiac catheterization programs through out the tri-state area, four elective angioplasty programs and one primary angioplasty program.
    - In this proposal, the cardiac surgery professional services will be provided exclusively by full-time faculty of the Division of Cardiothoracic Surgery, Department of Surgery of Columbia College of Physicians and Surgeons.
    - Oversight of elective angioplasty shall be through a joint committee co-chaired by Drs. Moses and Stone, senior faculty from Columbia University's Division of Cardiology and Stamford Hospital's cardiology leadership.

    (Prefiled Testimony of Arthur A. Klein, M.D., September 19, 2005)

27. Dr. Eric A. Rose testified at the public hearing that Columbia University Department of Surgery's professional expertise in cardiothoracic research, its strategic network of partnerships and its vast clinical experience will help support TSH in their cardiac health services. *(Prefiled Testimony of Eric A. Rose, M.D., Chairman for the Dept. of Surgery at NYP/C, September 19, 2005)*

28. TSH submitted a signed Draft Agreement with NYPHS. NYPHS' role is defined as follows:
    - Arrange consultative assistance to the Hospital in the following areas:
        - Preparation of the CON Application;
        - Clinical training of nursing and technical staff;
        - Development of the Hospital's standards of care, risk stratification criteria and operational policies;
        - Development of clinical guidelines and protocols;
        - Collection and analysis of quality data for clinical outcomes and performance monitoring;
        - Recruiting procedures; and

- Adoption by the Hospital of policies, procedures and protocols, including developing practice guidelines and requirements related to the proposed program.

- Recommend CPC standards and/or the standards of NYPHS-affiliated Connecticut institutions for physician, nursing and technical staff protocols to foster a high-quality credentialing program; and
- Advise the Hospital with respect to quality assurance and utilization management functions related to the proposed program.

(Completeness Responses, August 15, 2005, Draft Agreement between the Applicants, Exhibit 4, page 4)

29. TSH proposes to provide elective PCI utilizing five (5) interventional cardiologists, who are currently providing primary PCI services at TSH. *(Certificate of Need Application, August 15, 2005, page 11)*.

30. The PCI volumes for the proposed interventionalists for FYs 2002-2005 1st two quarters are as follows:

Table 9: Volume of Proposed Program Interventionalists (FYs 2002 – FY 2005 1st Two Quarters)

Physician	Hospital Affiliation	Office/Home	Average Annual PTCA Volume
Alcan[1]	St. Vincent's & TSH	Norwalk	347
Jumper[2]	St. Vincent's & TSH	Valhalla, NY	119[3]
Charney	NY Presbyterian, Greenwich, & TSH	New Rochelle	X[4]
Messinger	NY Presbyterian, Greenwich, & TSH	New Rochelle	X[4]
Stone	NY Presbyterian, TSH (pending)	Greenwich	-

[1]Member of Cardiology Associates of Fairfield County
[2]In training
[3]Dr. Jumper performed 57 in FY 2004 and 122 in the first two quarters of FY 2005.
[4] TSH reported volume (FYs 2003 & 2004 – NYP physicians not specifically identified)
Physician C: 156 & 145 and Physician D: 108 & 126
(OHCA Acute Care Hospital Inpatient Discharge Database and CON Application, August 15, 2005, page 11&58 and Completeness Responses, August 15, 2005, page 8)

31. TSH stated that three additional cardiac interventionalists, Drs. Portnay, Lorenz and Corvaja will be added to the proposed program to perform PCIs at TSH. *(CON Application, August 15, 2005, pages 11&58 and Completeness Responses, August 15, 2005, page 8)*

32. TSH proposes to staff the proposed OHS program with two (2) board-certified cardiac surgeons, who will practice full-time at TSH and be credentialed at both TSH and at NYP/C. These two surgeons will be recruited through the formation of a three (3) person committee which will include as its members, Dr. Craig Smith, Dr. Mehmet Oz and Dr. Eric Rose, Chair of the Surgery Department at NYP/C. *(Certificate of Need Application, August 15, 2005, page 11)*

33. The average annual PCI and OHS volumes in TSH's TSA by hospital provider for FYs 2000-2005 (1st two quarters) are as follows:

Table 10: Average Annual PCI and Open-Heart Surgery Volumes by Provider in TSH's TSA by Provider, (FYs 2002 – 2005 1st Two Quarters)

	PCIs			Open-Heart Surgeries		
Hospital	Procedures	Market Share	Area Volume as Share of Total Provider Volume (%)	Procedures	Market Share	Area Volume as Share of Total Provider Volume (%)
Bridgeport	154	22.2%	12.3%	75	23.1%	24.3%
Danbury	0	0.0%	-	0	0.0%	-
Greenwich	1*	0.1%	100%	-	0.0%	-
Hartford	0	0.0%	-	0	0.0%	-
John Dempsey	1	0.1%	0.2%	0	0.0%	-
Saint Francis	0	0.0%	-	1	.3%	.1%
Saint Raphael's	4	0.5%	0.4%	3	.9%	.4%
Saint Vincent's	392	56.4%	34.9%	119	36.6%	39.7%
Yale	78	11.2%	4.8%	57	17.5%	6.4%
Out of State	65	9.3%	-	70	21.6%	-
Totals	**695**	**100%**	-	**325**	**100%**	-

*Greenwich Hospital began providing primary PCI in February 2005.
(OHCA Acute Care Hospital Inpatient Discharge Database and MA, NY, and RI Hospital Discharge Databases)

34. Danbury Hospital, along with Waterbury Hospital and St. Mary's Hospital (one program, two sites in Waterbury) were authorized by OHCA to offer full-service cardiac programs in 2003. *(Certificate of Need Applications, Final Decision Docket Numbers 03-30167 & 03-30143, both dated July 23, 2005)*

35. St. Vincent's Medical Center ("SVMC") testified to the following:
    a. Angioplasty volume is flat nationally and has begun to decline in Connecticut.
    b. If TSH proposal is approved, St. Vincent's Medical Center would not be able to achieve both institutional and surgeon specific minimum volumes for OHS and would put the quality of St. Vincent's Medical Center at significant risk.
    c. SVMC performed 1,097 PCIs and 283 OHS in FY 2005.
    d. The overall risk adjusted mortality rate at SVMC is 1.3%.
    e. Other than volume, SVMC measures quality through independent third party companies (to whom they report data to).
    (Prefiled Testimony of Jose Missri, M.D. St. Vincent's Medical Center, September 28, 2005 and Public Hearing Testimony, October 6&27, 2005)

36. Bridgeport Hospital ("BH"), as part of Yale-New Haven Health Heart Institute, testified to the following:
    a. BH performed under 1,200 PCIs and under 250 OHS in FY 2005.
    b. BH could not specify their overall risk adjusted mortality rate, BH simply stated that it was under 2.0%.
    c. Other than volume, BH measures quality through independent third party companies (to whom they report data to).

d. If the proposed CON was to be approved, this would not impact the physician coverage at BH.
(Prefiled Testimony of Stuart Zarich, M.D., Bridgeport Hospital, September 28, 2005 and Public Hearing Testimony, October 6&27, 2005)

37. Yale-New Haven Hospital ("YNHH"), as part of Yale-New Haven Health Heart Institute, testified to the following:
    a. There is a statewide decline in the number of OHS cases,
    b. There is a flattening of PCI volumes,
    c. Proliferation of full-service cardiac program will place additional stress on the state's staffing infrastructure,
    d. Additional cardiac programs will not improve mortality rates,
    e. The residents of Fairfield County have a wide range of options for their full-service cardiac care needs,
    f. There is a direct correlation between physician and institutional case volumes and quality outcomes, and
    g. In FY 2004, YNHH had 64 PCI discharges (4.3% of YNHH's total PCI) and 52 OHS discharges (6.2% of YNHH's total OHS) from the Stamford service area.
    (Prefiled Testimony of Kyle Kramer, Executive Director of the Yale-New Haven Health Heart Institute, September 28, 2005 and Public Hearing Testimony, October 6&27, 2005)

38. In order to implement the proposed project, TSH will require a series of facility renovations. The renovations will include an expansion of surgical facilities on Level 2 of TSH's North building to allow for the creation of two new, state-of-the-art operating rooms that will be the primary operating suites for the proposed program as well as enlarged perioperative and other surgical support areas.
(Certificate of Need Application, August 15, 2005, page 13)

Financial Feasibility of the Proposal and its Impact on the Hospital's Rates and Financial Condition

Impact of the Proposal on the Interests of Consumers and Payers of Health Care Services

Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines

39. The proposal has a total expenditure cost of $5,404,425 which consists of the following:

Table 11: Total Capital Expenditure

Description	Cost
Medical Equipment	3,109,345
Construction/Renovation	1,590,065
Project Contingency	704,925
Total Capital Expenditure	**$5,404,425**

(Certificate of Need, August 15, 2005, page 63)

40. The proposal will be financed from the TSH's equity through operations. *(Certificate of Need, August 15, 2005, page 64)*

41. TSH will pay NYPHS a fee for expenses related to training and oversight of TSH's proposed program. This arrangement will be finalized if the proposal is approved by OHCA. *(Arthur S. Klein, Chief Operating Officer of NYPHS, Public Hearing Testimony, October 6&27, 2005)*

42. TSH projects incremental to the project losses from operations for the first two years of operation for FYs 2007 and 2008 of ($1,940,000) and ($294,000), respectively. This is due to program start up. However, TSH is projecting incremental gains from operation of $1,082,000 for the third year of operation, FY 2009. *(Responses to the OHCA Completeness Letter, August 15, 2005, Updated Financial Attachment)*

43. TSH is projecting a gain from operations with the CON project of $10,137,000, $12,327,000 and $14,365,000, for FYs 2007, 2008 and 2009. *(Responses to the OHCA Completeness Letter, August 15, 2005, Updated Financial Attachment)*

44. TSH proposes to hire 26, 34 and 38 Full Time Equivalent employees for FYs 2007, 2008 and 2009, respectively. *(Responses to the OHCA Completeness Letter, August 15, 2005, Updated Financial Attachment)*

45. There is no State Health Plan in existence at this time. *(Certificate of Need Application, August 15, 2005, page 14)*

46. TSH has adduced evidence that this proposal is consistent with TSH's long-range plan. *(Certificate of Need Application, August 15, 2005, page 14)*

47. TSH has improved productivity and contained costs by participating in group purchasing, energy conservation, reengineering and through application of technology. *(Certificate of Need Application, August 15, 2005, page 59)*

48. TSH stated that this proposal will help enhance the existing academic affiliation with Columbia University College of Physicians and Surgeons. *(Certificate of Need Application, August 15, 2005, pages 59&60)*

49. TSH stated that the patient physician mix of TSH is unique as the cardiac patient care is fully integrated across all medical disciplines and is managed through a state-of-the-art multi-modality data management system. *(Certificate of Need Application, August 15, 2005, page 60)*

50. TSH's rates are sufficient to cover the proposed capital expenditure and operating costs associated with this proposal. *(Responses to Interrogatories, September 28, 2005, Updated Financial Attachment)*

Rationale

The Office of Health Care Access ("OHCA") approaches community and regional need for proposed services on a case-by-case basis. Certificate of Need ("CON") applications for cardiac services do not lend themselves to general applicability due to the variety and complexity of factors, which may affect any given proposal; e.g., the characteristics of the population to be served, the nature of the existing services, the specific services proposed to be offered, the current utilization of services, and the financial feasibility of the proposed service. In considering this application, OHCA determined that TSH's current cardiac utilization, population served, quality of providers and physicians and geographic accessibility were significant factors in determining need.

The Stamford Hospital ("TSH") and New York Presbyterian Healthcare System, Inc. ("NYPHS") (collectively known as "Applicants"), propose to expand the cardiac services delivered at TSH to include elective angioplasty services and open heart surgery. The Applicants based the need for the elective PCI and open heart surgery programs on improved accessibility for patients, improved continuity of care, historical and existing cardiac volume, adopting a standard of care that exists in the other large urban areas and improved quality of care.

TSH's primary and secondary service area ("TSA") consists of eight (8) towns. There are no providers of elective PCI or OHS in TSH's TSA. The Hospital's service area is comprised of a higher proportion of African American and Hispanic population when compared to the rest of the state overall. The primary service area has experienced higher adult per capita rates of AMI discharges for African American and Hispanic as compared to the state as a whole. In addition, there appears to be a disparity in the utilization rates for PCI and OHS for Hispanics and African Americans in the service area when compared to the Caucasian population. This proposed cardiac program will enhance the access for the African American and Hispanic population in TSH's TSA. OHCA concludes that the Applicants proposal will provide the residents of lower Fairfield County with improved access to the full continuum of cardiac care.

TSH's historical cardiac catheterizations volumes for FYs 2002, 2003, 2004, and 2005 (1st 2 quarters) were 675, 635, 628 and 147, respectively. OHCA determined that TSH could potentially perform a minimum of 244 annual total PCIs (primary & elective) and 102 OHS cases on residents of TSH's TSA in the first full year of operation of the proposal based upon historical catheterization volume and its market share. This volume increases to 276 total PCI procedures and 117 OHS cases for the second year of operation, and 316 total PCI procedures and 137 OHS cases for the third of operation. Based on historical inpatient diagnostic cardiac catheterization volume and market share, the proposed full-service cardiac program at TSH would exceed institutional minimum volumes recommended by the ACC/AHA for PCI (200) and the American College of Surgeons–Advisory Council for Cardiothoracic Surgery for open-heart surgery (100–125 surgeries per year).

The proposal involves offering of elective Percutaneous Coronary Intervention ("PCI") through the use of five (5) interventional cardiologists, who are currently providing primary PCI services at TSH. TSH also proposes to provide OHS utilizing two (2) surgeons will be recruited from outside of Connecticut, through the formation of a three (3) person committee comprised of TSH and Columbia physicians. Therefore this program will not impact coverage at any of the existing cardiac programs in Connecticut. In addition, OHCA concludes that even though the PCI and OHS volumes may decline at the existing providers, the PCI and OHS volumes will not fall below the institutional minimum volumes recommended by ACC/AHA for PCI and American College of Surgeons-Advisory Council for Cardiothoracic Surgery for OHS.

TSH's proposal will increase the availability of quality PCI and OHS services for residents of TSH's TSA. The proposed elective PCI and OHS program will be developed in collaboration with NYPHS. NYPHS will provide or arrange for TSH consulting in the areas of clinical training for staff, development of TSH's standards of care, development of clinical guidelines, collection and analysis of data and recruiting procedures. NYPHS expects the initial training to continue over an eighteen month period. NYPHS will also advise TSH with respect to quality assurances and utilization management and provide assistance to TSH concerning the adoption of policies, procedures and protocols, including developing practice guidelines and program requirements. This proposal will improve the quality of care and continuity of TSH's cardiac services.

Finally, the CON proposal is financially feasible. The proposal has a total capital expenditure of $5,404,425, which consists $3,109,345 for medical equipment, $1,590,065 for construction/renovations and $704,925 for contingency costs. TSH proposes to fund the proposed total capital expenditure through TSH's equity, specifically through operations. TSH will pay NYPHS a fee for expenses related to training and oversight of TSH's proposed program; however, the details have not yet been finalized. TSH projects incremental losses from project operations for the first two years of operation of ($1,940,000), and ($294,000), respectively. However, TSH is projecting an incremental gain from operation of $1,082,000 by the third year of operation. Further, TSH is projecting gains from total Hospital operations with the CON project of $10,137,000, $12,327,000 and $14,365,000 for the first three years of operations. The projected utilization and financials of this proposal appear to be reasonable, financially feasible and cost-effective and will not adversely impact the interests of consumers and payers of such services.

TSH's proposed elective angioplasty and open heart surgery program is differentiated from other cardiac-related proposals in the following ways. TSH currently operates a high volume diagnostic cardiac catheterization program and recently initiated a primary angioplasty program. The Hospital's service area is comprised of a higher proportion of African American and Hispanic population than the rest of the state. The implementation of the proposed program should address some of the disparities in utilization of cardiac services by this population. Additionally, the proposed program is not expected to impact the physician coverage at any of the existing cardiac programs in Connecticut because the interventionalists are already on staff at TSH and the cardiac surgeons will be

recruited from out of state. TSH's strong collaborative relationship with the NYPHS will enhance the accessibility of high-quality, community-based medical services offered by TSH. TSH will utilize the resources of NYPHS to further enhance provision of quality care including access to the expertise, information, and consultative support of a nationally recognized academic healthcare center renowned for the diagnosis and treatment of cardiac disease. Finally, implementation of TSH's proposal will bring appropriate access to high quality cardiac services to the residents of the proposal's TSA. In summary, the proposal will result in enhanced cardiac services in the Stamford region.

Order

NOW, THEREFORE, the Office of Health Care Access ("OHCA") and The Stamford Hospital ("TSH") and New York Presbyterian Healthcare System, Inc. ("NYPHS") (together referred to as "Applicants") hereby stipulate and agree to the terms of settlement with respect to the Applicants' request to establish elective angioplasty and open heart surgery program to be located at Stamford Hospital at a total capital expenditure of $5,404,425, as follows:

1. The Applicants' request for a CON to establish an elective angioplasty and open-heart surgery program to be located at TSH, a total capital expenditure of $5,404,425, is hereby approved.

2. TSH shall only commence operation of the OHS program at The Stamford Hospital initially. Once the number of OHS procedures exceeds 125, the Hospital may commence operation of the elective angioplasty program. Prior to commencement of the angioplasty services, TSH is required to provide OHCA evidence that it has performed the required 125 OHS.

3. TSH will have at least two cardiac surgeons as part of this proposal, who are in the process of being recruited and shall be identified prior to the beginning of the OHS program. The surgeons must be fully credentialed and have the following qualifications:
   - Board-Certified in cardiac surgery
   - Maintains a Connecticut license and admitting privileges at the Hospital
   - Has performed OHS procedures at a cardiac surgical center that meets or exceeds the annual ACCS/ACS minimum institutional volume standard for cardiac surgery for the past 2 years
   - TSH shall provide the Curriculum Vitae ("CV") of the cardiac surgeons prior to commencement of the OHS program. TSH shall demonstrate that the cardiac surgeons satisfy all requirements specified above. The OHS program shall not commence operation until OHCA acknowledges receipt of the CV and that it complies with this Order.

4. TSH shall provide the CVs of each of the cardiac operating room nurses, Board-certified cardiac anesthesiologists, intensivists and perfusionists for the authorized OHS program prior to commencement of the OHS program. Fifty percent (50%) of each of the core OR staff mentioned above must be trained in OHS prior to commencement of the OHS program. The OHS program shall not commence operation until OHCA acknowledges receipt of the CVs and that they comply with this Order.

5. TSH shall not exceed the approved total capital expenditure of $5,404,425. In the event TSH learns of potential cost increases or expects final project costs will exceed those approved, the Hospital shall file with OHCA a request for approval of

the revised CON project budget. The source of funding for the project will be The Stamford Hospital's operations and owner equity.

6. TSH shall complete and submit to OHCA on a quarterly basis the data elements in the Connecticut Cardiac Data Registry (**Attachment II**). Data should be submitted to OHCA on a computer disk in either an excel workbook or comma-delimited text file in a format specified by OHCA. The most current version of the Connecticut Cardiac Data Registry includes, but may not be limited to, the elements listed in **Attachment II**. Data must be reported to OHCA thirty (30) calendar days following the end of the quarter. Fiscal Year quarters end December 31st, March 31st, June 30th, and September 30th. Upon receipt, OHCA will check the data's conformance to the required specifications and within ten (10) business days notify TSH in writing of its evaluation. If OHCA finds questionable material, TSH will have fifteen (15) business days from notification by OHCA to submit a revised dataset for evaluation. All patient-level data submitted to OHCA to satisfy this requirement will be subject to the laws and regulations of the state of Connecticut and the Office of Health Care Access regarding its collection, use and confidentiality. If TSH does not submit the data elements in the Connecticut Cardiac Data Registry on a quarterly basis, the programs may be terminated. In the event of such a termination, TSH shall file a CON for reinstitution of the programs.

7. TSH shall submit on an annual basis to OHCA the following reports which must be reported to OHCA thirty (30) calendar days following the end the year, for the first three (3) years of operation:
   a. A report of all elective PCIs and OHS performed each year by ethnicity and race, in a format to be specified.
   b. A report which illustrates that this CON proposal helped relieve the barriers to access through comprehensive preventive and medical out-reach programs for the African American and Hispanic population within TSH's TSA.

8. If TSH does not perform 125 OHS procedures within twelve months of the initiation of the OHS program, TSH shall submit monthly reports of OHS arrayed by physician to OHCA until such time as these volumes are met by TSH. If these volumes are not met for a period of two consecutive 12-month periods, TSH's OHS program shall be terminated. In the event of such a termination, TSH shall file a CON for reinstitution of the OHS program.

9. If TSH does not perform 200 elective PCIs within twelve months of the initiation of the PCI program, TSH shall submit monthly reports of elective PCIs arrayed by physician to OHCA until such time as these volumes are met by TSH.

10. TSH shall participate in the Society of Thoracic Surgeons Database (STS-DB) database and the ACC National Cardiovascular Database Registry (ACC-NCDR) and report all data including the optional follow-up section. TSH shall provide OHCA quarterly data reports from STS-DB and ACC-NCDR. Data must be

reported to OHCA thirty (30) calendar days subsequent to TSH receiving the reports from the STS and ACC. TSH is required to comply with the STS and ACC/AHA criteria and standards. If TSH determines not to participate in the STS-DB or ACC-NCDR, TSH shall notify OHCA immediately, and continue to comply with the STS and ACC/AHA criteria and standards set forth in Attachment III.

11. TSH shall provide OHCA with a copy of a dated and signed Consulting Services Agreement with NYPHS or its Affiliates prior to commencement of operation of the OHS program. This contract shall be renewed annually for a period of three years.

12. OHCA and TSH agree that this Agreed Settlement represents a final agreement between OHCA and TSH with respect to this request. The signing of this Agreed Settlement resolves all objections, claims and disputes, which may have been raised by the Hospital with regard to Docket Number 04-30374.

13. This authorization for the OHS program shall expire on December 31, 2008. Should the TSH's open-heart surgery program not commence operation by that date, TSH must seek further approval from OHCA to complete the project beyond that date.

14. This Agreed Settlement is an order of the Office of Health Care Access with all the rights and obligations attendant thereto, and the Office of Health Care Access may enforce this Agreed Settlement pursuant to the provisions of Sections 19a-642 and 19a-653 of the Connecticut General Statutes at TSH's expense, if TSH fails to comply with its terms.

January 4, 2006

Brian G. Grissler
Duly Authorized Agent for
The Stamford Hospital

December 28, 2005

Arthur A. Klein, M.D.
Duly Authorized Agent for
New York Presbyterian Health System, Inc.

The above Agreed Settlement is hereby accepted and so ordered by the Office of Health Care Access on January 4, 2006.

January 4, 2006

Cristine A. Vogel
Commissioner & Presiding Officer

CAV:sl

ATTACHMENT III

Table 1A: Inpatient cardiac catheterization discharges by provider, FFYs 2002-2010

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	FFY 06-10 (5-yr) % Change	FFY 08-10 (3-yr) % Change	FFY 09-10 (1-yr) % Change
Backus	156	210	200	170	116	53	106	135	115	-1%	8%	-15%
Bridgeport	1,148	1,185	1,274	1,129	902	809	817	632	626	-31%	-23%	-1%
CT Children's								10	5	n/a	n/a	-50%
Danbury	263	299	260	327	748	633	475	452	418	-44%	-12%	-8%
Dempsey	519	564	633	640	487	439	480	419	462	-5%	-4%	10%
Greenwich	100	42	35	105	167	158	163	177	166	-1%	2%	-6%
Hartford	2,546	2,405	2,241	2,128	2,135	2,032	2,008	1,833	1,892	-11%	-6%	3%
Hospital of Central CT	448	466	409	411	436	401	319	344	269	-38%	-16%	-22%
Lawrence & Memorial	420	473	466	393	414	303	337	440	503	21%	49%	14%
Middlesex	38	169	168	150	182	142	161	138	138	-24%	-14%	0%
New Milford	0	0	0	22	37	38	65	37	0	-100%	-100%	-100%
Norwalk	247	203	195	182	128	67	77	104	126	-2%	64%	21%
Rockville	0	79	99	24	4	3	0	0	0	-100%	n/a	n/a
St. Francis	2,742	2,802	2,800	2,656	2,421	2,543	2,431	2,292	2,206	-9%	-9%	-4%
St. Mary's	291	299	260	307	519	469	455	480	469	-10%	3%	-2%
St. Raphael	1,744	1,878	1,833	1,496	1,383	1,200	1,113	1,062	1,098	-21%	-1%	3%
St. Vincent's	1,276	1,259	1,324	1,432	1,554	1,540	1,562	1,375	1,267	-18%	-19%	-8%
Stamford	354	352	296	299	311	297	293	358	321	3%	10%	-10%
Waterbury	451	477	387	412	658	622	611	675	608	-8%	0%	-10%
Yale	2,549	2,587	2,330	2,200	2,021	1,939	1,954	2,135	2,129	5%	9%	0%
Total	15,282	15,748	15,190	14,484	14,623	13,588	13,427	13,098	12,818	-12%	-5%	-2%

Source : CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database.

ICD-9-CM Procedure Codes: 37.21-37.23

Please note: unduplicated counts utilizing all procedure codes

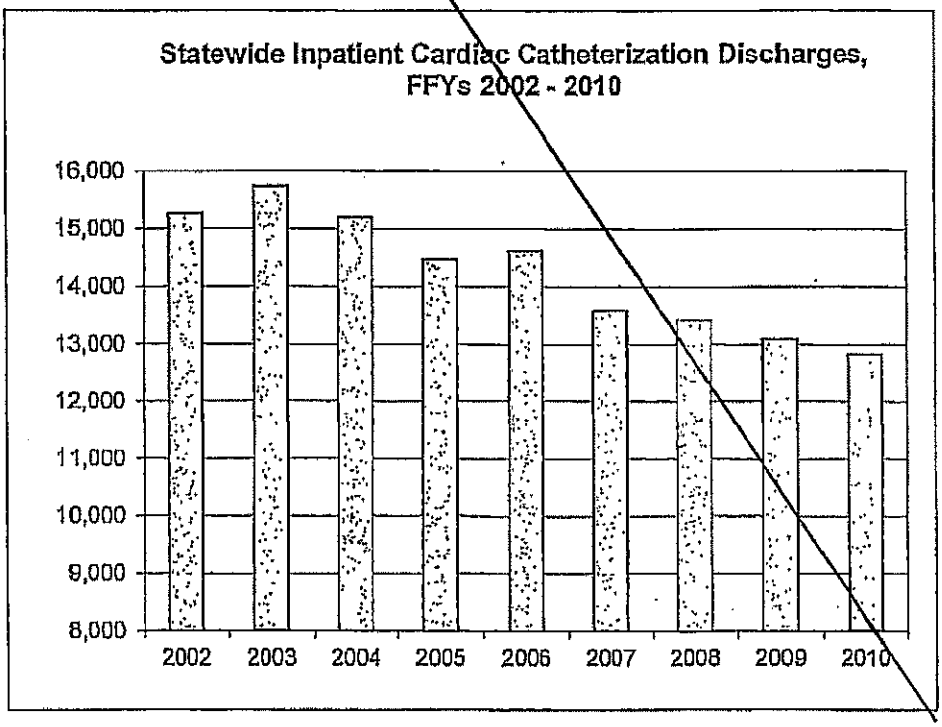


Table 2A: PCI discharges by provider, FFYs 2002-2010

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	FFY 06-10 (5-yr) % Change	FFY 08-10 (3-yr) % Change	FFY 09-10 (1-yr) % Change
Bridgeport	1,191	1,249	1,268	1,052	692	560	580	426	379	-45%	-35%	-11%
CT Children's								2	0	n/a	n/a	n/a
Danbury	0	0	0	0	453	409	330	326	277	-39%	-16%	-15%
Dempsey	452	464	453	519	401	353	376	334	368	-8%	-2%	10%
Greenwich	0	0	0	20	38	32	40	40	32	-16%	-20%	-20%
Hartford	1,312	1,483	1,321	1,282	1,246	1,206	1,093	1,031	1,122	-10%	3%	9%
Hospital of Central CT	0	0	0	26	61	70	60	74	69	13%	15%	-7%
Lawrence & Memorial	0	0	0	0	41	-	29	74	74	80%	155%	0%
New Milford	0	0	0	0	0	8	11	11	0	n/a	-100%	-100%
Norwalk								14	57	n/a	n/a	307%
St. Francis	1,192	1,253	1,349	1,223	1,170	1,188	1,171	1,232	1,030	-12%	-12%	-16%
St. Mary's	0	0	0	59	297	246	251	255	291	-2%	16%	14%
St. Raphael	715	970	924	708	680	632	595	534	523	-23%	-12%	-2%
St. Vincent's	1,063	1,035	1,086	1,150	1,181	1,101	1,124	958	925	-22%	-18%	-3%
Stamford	0	0	0	9	39	34	45	159	151	287%	236%	-5%
Waterbury	0	0	0	61	347	373	325	361	361	4%	11%	0%
Yale	1,635	1,715	1,480	1,297	1,218	1,131	1,186	1,352	1,469	21%	24%	9%
Total	7,560	8,169	7,880	7,406	7,864	7,341	7,216	7,185	7,128	-9%	-1%	-1%

Source: CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database

ICD-9-CM Procedure Codes: .66, 36.01, 36.02, 36.05, 36.06 and 36.07

Please note: unduplicated counts utilizing all procedure codes

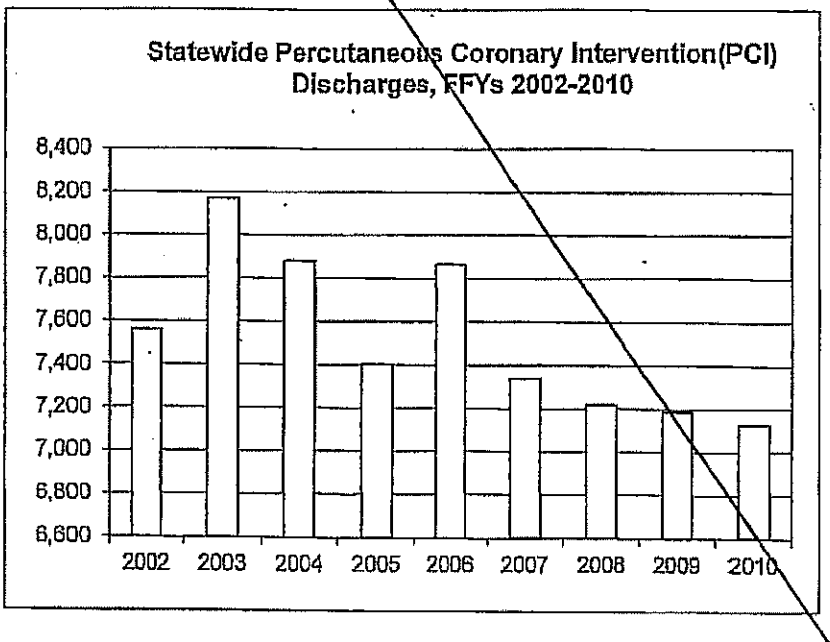


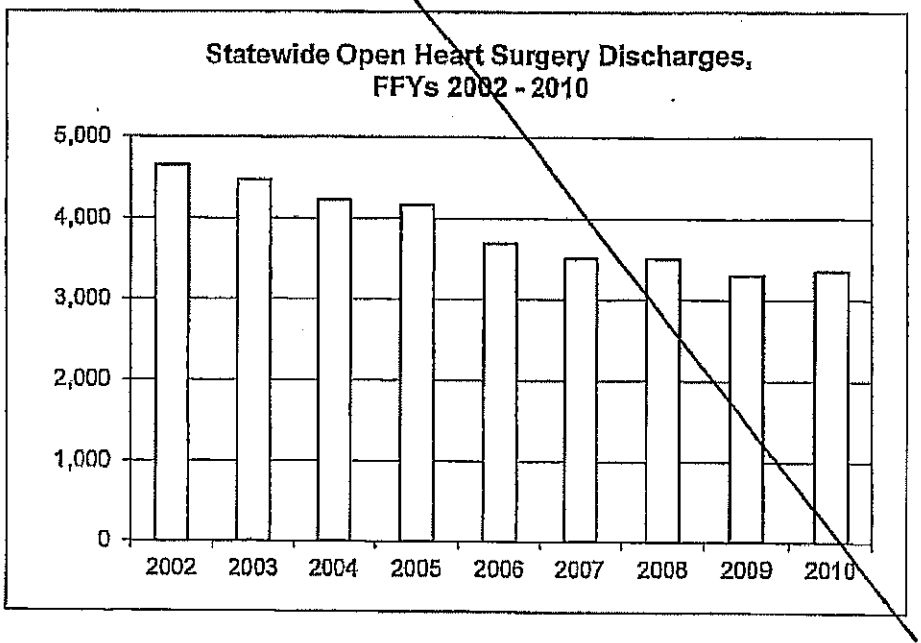
Table 3A: Open heart surgery discharges by provider, FFYs 2002-2010

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	FFY 06-10 (5-yr)% Change	FFY 08-10 (3-yr)% Change	FFY 09-10 (1-yr) % Change
Bridgeport	345	313	268	263	175	194	106	96	136	-22%	28%	42%
CT Children's								6	4	n/a	n/a	na
Danbury	0	0	0	114	177	121	162	148	174	-2%	7%	-9%
Dempsey	115	134	121	174	97	70	84	56	58	-40%	-31%	-33%
Hartford	901	844	756	726	742	685	671	652	695	-6%	4%	-3%
St. Francis	1,239	1,299	1,311	1,188	998	990	912	845	820	-18%	-10%	-7%
St. Mary's	0	0	0	19	72	100	85	114	112	56%	32%	34%
St. Raphael	761	687	617	510	353	342	321	299	318	-10%	-1%	-7%
St. Vincent's	310	296	293	291	259	232	257	219	195	-25%	-24%	-15%
Stamford	0	0	0	0	0	0	75	73	46	n/a	-39%	-3%
Waterbury	0	0	0	20	117	110	134	110	98	-16%	-27%	-18%
Yale	973	905	860	861	704	664	698	691	697	-1%	0%	-1%
Total	4,644	4,478	4,226	4,166	3,694	3,508	3,505	3,309	3,353	-9%	-4%	-6%

Source: CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database.

ICD-9-CM Procedure Codes: 35.10-35.28 and 36.10-36.19

Please note: unduplicated counts utilizing all procedure codes



ATTACHMENT IV

GUIDELINES FOR STANDARDS IN CARDIAC SURGERY

The following statement is an updated version of guidelines that were first published by the American College of Surgeons in 1991. The revised statement was developed by the Advisory Council for Cardiothoracic Surgery and approved by the College's Board of Regents in October 1996.

Preamble

This report provides guidelines to be used by hospital executives and appropriate medical staff only. It places no value judgment on existing successful programs or on the treatment of individual patients.

While current standards of practice form the basis of this report, it is recognized that large programs in cardiac surgery grow from smaller ones. Hospitals and their staffs should exercise their own discretion in approving programs based on local need and the responsibility for achieving a good standard of practice.

While attention is directed primarily to open-heart surgery, the proposed standards should apply to closed-heart operations as well as to operations on the great vessels within the chest.

In borderline situations, in which the number of open-heart operations does not meet the established guidelines, the American College of Surgeons recommends the use of peer review.

Professional team

Specification of the qualifications for cardiac surgeons in an established practice is beyond the scope of these guidelines. Surgeons practicing cardiac surgery should be certified or awaiting certification by the American Board of Thoracic Surgery or its Canadian equivalent within five years after completion of an approved residency program in cardiac surgery. It is recommended that hospital committees for staff accreditation exercise their judgments for privileges based on the nature of the cardiothoracic residency or postresidency experiences of the applicant.

A team approach with a minimum of two qualified cardiac surgeons is recommended to provide adequate and continuous perioperative care as well as assistance in the OR. It is recognized that, depending on the particular setting and situation, the assistant on a particular case may vary in experience and qualification.

Hospital operative volume–Adult cardiac surgery

The 1975 report of the Inter-Society Commission on Heart Disease Resources recommended that cardiac surgical programs in a *hospital* should perform at least 200 procedures annually. This recommendation was based on the premise of a hospital dedicating 1 operating room to cardiac surgery and functioning at 80 percent capacity (4 cases per week x 52 weeks = 200 per year). While there are no presently available data linking an *individual surgeon's* patient volume and hospital mortality rate, there are data to suggest that an annual volume of at least 100 to 125 open heart procedures (including coronary artery bypass procedures, valve replacements, and other operations requiring the use of cardiopulmonary bypass) per *hospital* is necessary from a quality standpoint and that there is a greater variation in adjusted mortality rates for teams doing lower volumes of procedures as compared with those doing a high volume. While 100 to 125 cases per year per *hospital* appears sufficient from a quality standpoint, it is likely that considerably more, and at least 200 procedures per year as previously recommended, are necessary in order for a program to function efficiently.

Congenital heart surgery

Surgery for congenital heart disease, especially in infants, requires a setting that readily meets the complex and special needs

of this group of patients. These requirements include a cardiac surgeon experienced in the operative and perioperative management of such patients. There should be a pediatric cardiologist, an anesthesia team, perfusionists, intensive care nurses, and appropriate intensive care facilities for the treatment of infants and children. At a hospital where congenital heart operations are performed, a total of 100 congenital heart operations (both open and closed, not including neonatal ductus ligations) should be done. The occasional management of an infant or child with congenital heart disease by an otherwise busy and well-functioning adult cardiac surgical team is strongly discouraged.

Hospital facilities and personnel

It is urged that hospital committees for staff accreditation use peer review to determine that adequate standards of practice are maintained in terms of case frequency and results. A registry for the recording of cardiac surgical results is mandatory.

The complex operating room environment required by cardiac surgery in terms of equipment and instruments requires constant improvement in technique and proper indoctrination of personnel. Such educational programs should be under the direction of a clearly designated individual with particular interest and skill in cardiac surgery. Operating room nurses and technicians specializing in cardiac surgery are important. It should be mandatory that operating room nurses and technicians be assigned to cardiac surgery sufficiently often to develop and maintain the skills required for proficient performance in this area.

Anesthesia for cardiac surgical patients encompasses a variety of special problems. To ensure technical competence, frequent changing of the anesthesiologists assigned to cardiac surgery should be avoided.

The operation of a heart-lung machine should be performed by a specially trained nurse or technician under the supervision of the operating surgeon. A perfusionist certified by the American Board of Cardiovascular Perfusion is recommended. Perfusionists who are not certified should have at least two years of experience under supervision in an active clinical program in open-heart surgery and have a thorough background in operating room sterile techniques, perfusion physiology, the use of monitoring equipment, and a general understanding of commonly performed cardiac surgical procedures. The primary responsibility for determining the capability of the perfusionist remains with the cardiac surgeon.

Cardiac surgeons must be primarily responsible for the postoperative care of their patients, including that provided in the intensive care unit. Portions of that care may be shared with others, such as nurses and other physicians. However, only the cardiac surgeon is fully cognizant of all aspects of a given patient's condition and retains the responsibility for the continuity of care, which includes the preoperative status, the operative management, and the postoperative care.

Intensive care nursing of cardiac surgical patients is recognized as a true specialty involving skills in dealing with cardiac and respiratory emergencies. Assignment to cardiac surgical patients should be sufficiently often to maintain competence in this area of nursing. The surgeon should participate in the supervision of cardiac intensive care unit nurses.

The operating room, intensive care unit, and other facilities must conform to standards mandated by the Joint Commission on Accreditation of Health Care Organizations.

The nature of cardiac surgery makes it mandatory that diagnostic facilities be available to the surgical team. A proper cardiac catheterization laboratory must be available for hemodynamic and cine' angiographic studies. This laboratory should be under the direction of a qualified specialist and be accessible for preoperative elective studies, postoperative elective studies, and emergency procedures on a 24-hour basis.

Standard laboratory studies should be available on a 24-hour basis, including blood-gas analysis.

A blood bank facility with full resources under the direction of qualified specialists in this field is mandatory.

An intensive care facility must be available for all patients following cardiac surgery, and in some instances, for patients who are severely ill, preoperatively. This should be a limited-access area that is off limits to nonparticipating personnel and should have facilities for the adequate isolation of septic patients.

Patient follow-up

Proper patient follow-up is an integral part of surgical treatment. An effective follow-up system for patients having open-heart surgery is the responsibility of the surgical team. The team should be able to demonstrate that it has an adequate follow-up system and that patients are seen as often as necessary during the immediate postdischarge period and, subsequently, are followed up at appropriate intervals.

Bibliography

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Guidelines

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sponsor hospitals and OEMS the ability to begin to collect EMS data, creating the potential in the near future to begin to analyze the data and create best practices to elevate the quality of care and delivery of Emergency Medical Services to the residents and visitors of Connecticut.

In late 2008/early 2009 the AHA formed a "STEMI stakeholders group" comprised of three sub-committees (pre-hospital, timely transfers and education) intended to develop and promulgate best practice related to ST segment myocardial infarction (STEMI). The group had a varied composition including physicians (EMS/ED, cardiology, and interventional cardiology), nurses, pre-hospital providers and health care administrators/regulators. This group drafted a document outlining recommendations to improve care in relation to pre-hospital triage of STEMI patients, timely transfers of patients between facilities and issues of education for pre-hospital providers. A "STEMI Protocol" was also drafted that was intended to offer state-wide guidance for best practice regarding patients experiencing chest pain and subsequently diagnosed with a STEMI by pre-hospital EKG (including bypass for more timely cardiac catheterization).

The "STEMI Protocol" was reviewed by the CT EMS Medical Advisory Committee (CEMSMAC) beginning in 2010. In 2011, after a significant amount of thoughtful work by the CEMSMAC, a revised version of the document entitled "CT EMS STEMI Guideline" was completed and submitted to the Commissioner of Public Health for review; it was approved in January 2012.

OHCA would encourage the adherence of the "CT EMS STEMI Guideline." The foremost goal is for authorized EMS personnel to obtain a 12-lead electrocardiogram in the field for all patients suspected of myocardial infarction, thereby increasing the likelihood for percutaneous coronary intervention (PCI) within 90 minutes of first medical contact. Please see link below for the complete "CT EMS STEMI Guideline" document:

http://www.ct.gov/dph/lib/dph/ems/pdf/stemi_patients.pdf

CARDIAC SERVICES

Heart disease is the leading cause of death for both men and women in the United States.[53] In 2010, coronary heart disease alone was projected to cost the United States approximately $108.9 billion in health care services, medications, and lost productivity.[54] In Connecticut, cardiovascular disease (CVD) is also a significant public health concern and contributor of resident deaths. In fact, about one third of Connecticut resident deaths are due to CVD; coronary heart disease (48%), cerebrovascular disease (15%) also known as stroke and heart failure (8%) account form the majority of CVD deaths.[55]

Existing Connecticut statute requires CON authorization for the establishment of cardiac services, including inpatient and outpatient cardiac catheterization, interventional cardiology and cardiovascular surgery. According to OHCA's Policies and Procedures, "interventional cardiology" is defined as non-

surgical procedures performed in the cardiac catheterization laboratory for the treatment of coronary artery and peripheral vascular disease. Procedures include, but are not limited to, angioplasty, valvuloplasty, cardiac ablation, coronary thrombectomy, and congenital heart defect correction. Only those procedures authorized pursuant to CON may be performed by a health care facility or provider. Multiple cardiac services may be authorized under one CON decision. A facility that is authorized to provide open heart surgery is also authorized to provide the full range of cardiac procedures mentioned above.

CARDIAC CATHETERIZATION

Cardiac catheterization is defined as a medical procedure requiring the passage of a catheter into one or more cardiac chambers of the left and right heart, with or without coronary arteriograms, for the purpose of diagnosing congenital or acquired cardiovascular disease, or for determining measurement of blood pressure flow.

ANGIOPLASTY/PERCUTANEOUS CORONARY INTERVENTION

Primary (emergent) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a previously diagnosed blockage in the heart. An expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow

Elective (scheduled) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure performed in a catheterization lab whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a previously diagnosed blockage in the heart. An expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow.

PCI and Elective PCI are often combined with the permanent placement of a small wire mesh tube called a stent to help prop the artery open and decrease the chance of it narrowing again. Some stents are coated with medication to help keep the artery open (drug-eluting stents), while others are not (bare-metal stents).

OPEN HEART SURGERY

Open heart surgery refers to a therapeutic operative procedure performed on the heart and/or its coronary arteries in order to correct anomalous conditions (for example, coronary artery bypass surgery, heart valve replacement), often using a heart-lung by-pass machine to perform the functions of circulation during surgery.

Authorization for Connecticut hospitals to perform elective catheter-based interventions for coronary artery disease has been limited in the past to hospitals with the ability to perform cardiac surgery onsite. However, increasing operator experience, improvements in surgical technique and major advances in technology and pharmacology have contributed to a progressive trend to allow PCI without on-site surgical backup. New evidence gives support to the positive effects that these medical advances have contributed to the significant reduction in emergency surgery following PCI[56]. Elective PCI without on-site surgical backup was, until recently, recommended as class III (not recommended, potentially harmful). However, an important change occurred in 2011, when the ACCF-AHA-SCAI PCI guidelines were modified to a class IIb (Level of evidence B) recommendation. CPORT-E trial findings conclude that patients have no greater risk of death or complications when they have Elective PCI at a hospital without cardiac surgery backup. However, similar to the 2007 SCAI Expert Consensus document, the revised guidelines also recommend stringent criteria for such programs. Connecticut hospitals seeking authorization to initiate an Elective PCI program without on-site cardiac surgery capabilities will be required to meet the SCAI conditions required in guidelines as well as demonstrate clear public need for the program.

DESCRIPTION OF DATA SOURCES

The primary source to be used for Acute Care utilization will be the CT Office of Health Care Access Acute Care Hospital Inpatient Discharge Database.

MAP OF CURRENT SERVICE LOCATIONS

Table 3.10: Adult Cardiac Services in Connecticut[57]

Hospital	Cardiac Cath	Primary PCI	Elective PCI	Open Heart
William. W. Backus	X			
Bridgeport Hospital	X	X	X	X
Danbury Hospital	X	X	X	X
John Dempsey Hospital	X	X	X	X
Greenwich Hospital	X	X		
Hartford Hospital	X	X	X	X
Lawrence & Memorial Hospital	X	X		
Middlesex Hospital	X			
Hospital of Central CT	X	X		
Norwalk Hospital	X	X		
Rockville General[1]	X			
St. Francis Hospital	X	X	X	X
HCGW (Saint Mary/Waterbury)	X	X	X	X

Hospital of Saint Raphael	X	X	X	X
St. Vincent's Medical Center	X	X	X	X
Stamford Hospital	X	X	X	X
Yale-New Haven Hospital	X	X	X	X

[1]Although allowed to provide the service, the hospital has not provided the cardiac services.
Source: CT DPH-OHCA Acute Care Hospital Service Line Survey, 2012

STANDARDS/GUIDELINES

Connecticut General Statutes Section 19a-638 specifies that at CON is required for: the establishment of cardiac services, including inpatient and outpatient cardiac catheterization, interventional cardiology and cardiovascular surgery.

The Office of Health Care Access has historically utilized Professional Societies and Organizations held to be the experts for establishing standards and guidelines for cardiac care and will continue to make appropriate use of their recommendations in the future review and determination of CON applications. Examples of expert sources to be used in determining standards and guidelines include: the American College of Cardiology, the American Heart Association and the Advisory Council for Cardiothoracic Surgery.

PERCUTANEOUS CORONARY INTERVENTION (PCI)

Primary PCI

1. Based on ACC and AHA, Primary PCI for STEMI should be performed by experienced operators who perform more than 75 elective PCIs per year and, ideally, at least 11 PCI procedures for STEMI per year. Ideally, these procedures should be performed in institutions that perform more than 400 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year.
2. A report by the American College of Cardiology/American Heart Association Task Force on practice guidelines, referring to Class II b, suggests that Primary PCI for patients with STEMI might be considered in hospitals without on-site cardiac surgery provided that appropriate planning for program development has been accomplished and includes: appropriately experienced physician operators (more than 75 total PCIs and, ideally, at least 11 primary PCIs per year for STEMI); an experienced catheterization team on a 24 hours per day; a 7 day per week call schedule; a well-equipped catheterization lab with digital imaging equipment; a full array of interventional equipment; intra-aortic balloon pump capability; and a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital with appropriate hemodynamic support capability for transfer. Primary PCI should be limited to patients with STEMI or MI with new or presumably new LBBB on ECG and should be performed in a timely fashion (goal of balloon inflation within 90 minutes of presentation) by persons skilled in the procedure (at least 75 PCIs per year) and at hospitals that perform a minimum of 36 Primary PCI procedures per year. (Level of Evidence: B - Limited populations evaluated. Data derived from a single randomized trial or nonrandomized studies).

Elective PCI

1. Elective/urgent PCI should be performed by operators with an acceptable annual volume (>75 procedures) at high volume centers (> 400 procedures) with on-site cardiac surgery (Level of Evidence: C)
2. Elective/urgent PCI should be performed by operators and institutions whose current risk-adjusted outcome statistics are comparable to those reported in contemporary national data registries, (Level of Evidence: C)
3. It is reasonable that low volume operators (< 75 PCI procedures per year) perform elective/urgent PCI at high volume centers (> 400 PCI procedures per year) with on-site cardiac surgery. Ideally, operators with an annual procedure volume of fewer than 75 procedures per year should only work at institutions with an activity level of more than 600 procedures per year. Operators who perform fewer than 75 procedures per year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume of at least 150 procedures per year. (Level of Evidence C)
4. It is not recommended that elective/urgent PCI be performed by low volume operators (< 75 PCI procedures per year) at low volume centers (200 to 400 procedures per year) with or without on-site cardiac surgery. An institution with a volume of fewer than 200 procedures per year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer this service. (Level of Evidence: C)
5. The 2005 PCI Guideline does not establish an explicit minimum hospital volume threshold for elective PCI; there are multiple references in the context of operator and institutional competency to "centers" performing 200 – 400 elective PCI procedures per year.
6. The 2011 PCI Guideline states that operator and hospital volume recommendations have been carried over from the ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention.

a. PCI in Hospitals without On-Site Surgical Back-up is in the Class IIb category.

Class IIb: Elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection (Level of Evidence: B)

Any hospital considering elective PCI without on-site-cardiac surgery must meet the criteria set forth in the 2011 ACCF/ANA/SCAI PCI Guideline, Section 4.8., PCI in Hospitals Without On-Site Surgical Backup: Recommendations (see link below):

http://content.onlinejacc.org/cgi/reprint/58/24/e44.pdf

Any hospital not meeting the 2011 ACCF/ANA/SCAI PCI Guideline criteria will be considered to be in Class III.

Class III–Harm: Primary and elective PCI should not be performed in hospitals without on-site cardiac surgery capabilities without a proven plan for rapid transport to a surgery operating room in a nearby hospital or without appropriate hemodynamic support capability for transfer. (Level of Evidence: C)

Quality and Performance Considerations for PCI Programs

Based on the 2011 American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions Guidelines for Percutaneous Coronary Intervention:

1. Every PCI program should operate a quality improvement program that routinely:
   a) reviews quality and outcomes of the entire program;
   b) reviews results of individual operators;
   c) includes risk adjustment;
   d) provides peer review of difficult or complicated cases; and
   e) performs random case reviews (Level of Evidence: C)
2. Every PCI program should participate in a regional or national PCI registry for the purpose of benchmarking its outcomes against national norms. (Level of Evidence: C)

PCI quality and performance considerations are defined by attributes related to structure, processes, and risk adjusted outcomes. Structural elements include, for example, staffing, equipment, supplies, operator and institutional volumes, and the availability of electronic medical records. Processes include strategies for the appropriate patient, protocols for pre- and post-procedural care, appropriate procedural execution and management of complications; and participation in databases and registries for benchmarking program and individual operator performance. The end result of these structures and processes of care are risk-adjusted outcomes, and when available, are more reliable measures of quality than the institutional and individual operator volumes.[58]

CARDIAC SURGERY/OPEN HEART SURGERY[59]

1. Guidelines for Standards in Cardiac Surgery developed by the Advisory Council for Cardiothoracic Surgery and approved by the American College of Surgeons' Board of Regents in October 1996 – Bulletin of the American College of Surgeons, Vol. 82, No. 2, February 1997
   a. An annual volume of at least 100 to 125 open heart procedures per hospital is necessary from a quality standpoint and there is a greater variation in adjusted mortality rates for teams doing lower volumes as compared with those doing a high volume.
   b. At least 200 procedures per year are necessary in order for a program to function efficiently
   c. A team approach with a minimum of 2 qualified cardiac surgeons is recommended to provide adequate and continuous perioperative care as well as assistance in the OR.
2. The following conditions must be met to initiate a new OHS program:

a. The annual caseload of other programs w/in the proposed PSA shall not drop below 350 procedures.
b. Epidemiological evidence of conditions for which OHS is appropriate w/in the PSA or demonstrates a significant unmet need in the PSA for these procedures.
c. Existing program(s) in the service area are performing at least 350 open heart surgeries annually.
d. Evidence demonstrating the performance of a minimum of 200 open heart surgeries annually within the first three years of the start of the new Open Heart Surgery program.

CARDIAC UTILIZATION

Based on hospital discharge data, inpatient cardiac care is declining both in patient volume and overall patient days (see Table 4.7 and Chart 4.3). From FY 2008 to FY 2011, Cardiac Care-Medical discharges dropped 6%, while the corresponding patient days declined by 3%. During the same time period, Cardiac Care-Surgical care declined even more significantly, with both discharges (11%) and patient days (8%) falling.

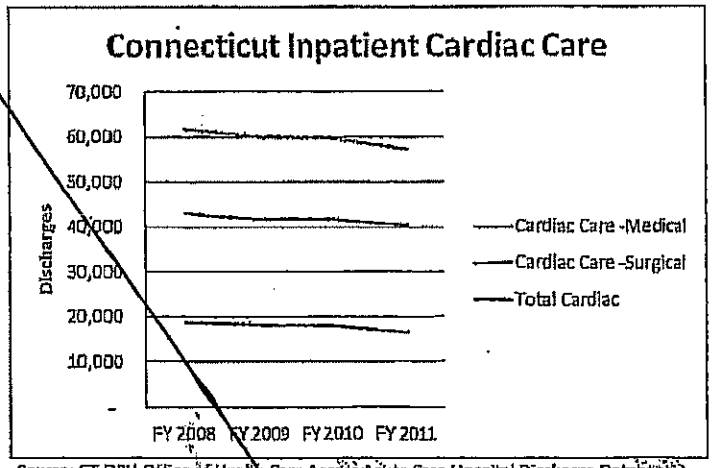
Table 3.11: Statewide Cardiac Inpatient Data

Discharges	FY2008	FY2009	FY2010	FY 2011	chg 08-11	chg 10-11
Cardiac Care -Medical	43,072	41,747	41,795	40,542	-6%	-3%
Cardiac Care -Surgical	18,681	18,299	18,104	16,710	-11%	-8%
Total Cardiac	61,753	60,046	59,899	57,252	-7%	-4%

Patient Days	FY2008	FY2009	FY2010	FY 2011	chg 08-11	chg 10-11
Cardiac Care -Medical	159,087	156,890	155,239	153,817	-3%	-1%
Cardiac Care -Surgical	95,344	93,054	90,455	87,361	-8%	-3%
Total Cardiac	254,431	249,944	245,694	241,178	-5%	-2%

Source: CT DPH Office of Health Care Access Acute Care Hospital Discharge Database

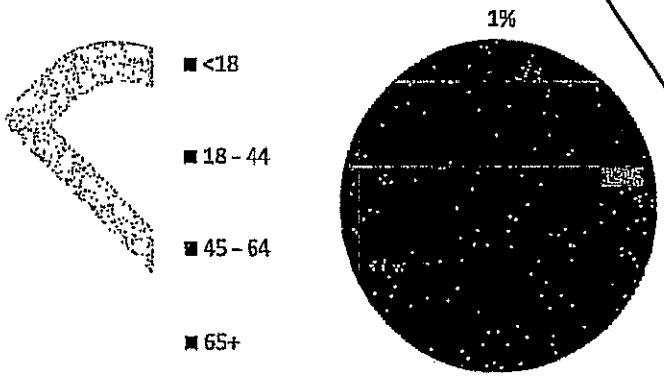
Chart 3.4: Connecticut Inpatient Cardiac Care



Source: CT DPH Office of Health Care Access Acute Care Hospital Discharge Database

Cardiac discharges are highly prevalent among the elderly. As seen in Chart 4.3, sixty-four percent of inpatient cardiac discharges in FY 2011 were for patients age 65 and older.

Chart 3.5: Cardiac Discharges by Age (FY 2011)



Source: CT DPH Office of Health Care Access Acute Care Hospital Discharge Database

DISCUSSION OF UNMET NEED AND GAPS IN SERVICES, CAPACITY ISSUES, ETC.

The tables below provide an initial step toward the identification of potential areas of unmet need for cardiac care in the state. The tables below provide information that compares the number of residents from a given region that received treatment for cardiac medical services or surgery in a given year (patient demand). This patient demand is compared to the overall volume of cardiac patients served by hospitals in the same region. If hospital volumes are lower than patient demand in the region, it may indicate the need for additional capacity and warrants additional study to examine patient migration patterns to confirm or refute this assertion.

Table 3.12: Bed Need for Inpatient Cardiac Services

Hospitals	DEMHS Region	Service		Discharges 2007	Discharges 2008	Discharges 2009	Discharges 2010	Patient Days 2007	Patient Days 2008	Patient Days 2009	Patient Days 2010
Bridgeport, Norwalk, Greenwich, Stamford, St Vincent's	1	Medical	Demand	7,509	7,249	7,242	7,060	29,191	28,470	27,882	27,702
			Served	8,642	8,345	8,412	8,230	32,392	32,060	31,436	31,124
			Surplus (-) or Deficit (+)	(1,053)	(1,096)	(1,170)	(1,170)	(3,201)	(3,590)	(3,654)	(3,422)
		Surgical	Demand	3,418	3,340	3,031	2,926	17,819	16,340	15,777	14,429
			Served	3,850	3,728	3,263	3,205	18,893	17,724	16,198	15,181
			Surplus (-) or Deficit (+)	(432)	(388)	(232)	(279)	(1,663)	(1,384)	(421)	(752)

Hospitals	DEMHS Region	Service		Discharges 2007	Discharges 2008	Discharges 2009	Discharges 2010	Patient Days 2007	Patient Days 2008	Patient Days 2009	Patient Days 2010
Yale, Griffin, Milford, St Raphael, MidState	2	Medical	Demand	10,202	10,250	9,967	10,664	36,304	37,846	38,740	38,336
			Served	10,000	9,936	9,745	10,539	35,660	37,066	38,198	38,379
			Surplus (-) or Deficit (+)	202	314	222	125	644	580	542	(41)
		Surgical	Demand	4,243	4,119	4,088	4,176	21,400	21,045	20,669	20,451
			Served	5,117	5,118	5,323	5,441	25,969	26,043	26,558	25,675
			Surplus (-) or Deficit (+)	(874)	(999)	(1,235)	(1,265)	(4,563)	(4,998)	(5,973)	(5,224)

Hospitals	DEMHS Region	Service		Discharges 2007	Discharges 2008	Discharges 2009	Discharges 2010	Patient Days 2007	Patient Days 2008	Patient Days 2009	Patient Days 2010
Dempsey, Saint Francis, Bristol, HOCOT, Manchester, Hartford, CTGMC, Middlesex, Rockville, Johnson	3	Medical	Demand	12,700	12,162	11,848	10,991	45,821	47,067	48,730	44,209
			Served	14,235	13,846	13,164	12,561	51,503	53,844	53,461	50,397
			Surplus (-) or Deficit (+)	(1,535)	(1,684)	(1,618)	(1,570)	(6,882)	(6,577)	(6,731)	(6,188)
		Surgical	Demand	5,902	5,569	5,600	5,357	33,5[illegible]	29,771	30,034	29,483
			Served	7,704	7,280	7,172	6,951	43,656	39,799	39,143	39,204
			Surplus (-) or Deficit (+)	(1,802)	(1,681)	(1,572)	(1,594)	(10,109)	(10,028)	(9,109)	(9,721)

Hospitals	DEMHS Region	Service		Discharges 2007	Discharges 2008	Discharges 2009	Discharges 2010	Patient Days 2007	Patient Days 2008	Patient Days 2009	Patient Days 2010
Backus, L&M, Day Kimball, Windham	4	Medical	Demand	5,252	5,773	5,422	5,451	17,269	19,042	18,659	17,806
			Served	4,772	5,187	4,904	4,926	14,985	16,203	15,676	15,085
			Surplus (-) or Deficit (+)	480	586	518	525	2,404	2,839	2,983	2,721
		Surgical	Demand	1,946	2,051	1,980	2,129	10,652	10,340	9,556	10,659
			Served	382	426	396	414	2,227	1,982	1,923	2,052
			Surplus (-) or Deficit (+)	1,568	1,625	1,584	1,706	8,425	8,358	7,633	8,606

Hospitals	DEMHS Region	Service		Discharges 2007	2008	2009	2010	Patient Days 2007	2008	2009	2010
Danbury, New Milford, Hungerford, Sharon, St Mary's, Waterbury	5	Medical	Demand	5,454	6,026	5,884	5,864	22,071	21,794	21,909	21,740
			Served	5,183	5,758	5,522	5,539	20,718	20,114	20,119	20,254
			Surplus (-) or Deficit (+)	271	268	382	325	1,353	1,680	1,860	1,488
		Surgical	Demand	3,001	2,864	2,901	2,811	14,989	14,367	13,705	12,905
			Served	2,164	2,129	2,145	2,093	10,302	9,796	9,232	9,343
			Surplus (-) or Deficit (+)	837	735	756	718	4,697	4,571	4,473	3,563

Hospitals		Service		Discharges 2007	2008	2009	2010	Patient Days 2007	2008	2009	2010
Distributed among several hospitals	Out of State, Unk Address	Medical	Demand	1,635	1,612	1,586	1,765	4,862	5,060	4,891	5,444
			Served								
			Surplus (-) or Deficit (+)								
		Surgical	Demand	705	708	699	714	3,433	3,481	3,399	3,528
			Served								
			Surplus (-) or Deficit (+)								

RECOMMENDATIONS

1. Examine volume as indicator of quality, as well as other indicators, by examining institutional and operator performance.
2. Continue to review and update Connecticut's cardiac guidelines to reflect updated information and recommendations provided by Professional Societies and Organizations with expert knowledge of cardiac care.

CANCER TREATMENT

Oncology is the branch of medicine concerned with the study and treatment of cancer, including screening, diagnosis, therapy, follow-up and palliative care. It includes various sub specialties such as radiation oncology (medical use of high-energy radiation to kill malignant cells), surgical oncology, and pediatric oncology. Chemotherapy, most generally the treatment of disease by chemicals, can be used for a range of diseases but most frequently refers to antineoplastic drugs to treat cancer.

In Connecticut, there is no unique licensure category for cancer treatment. The Commission on Cancer (CoC), a consortium of professional organizations dedicated to improving cancer patients' lives, administers an accreditation program that encourages hospitals, treatment centers, and other facilities to improve the quality of patient care by focusing on prevention, early diagnosis, pretreatment evaluation, staging, optimal treatment, rehabilitation, surveillance for recurrent disease, support services, and end-of-life care. A broad range of available medical services combined with a multidisciplinary team approach has resulted in 80 percent of all newly diagnosed cancer patients in the US being treated in CoC-accredited cancer programs.[60] According to the CT Cancer Partnership, 67% of acute care hospitals in Connecticut are ACoS accredited.[61].

The change in the 2011 ACCF/AHA/SCAI guidelines for elective angioplasty without onsite cardiac surgery from a Class III to a Class IIb is significant. Dr. Gray states this change is only "incremental", but my opinion is to move from a Class III which indicates harm to a Class IIb which states such a program might be considered as long as there is appropriate program development and rigorous criteria for proper patient selection is beyond "incremental". ~~OHCA has recognized this significant change and incorporated in their Cardiac Services section of the new State Health Plan (draft form) the following statement:~~

~~"...an important change occurred in 2011, when the ACCF-AHA-SCAI PCI guidelines were modified to a class IIb (Level of evidence B) recommendation".~~

- Dr. Gray discusses the results of the CPORT-E study recently published in the New England Journal of Medicine and suggests that our CON application included the position that elective angioplasty without onsite cardiac surgery is preferred over sites with onsite surgery. Our application never included any such suggestion. But the CPORT-E study, along with others noted in Dr. Cabin's prefiled testimony, and the shift from a Class III to a Class IIb assignment by the ACCF/AHA/SCAI Angioplasty Guidelines all support the reasonableness of offering elective angioplasty without onsite cardiac surgery as long as number of criteria are met which we have already addressed in our CON application. Dr. Gray's skepticism and criticism of angioplasty without onsite cardiac surgery is puzzling given his institution's (NYP) support of White Plains Hospital's program as well as support of a similar program by another NYP affiliate, Holy Name Hospital in Teaneck, New Jersey.

- Dr. Gray also highlights the statement in the 2011 ACCF/AHA/SCAI Guidelines which discusses competition with another angioplasty program in the same geographic area, particularly an established program with surgical back-up and that such competition MAY not be in the best interests of the community. The data we included in our prefiled testimony clearly shows that Greenwich and Stamford Hospitals are overwhelmingly serving residents of different communities. I would go so far as to say that we do not compete in the area of cardiology, despite our close geography. Our medical staff in

cardiovascular services does not overlap to any measurable degree and referral patterns to the interventional cardiologists are different. We have offered emergency angioplasty for approximately 8 years and despite the entrance of Stamford Hospital's program, we have maintained our emergency and elective transfer volume because patients want their care from Greenwich Hospital and the YNHHVC. In this case, a program at Greenwich Hospital IS in the best interest of the community because the Greenwich Hospital community has demonstrated that is where they want their care.

- Dr. Gray states that if the program at Greenwich Hospital is approved there is a risk that Stamford and Greenwich Hospital's angioplasty programs may perform less than 200 PCIs per year. For the reasons I have outlined above, we do not believe our program will impact Stamford's program due to the lack of patient and physician crossover. It is worthy to note that since the opening of White Plains Hospital's program, Stamford Hospital has not seen any decline in their angioplasty volume. According to Stamford Hospital's Petition, Stamford Hospital "...is on track to perform 277 PCIs in FY 2012" which represents a 25% increase from its 2011 volume as noted on Dr. Kiely's testimony page 32 (PCR data). Clearly, the presence of the White Plains Hospital program, which is located only 15 miles from Stamford Hospital and performed as many as 290 PCIs last year, has not had any impact on Stamford Hospital's angioplasty volumes.

- I must comment on Dr. Gray's suggestion that approval of the proposed program at Greenwich Hospital would in some way encourage physicians to feel "...pressure to refer patients for procedures to keep institutional volumes up. Occurrences like these will only drive up healthcare costs for payers and patients." ~~Dr. Gray is suggesting that physicians may send a patient for an unnecessary procedure just to increase institutional volumes. This may be the practice at New York Presbyterian, but I can assure you that this is NOT the practice of YNHHVC physicians nor would it ever be condoned or permitted.~~

BEFORE THE OFFICE OF HEALTH CARE ACCESS DIVISION OF THE DEPARTMENT OF PUBLIC HEALTH	:	Docket No. 12-31748-CON
IN RE APPLICATION OF YALE-NEW HAVEN HOSPITAL AND GREENWICH HOSPITAL TO ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM AT GREENWICH HOSPITAL	:	July 17, 2012

Rebuttal Testimony of Dr. William A. Gray

I would like to address some of the statements made by Dr. Howes in his pre-filed and rebuttal testimonies and by Dr. Cabin in his pre-filed testimony.

First, I would like to address statements made by Dr. Howes. On page 668 of his pre-filed testimony, he states that the 2011 ACCF/AHA/SCAI Guideline along with the CPORT-E study results "essentially end the debate over the safety of elective angioplasty programs without onsite cardiac surgery as long as programs adhere to the SCAI program requirements." This statement is a clear mischaracterization of the Guideline and the study results.

In addition, Dr. Howes, on page 761 of his rebuttal testimony, goes on to cite language from page 5 of the 2012 ACCF/SCAI Expert Consensus Document Update stating that

> It is generally believed that elective and primary PCI are permissible in sites without cardiovascular surgery, if there is strict adherence to national guidelines. In particular, there must be a documented working relationship with a larger facility with cardiovascular surgical services and an emergency transportation system operative.

What Dr. Howes fails to mention in providing the above two excerpts is that the 2012 ACCF/SCAI Expert Consensus document also states that performance of elective PCIs without on-site surgical back-up "remains controversial," especially when other active PCI programs are located in the same geographic area. 2012 ACCF/SCAI Expert Consensus Document Update, p.

197 (page reference is to Exhibit 4 of my Pre-filed Testimony). He also fails to mention that the same 2012 ACCF/SCAI Expert Consensus document states that

> there is a declining volume of PCI despite the improvement in outcomes from stent technology and consistent with a better appreciation of which procedures provide optimal benefit to patients. These types of studies suggest maturation of the technology so that further expansion may be limited despite concerns regarding a need for more procedures in the aging population. To this end, some have called for a moratorium on allowing any further expansion of PCI services, especially to low-volume facilities without cardiovascular surgical backup.

2012 ACCF/SCAI Expert Consensus Document Update, p. 197. Finally, he also omits from his testimony the notion that the 2011 ACCF/AHA/SCAI Guideline states that it is only reasonable to consider elective angioplasty programs without on-site cardiac surgery if such programs will "clearly fill a void in the healthcare needs of the community." *See* ACCF/AHA/SCAI Guideline, p. 164 (page reference is to Attachment VI of Applicants' CON Application)).

Given these statements, it is misleading for Dr. Howes to state that the 2011 Guideline and CPORT-E study "essentially end the debate" on this point. The debate may be ended with regard to those programs that will fill a void in the healthcare needs of the community and will improve access to a higher level of care than would otherwise be available, but none of the 2011 Guideline, the 2012 Expert Consensus document or the CPORT-E study in any way endorses duplicative elective angioplasty programs located close to established, high-quality providers with existing capacity. As TSH has said time and again, another elective PCI program in lower Fairfield County will not improve access to cardiovascular care – it will merely shift the volume in the service area from existing programs to a new program, and, in doing so, jeopardize the quality of care rendered by each program. Furthermore, it does not matter that a proposed program intends to strictly adhere to national guidelines if there is not a need for the proposed

program in the first place (*i.e.* if the program will not fill a void in the healthcare needs of the community).

I would also like to state that I did not indicate that I believed Applicants' CON application included the position that elective angioplasty without onsite cardiac surgery is preferred over sites with cardiac surgery. *See* Dr. Howes Rebuttal Testimony, p. 762. I do not believe any cardiac physician would take such a position. I merely indicated that it is only reasonable to consider an elective angioplasty program without onsite cardiac surgery back-up if it will "clearly fill a void in the healthcare needs of the community" and will "improve access to a higher level of cardiovascular care than would otherwise be available." *See* 2011 ACCF/AHA/SCAI Guideline, p. 164; 2012 ACCF/SCAI Expert Consensus Document Update, p. 197; Pre-filed Testimony of Dr. William A. Gray, pp. 5, 7. Here, as we have previously established, there is no such void and, with high-quality programs in the service area already providing the service, it can hardly be stated that the proposed program will improve access to a higher level of care than is already available.

Finally, with regard to page 762 of Dr. Howes' rebuttal testimony, NYP/C's support for White Plains Hospital's program filled a void in the healthcare needs of the community by providing Westchester County with a second, local elective angioplasty program. The Teaneck, New Jersey program and service areas also involved unique factors which are not replicated here.

I would also like to briefly address statements made by Dr. Cabin in his pre-filed testimony. Like Dr. Howes, Dr. Cabin emphasizes Applicants' intent to strictly adhere to the SCAI facility and personnel requirements incorporated into the 2011 ACCF/AHA/SCAI Guideline. *See* Pre-filed Testimony of Dr. Cabin, p. 636. However, like his colleague, Dr. Cabin

also fails to address the fact that a proposed program should only be approved if it will fill a void in the healthcare needs of the community, regardless of whether it can meet the SCAI requirements or not, as I discuss above. Furthermore, Dr. Cabin neglects to mention the risks inherent in angioplasty procedures which are discussed right in the 2011 ACCF/AHA/SCAI Guideline – for example, procedural and periprocedural MI, PCI-related stroke and vascular complications such as access site hematoma and coronary perforation, as well as the need for coronary artery bypass graft (CABG) surgery in some cases. *See* 2011 ACCF/AHA/SCAI Guideline, p. 159. The previous 2005 ACC/AHA/SCAI Guideline Update stated directly that a "small but real fraction of patients undergoing elective PCI will experience a life-threatening complication that could be managed with the immediate onsite availability of cardiac surgical support but cannot be managed effectively by urgent transfer." 2005 ACC/AHA/SCAI Guideline Update, p. 78 (page reference is to Exhibit 2 of my Pre-filed Testimony). These risks have not been eliminated, and they cannot be ignored.

BEFORE THE OFFICE OF HEALTH CARE ACCESS DIVISION OF THE DEPARTMENT OF PUBLIC HEALTH	:	Docket No. 12-31748
PROPOSAL TO ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM WITHOUT ONSITE SURGICAL BACKUP AT GREENWICH HOSPITAL	:	July 17, 2012

Rebuttal of Sharon Kiely, M.D. to Testimony of
Marna Borgstrom, Christopher Howes, M.D. and Frank Corvino

I am submitting this testimony in rebuttal to various statements made in the July 12, 2012 pre-filed testimonies of Marna Borgstrom, Frank Corvino and Dr. Christopher Howes.

Rebuttal of Ms. Borgstrom's Testimony

With regard to Ms. Borgstrom's testimony, beginning at page 629 she discusses at considerable length the credentials of the Yale New Haven Heart and Vascular Center (YNHHVC) and its personnel, and its ranking for cardiac services in U.S. News and World Report. We agree that YNHHVC, YNHH and their cardiology specialists have the requisite capabilities and experience to assist its affiliate, Greenwich Hospital, with the development of the proposed satellite elective angioplasty program.

However, just because something can be done does not mean that it should be done. YNHH and YNHHVC will not bring a superior level of expertise or experience to the service area. The region's two existing elective angioplasty providers, The Stamford Hospital (TSH) and White Plains Hospital (White Plains) are affiliated with the New York Presbyterian Hospital of Columbia and Cornell (NY Presbyterian), a world-renowned academic medical center which was ranked substantially higher than YNHH in the most recent U.S. News and World Report rankings of cardiac hospitals (NY Presbyterian was #6 and YNHH was #26).

Ms. Borgstrom's testimony also suggests that the need for another elective angioplasty program in Southwestern Connecticut is established, in large part, by the "telephone survey" conducted by Ms. Hamson. This is indeed a flawed methodology as there is a conspicuous lack of information regarding the nature of this purported survey, the underlying assumptions of respondents or statistical controls. This leaves little doubt of its self-serving nature and the level of credibility it should be accorded.

Finally, Ms. Borgstrom, through her rebuttal testimony, references the discussions between TSH and YNHHVC/Greenwich Hospital regarding a possible collaboration. It is true that there were discussions and that a collaboration ultimately did not come to fruition. However, Ms. Borgstrom misstates the series of events leading up to the termination of discussions and the reason why TSH did not continue to pursue the collaboration.

It should be noted that TSH regularly assesses opportunities to collaborate with other providers to improve the delivery and coordination of care in its service area. In fact, there is a Board-designated task force that meets regularly to assess the market and identify potential opportunities. Greenwich Hospital asked TSH to support its CON application for an elective angioplasty program. TSH responded that this could only be considered within the context of a regional collaboration.

Subsequently, TSH, Greenwich Hospital, and Yale New Haven Health began exploring potential collaboration opportunities to better coordinate heart and vascular care in the region. After a series of discussions, an outline of principles and draft letter of intent were prepared by YNNH for review by TSH in order to conceptualize what a collaboration might look like. As set forth in the letter of intent, the parties were to keep any information furnished to one another

confidential and not make any public statement or comment regarding their discussions without mutual consent.

Contrary to Ms. Borgstrom's assertion, David Smith never told the parties that the terms of the draft letter of intent were acceptable to TSH. Mr. Smith did tell the parties that the draft addressed TSH's initial concerns regarding the collaboration, but he was clear that TSH felt an obligation to continue to explore opportunities with its current partner, New York Presbyterian Health Care System, to improve delivery and coordination of care. He also informed Yale's representative that time did not permit TSH to evaluate the preliminary conceptual framework as well as hold the necessary discussions with NY Presbyterian to see if its existing partnership could be enhanced prior to Greenwich/Yale proceeding with the hearings on this CON Application. TSH asked the Applicants to withdraw this CON Application. The Applicants declined and TSH informed them that it would oppose the proposed competing program.

Rebuttal of Dr. Howes' Testimony

Dr. Howes concludes his testimony by stating that "[w]*e have reached the point in time where the proposal can and should be approved. Earlier barriers have been removed and patients and physicians seek these services at Greenwich Hospital.*" Notwithstanding this proclamation, Dr. Howes has clearly chosen to ignore the largest and most important barrier, which existed in 2009 when Greenwich Hospital was most recently denied an elective angioplasty program, and which continues today – the lack in growth in PCI volume.

YNHH and Greenwich Hospital do not refute but apparently refuse to acknowledge the widely-accepted data showing that PCI volume has been flat to declining in the service area. Rather, the Applicants have based their projected volumes on a series of tenuous assumptions

and misleading information. Some of the more puzzling aspects of Dr. Howes' testimony include:

1. Greenwich Hospital and YNHH's projecting higher volumes now than were projected in 2009 despite the fact that the White Plains angioplasty program has been added to the service area since that time.

2. Greenwich Hospital and YNHH's projecting higher volumes now than were projected in 2009 despite the fact that the number of elective angioplasty cases that Greenwich Hospital has transferred or referred to another facility has dropped each year since that time.

3. Greenwich Hospital and YNHH's claim that TSH and Greenwich Hospital serve different patient populations even though the eight Connecticut towns identified in the Greenwich Hospital Service Area are the same as those identified by Stamford Hospital in its approved 2006 CON to establish a full-service cardiac program.

4. Greenwich Hospital and YNHH are basing their volume projections, in part, on a representation from two interventional cardiologists (Dr. Monsen of NY Presbyterian and Dr. Newman of WestMed Medical Group) who have indicated that, combined, they could bring between 80-105 angioplasty cases to Greenwich Hospital each year (see letters attached to Dr. Howes' testimony).

In support of item 3 above, Dr. Howes refers to Table 2 on page 670 of his testimony as evidence that of the top 20 TSH attending physicians, only one had any admission volume at Greenwich Hospital. Of course, what Dr. Howes fails to mention is that 10 of the physicians listed on Table 2 are Hospitalists who are employed by TSH, do not have offices in the community, and whose job it is to act as attending physicians for unassigned patients whose community physicians do not want to follow the patient into the hospital or who do not have admitting privileges at TSH. Accordingly, these physicians have no opportunity to refer patients outside of TSH. In addition, another physician, Dr. Coady, is a cardiac surgeon. Since Greenwich does not have a cardiac surgery program, he would have no reason to admit patients there.

Item #4 is also emblematic of the serious flaws in the applicant's volume projection methodology. First, it is must be noted that WestMed (then known as The Westchester Medical Group) provided a similar letter in support of Greenwich Hospital's 2009 CON application (see letter attached hereto as Exhibit A). At that time, WestMed represented that it would shift approximately 100 cases to Greenwich Hospital, whereas in 2012 that number fell to 50-75 (at best, a 25% reduction). This would further support the decline in PCI volume from 2009 to present.

Including the volume promised by these physicians in the projections is also misleading, since it merely reflects shifting cases from an existing provider. It does nothing to substantiate the need for the additional PCI program. As stated by Dr. Newman in his letter in support of this application, "*I estimate that we would complete 50-75 angioplasties at Greenwich Hospital that **we currently treat at a hospital outside of Connecticut.***" (emphasis added).

Relying on such promises is tantamount to building a house of cards. These physicians are under no contractual obligation to transfer cases to Greenwich Hospital, and Greenwich Hospital would have no recourse should these physicians decide to direct their patients elsewhere or should there be a change in the structure or ownership of the physician practice. Evidence of changing allegiances of referring doctors is also evidenced by Dr. Monsen's letter of support. Three years ago, Dr. Monsen was affiliated with Westchester Medical Center; today he is a member of NY Presbyterian Hospital. Given the current economic climate and the significant increase in the merger and acquisition of physician practice groups, any promises of future referrals are illusory at best, and should not be given serious consideration when determining a Certificate of Need application.

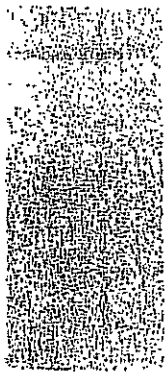
Rebuttal of Frank Corvino's Testimony

Mr. Corvino states on page 682 of his testimony that "*I want to emphasize that this proposal is all about patient care and patient access.*" As evidenced on page 15 of the CON Application, this statement is inaccurate. In fact, Greenwich and YNHH put forth three reasons to support its contention of public need. Admittedly, two of those reasons were: (1) to improve local access to elective angioplasty care at Greenwich Hospital; and (2) to improve the quality of care of elective angioplasty services provided to Greenwich Hospital service area patients. However, it is the third reason that is the most telling of the true nature of the CON Application and why Greenwich Hospital is seeking an elective angioplasty program. Simply put, it's about money.

Therefore, I respectfully submit that, based on the 2011 ACCF/AHA/SCAI Guideline, which flatly states that financial considerations are inappropriate in determining public need in this context, OHCA deny this CON Application.

EXHIBIT A

000120



The Westchester Medical Group

SIMEON A. SCHWARTZ, M.D.
PRESIDENT

November 14, 2008

Commissioner Cristine Vogel
Office of Health Care Access
MS # 13 HCA
410 Capital Avenue
Hartford, CT 06134-0308

Dear Commissioner:

On behalf of the Westchester Medical Group, I am writing this letter to support the application for Elective PCI at Greenwich Hospital. Over the past several years a growing number of physicians from our practice are on staff at Greenwich Hospital and many of our patients seek their hospital based services there.

An elective PCI service at Greenwich Hospital will provide our cardiac patients with choice and local access to high quality interventional cardiology services. The ability to provide elective angioplasty will also improve continuity of care for patients at Greenwich Hospital.

The Westchester Medical Group projects that on an annual basis there would be 200 cardiac catheterization cases and 100 elective angioplasty cases performed on our patients at Greenwich Hospital.

We urge you to approve this proposal.

Thank you.

Sincerely,

MD

Simeon Schwartz, MD
President

THE WESTCHESTER MEDICAL GROUP, P.C. • 210 WESTCHESTER AVENUE, WHITE PLAINS, NEW YORK 10604
TEL. (914) 682-6404 • FAX (914) 457-1440 • sschwartz@westchestermed.com

WESTCHESTER MEDICAL CENTER NEW YORK MEDICAL COLLEGE
DEPARTMENT OF MEDICINE
DIVISION OF CARDIOLOGY

November 6, 2008

Commissioner Cristine Vogel
Office of Health Care Access
MS # 13 HCA
410 Capital Avenue
Hartford, CT 06134-0308

Dear Commissioner:

I am writing this letter to express my support for the proposed elective angioplasty program at Greenwich Hospital. An elective PCI service at Greenwich Hospital would provide patients in the region with choice and greater access to interventional cardiology services. In addition, this program will improve continuity of care to cardiac patients at Greenwich Hospital.

Our practice, which is located predominantly in the immediately adjacent geographic region of Westchester County is made up of 40 physicians in a single specialty cardiovascular practice. It is one of the largest single specialty groups in the region, if not the East Coast. We presently perform approximately 1500 coronary interventions per year. Many of our patients live very close to Greenwich Hospital. I am sure that a number of them would prefer Greenwich Hospital over the Westchester County Medical Center in Valhalla, New York for their coronary interventions if an elective program were in existence. Presently, the Westchester Medical Center is the only local facility that can perform both emergency and elective PCI. Adding an elective PCI program to Greenwich Hospital would improve access and choice for a significant group of our patients.

We urge you to approve this proposal.

Yours very truly,

Craig Hjemdahl-Monsen, M.D.
Director, Interventional Cardiology
Associate Chief, Division of Cardiology
Westchester Medical Center
CHM:db

Westchester Medical Center
Cardiology Division, Valhalla, NY 10595 (914) 493-8811
19 Bradhurst Avenue, Hawthorne, NY 10532 (914) 593-7800
FAX (914) 593-7857

BEFORE THE OFFICE OF HEALTH CARE ACCESS DIVISION OF THE DEPARTMENT OF PUBLIC HEALTH	:	Docket No. 12-31748-CON
IN RE APPLICATION OF YALE-NEW HAVEN HOSPITAL AND GREENWICH HOSPITAL TO ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM AT GREENWICH HOSPITAL	:	July 17, 2012

RESPONSE TO GREENWICH AND YALE-NEW HAVEN HOSPITALS' OBJECTION TO INTERVENOR'S REBUTTAL TESTIMONY AND MOTION TO STRIKE TESTIMONY

Rebuttal Testimony

The Stamford Hospital ("TSH") hereby responds to Greenwich Hospital's ("GH") and Yale-New Haven Hospital's ("YNHH," and, together with GH, the "Applicants") request that the Office of Health Care Access ("OHCA") preclude TSH's submission of rebuttal testimony. Applicants cite absolutely no legal or equitable rationale for precluding such submission. OHCA's Ruling issued on July 16, 2012 regarding TSH's petition to be granted intervenor status does not expressly address Applicants' request to preclude TSH from submitting rebuttal testimony, but such ruling grants TSH intervenor status, including the right "to introduce evidence." Since there is no limitation on such right in OHCA's Ruling – and no possible reason to grant Applicants' unusual request – TSH has submitted herewith written rebuttal testimony. For the record, however, TSH wishes to make the following points.

By granting TSH intervenor status, OHCA has determined that TSH can assist OHCA in resolving the issues raised by Applicants' application. *See* Regs. Conn. State Agencies § 19a-9-27. To place unnecessary and unjustified limits on the submission of evidence by TSH would fly in the face of OHCA's determination. As stated in TSH's Petition for Intervenor Status, its position as an existing provider of elective angioplasty in the same geographic area which would

be served by Applicants' proposed program makes it uniquely qualified to offer evidence and information that would otherwise not be available to OHCA to assist in evaluating Applicants' proposal. Both parties submitted their written testimony on June 12, 2012. Applicants have filed their rebuttal to the testimony submitted by TSH, and in the interest of justice and the public good, TSH must have the same opportunity.

This opportunity, which TSH assumed it would have in addition to full intervenor status, is even more critical now that OHCA has granted TSH only limited intervenor status, precluding TSH from conducting cross-examination of Applicants' witnesses. OHCA's decision to limit TSH's rights as an intervenor is virtually unprecedented in the context of cardiac Certificate of Need applications. To TSH's knowledge, in every such application filed in recent memory, each intervenor has been permitted to cross-examine witnesses. More importantly, when Applicants filed a nearly identical application three (3) years ago seeking permission to provide elective angioplasty, TSH was granted full intervenor status, including the right to cross-examine witnesses. *See* Docket No. 08-31210-CON.

TSH believes that OHCA's decision to deny TSH the right to cross-examine witnesses is not justified by law or precedent and does not serve the interests of OHCA or the public. In addition, as a provider of cardiac services, including elective angioplasty, in the very geographic area which is the subject of Applicants' proposal, TSH's interests are profoundly implicated here – providing yet another reason to have granted TSH full procedural rights as an intervenor. Still, OHCA has denied TSH such rights.

In their motion, Applicants attempt to justify precluding TSH from submitting additional useful information to OHCA via rebuttal testimony by arguing that "*if OHCA grants TSH full procedural rights, TSH will have an opportunity to rebut any information contained in*

Applicants' pre-hearing submissions through cross-examination of Applicants' witnesses." Applicants' Objection to The Stamford Hospital's Petition for Intervenor Status and Motion to Strike Testimony at p. 768. Since OHCA has now denied TSH the right to cross-examine witnesses, without the submission of rebuttal testimony, inaccuracies or distortions in the record which only TSH may be in a position to correct would otherwise go unaddressed.

Unlike a private lawsuit between two parties where a judge's decision will affect only those parties, here, OHCA's decision will affect not only TSH and other health care providers, but the public as well. In Certificate of Need proceedings, OHCA is charged with determining the need for the proposed new service, taking into account services already available and all other information relevant to determining such need, including, without limitation, how the proposed services will impact the financial strength of the state's health care system and whether the proposed services will result in unnecessary duplication of existing health care services. Conn. Gen. Stat. § 19a-639. To fulfill this responsibility, OHCA's decision to accept evidence from TSH, including written rebuttal testimony, is clearly necessary and appropriate.

TSH's rebuttal testimony is not voluminous and will not disrupt the orderly conduct of the proceedings. *See* Conn. Gen. Stat. § 4-177a(b). Applicants have provided no rationale for precluding the acceptance of such testimony, while the benefit of receiving it is obvious – more relevant information is available to OHCA. Moreover, since Applicants' counsel has the right to cross-examine TSH's witnesses with respect to such testimony, Applicants are not at all prejudiced by its submission.

Motion to Strike

Applicants move to strike all references to Lawrence & Memorial Hospital's ("L&M") CON application. The references to that application in TSH's testimony are included simply to

contrast certain elements that are present in the L&M situation which are clearly lacking in Applicants' proposal. On this basis, TSH believes that the inclusion of such information is appropriate.

For the reasons stated above, OHCA's decision to permit the submission of evidence, including rebuttal evidence, from TSH is justified and appropriate and OHCA should deny Applicants' motion to strike testimony relating to L&M's CON application.

Respectfully submitted,

THE STAMFORD HOSPITAL

BY _____

Carolyn R. Linsey
Stephen M. Cowherd
Jeffers Cowherd P.C.
55 Walls Drive
Fairfield, CT 06824
Tel.: 203-259-7900
Fax: 203-259-1070
clinsey@jeffers-law.com
scowherd@jeffers-law.com
Its Attorneys

CERTIFICATE OF SERVICE

This is to certify that a true and accurate copy of the foregoing was sent by electronic mail this 17th day of July 2012 to:

Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.
265 Church Street
New Haven, CT 06510
jgroves@uks.com

Jean Ahn
System Director
Yale-New Haven Hospital
Planning & Business Development
20 York Street (Howe 3)
New Haven, CT 06504
jean.ahn@ynhh.org

Carolyn R. Linsey

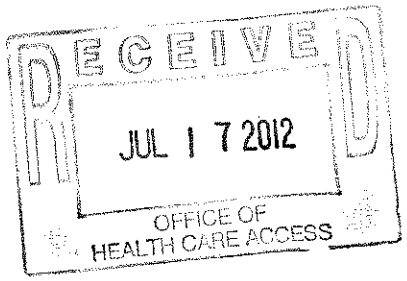
JEFFERS
COWHERD

JEFFERS COWHERD P.C.
ATTORNEYS AT LAW

55 WALLS DRIVE
FAIRFIELD, CT 06824
203-259-7900
203-259-1070 FAX
WWW.JEFFERS-LAW.COM

STEPHEN M. COWHERD
Email: scowherd@jeffers-law.com

July 17, 2012



Via Hand Delivery

Kimberly R. Martone
Director of Operations
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: Docket Number: 12-31748-CON

Dear Ms. Martone:

Enclosed please find an original and five (5) copies of the documents submitted by email earlier today with respect to the above-referenced docket.

Respectfully submitted,

Stephen M. Cowherd/am

Stephen M. Cowherd

SMC:pad
Enclosure

BEFORE THE OFFICE OF HEALTH CARE ACCESS DIVISION OF THE DEPARTMENT OF PUBLIC HEALTH	:	Docket No. 12-31748-CON
IN RE APPLICATION OF YALE-NEW HAVEN HOSPITAL AND GREENWICH HOSPITAL TO ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM AT GREENWICH HOSPITAL	:	July 17, 2012

INTERVENOR THE STAMFORD HOSPITAL'S OBJECTION TO AND MOTION TO STRIKE A PORTION OF REBUTTAL TESTIMONY OF MARNA BORGSTROM AND CHRISTOPHER HOWES, M.D.

Intervenor The Stamford Hospital ("TSH") hereby objects to and moves to strike portions of the pre-filed rebuttal testimony of Marna Borgstrom and Christopher Howes, M.D. submitted by Greenwich Hospital ("Greenwich") and Yale-New Haven Hospital ("YNHH") (collectively "Applicants") for the public hearing. The portions of the testimony sought to be stricken are identified on the pages of testimony attached as Exhibit A hereto. As set forth more fully below, Ms. Borgstrom's pre-filed rebuttal testimony (pages 698-701) includes extensive commentary regarding open heart surgery, which is totally irrelevant and immaterial to the pending Application. Additionally, Dr. Howes' pre-filed rebuttal testimony (pages 762-763) inappropriately quotes the State Health Plan, which at the present time is a draft not yet finalized or adopted, and includes an unwarranted caustic and insulting comment directed at New York Presbyterian Hospital. TSH, therefore, respectfully requests that OHCA strike the foregoing impermissible testimony.

Ms. Borgstrom's pre-filed rebuttal testimony (pages 698-701 and Attachments II, III and IV (pages 716-756)) includes extensive commentary and statistical data regarding inpatient open heart surgery volume, both state-wide and at TSH, which is irrelevant and immaterial to the pending application for approval to perform elective angioplasty without open heart surgery. Ms. Borgstrom's testimony about TSH's open heart surgery program is especially prejudicial because TSH will not have the opportunity to cross-examine this witness. This rebuttal testimony has no arguable relevance to the issues pending before OHCA and should be stricken in its entirety.

Dr. Howes' pre-filed rebuttal testimony (pages 762-63) is likewise objectionable for two reasons. First, Dr. Howes quotes a single sentence from the Draft State Health Plan referencing a change in the ACCF-AHA-SCAIPCI guidelines. The best evidence in this regard is the ACCF-AHA-SCAIPCI guidelines, and it is not appropriate for the Applicant's witness to refer to a plan which exists only in draft form which has not been finalized or adopted. Moreover, if OHCA determines that it is appropriate to consider the draft State Health Plan, then the draft Plan should be considered in its entirety, rather than one sentence taken out of context, as reflected in Dr. Howes' rebuttal testimony. In addition, Dr. Howes' rebuttal testimony includes a spurious remark directed at New York Presbyterian Hospital, which bears no relevance to the issues in this proceeding and is inconsistent with the professionalism and civility customarily demonstrated by witnesses who testify before OHCA.

Wherefore, for the foregoing reasons, Intervenor's objection to the rebuttal testimony should be sustained and the testimony stricken as set forth in Exhibit A hereto.

Respectfully submitted,

THE STAMFORD HOSPITAL

BY _____

Carolyn R. Linsey
Stephen M. Cowherd
Jeffers Cowherd P.C.
55 Walls Drive
Fairfield, CT 06824
Tel.: 203-259-7900
Fax: 203-259-1070
scowherd@jeffers-law.com
clinsey@jeffers-law.com
Its Attorneys

CERTIFICATE OF SERVICE

This is to certify that a true and accurate copy of the foregoing was sent by electronic mail this 17 day of July 2012 to:

Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.
265 Church Street
New Haven, CT 06510
jgroves@uks.com

Jean Ahn
System Director
Yale-New Haven Hospital
Planning & Business Development
20 York Street (Howe 3)
New Haven, CT 06504
jean.ahn@ynhh.org

Carolyn R. Linsey

EXHIBIT A

YNHHVC. Ms. Capozzalo will be in attendance at the hearing and can address her discussions with Stamford Hospital under oath.

~~YNHHVC and Greenwich Hospital fully intended to collaborate with Stamford Hospital in~~ the area of cardiac care and had sought to help strengthen Stamford's open heart surgery program, which is suffering from low volume. The presence of Yale faculty based in southwestern Connecticut communities along with the YNHHVC's clinical program support and quality improvement systems would have significantly improved Stamford Hospital's cardiac surgery program's credibility, which is at significant risk, evidenced by the fact that they performed only 80 open heart cases last year and are on track to perform approximately 50 this fiscal year based on 6 months volumes from CHIME (see Table below).

Connecticut Inpatient Volume for Open Heart Surgery by Hospital for FY 2010 - FY 2012 (6 Months)				
Hospital	FY 2010	FY 2011	FY 2012*	
Bridgeport	152	127	140	
Danbury	181	182	150	
Dempsey	67	71	72	
Hartford	793	801	702	
HSR	343	313	300	
St. Francis	867	781	734	
St. Mary's	118	100	114	
St. Vincent's	239	223	200	
Stamford	84	80	54	
Waterbury	109	102	104	
YNHH	869	800	820	
TOTAL	**3,792**	**3,580**	**3,390**	
Source: CHIME				
*FY 2012 annualized based on 6 months actual				

It is clear that YNHHVC acted in good faith to create a cost effective care model for cardiology services in the Stamford and Greenwich area, but it is Stamford Hospital that does not want to collaborate.

- I would also like to point out that Stamford Hospital's extremely low cardiac surgery volume does not come close to meeting professional society recommendations or OHCA's own standards as outlined in the Agreed Settlement for Stamford Hospital (DN: 04-30374-CON) (see Attachment II). Condition #8 states:

  "If TSH does not perform 125 OHS procedures within twelve months of the initiation of the OHS program, TSH shall submit monthly reports of OHS arrayed by physician to OHCA until such time as these volumes are met by TSH. **If these volumes are not met for a period of <u>two consecutive 12-month periods</u>, TSH's OHS program <u>shall be terminated</u>...**"

  We are not aware that this condition has been modified by OHCA based on a review of OHCA's website and modifications pursued by Stamford Hospital.

  According to OHCA's own data (see Attachment III) through 2010, Stamford Hospital has never come close to reaching 125 open heart surgeries in a year. In fact, it appears that its highest volume was 80 in FY 2011. As previously shown above, based on 6 months of CHIME data for 2012, they are on track to perform about 54 surgeries this year, less than half of the guidelines requirement. These low volumes have been of concern to YNHHVC physicians and we suspect have contributed to fewer referrals to their surgery program. Low surgical volume can also affect the physicians' decisions to transfer patients to Stamford for elective angioplasty, given the uncertain quality of the surgical backup available at that site. Such low surgical volumes present a significant quality concern as identified by the American College of Surgeons which published that an annual volume of 100-125 is **<u>necessary</u>** from a quality standpoint and this requirement has also been noted by OHCA in its draft Cardiac Services section of the new State Health Plan (see Attachment IV).

- Dr. Kiely states that OHCA should not approve Greenwich Hospital's proposed elective angioplasty program because elective angioplasty volumes are flat in Connecticut and the proposed service area. Stamford Hospital did not previously view flat or declining volumes as problematic when it pursued its full service cardiac program CON. At that time, their own cardiac catheterization volumes had been in decline as noted in OHCA's

Agreed Settlement's Findings of Fact #11 (previously referenced as Attachment II); statewide inpatient cardiac catheterization and angioplasty volumes had declined steadily between 2003 and 2005, as shown in Dr. Kiely's own testimony and open heart surgery volumes had also been declining between 2002 and 2005 as shown in the OHCA table and graph below.

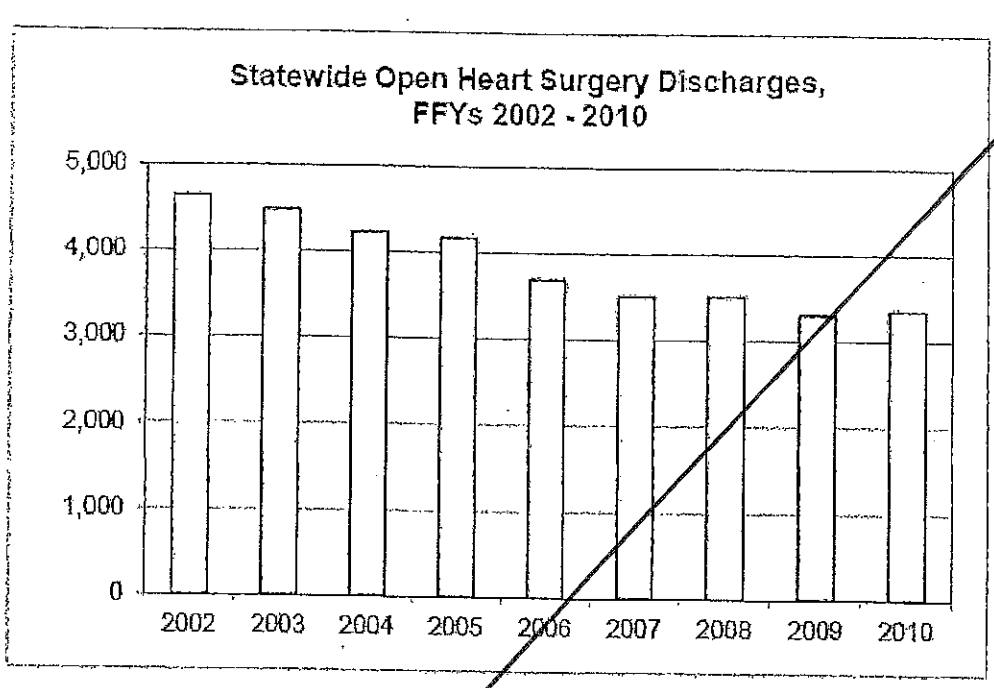
Table 3A: Open heart surgery discharges by provider, FFYs 2002-2010

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	FFY 05-10 (5-yr)% Change	FFY 08-10 (3-yr)% Change	FFY 09-10 (1-yr) % Change
Bridgeport	345	313	268	263	175	194	100	96	136	-22%	28%	42%
CT Children's								6	4	n/a	n/a	na
Danbury	0	0	0	114	177	121	162	148	174	-2%	7%	-8%
Dempsey	115	134	121	174	97	70	84	56	58	-40%	-31%	-33%
Hartford	901	844	756	726	742	685	671	652	695	-6%	4%	-3%
St. Francis	1,239	1,299	1,311	1,188	998	990	912	845	820	-18%	-10%	-7%
St. Mary's	0	0	0	19	72	100	85	114	112	56%	32%	34%
St. Raphael	761	687	617	510	353	342	321	299	318	-10%	-1%	-7%
St. Vincent's	310	286	293	291	259	232	257	219	195	-25%	-24%	-15%
Stamford	0	0	0	0	0	0	75	73	46	n/a	-39%	-3%
Waterbury	0	0	0	20	117	110	134	110	98	-16%	-27%	-18%
Yale	973	905	860	861	704	664	698	691	697	-1%	0%	-1%
Total	4,644	4,478	4,226	4,166	3,694	3,608	3,505	3,309	3,353	-9%	-4%	-8%

Source: CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database.

ICD-9-CM Procedure Codes: 35.10-35.28 and 36.10-36.19

Please note: unduplicated counts utilizing all procedure codes



All of these related and declining volumes did not seem relevant to Stamford Hospital or OHCA as a full service cardiac program was proposed and approved. Stamford Hospital expended more than $8 million dollars in capital expenses to develop their angioplasty and surgery program in a declining volume market (modified from the $5.4 million they estimated at the time of their original CON filing). They based their need on such factors as improved accessibility, continuity of care and improved quality. These are the same reasons why Greenwich Hospital seeks to offer elective angioplasty and ~~can do so without any capital expense.~~

- Dr. Kiely's testimony includes conflicting statistics and information about New York programs. First, I would like to highlight the following statement from OHCA's 2010 Declaratory Ruling, Docket Number: 09-31433-DCR, which specifically states that:

  "...OHCA only has the authority to act on behalf of the state within the parameters of its enabling statutes and its jurisdiction is limited to health care facilities located within the state. Thus, OHCA has no jurisdiction over health care facilities located in other states just as those states have no authority to regulate facilities located within Connecticut."

ATTACHMENT II

Office of Health Care Access
Certificate of Need Application

Agreed Settlement

Hospital:	The Stamford Hospital and New York Presbyterian Healthcare System, Inc.
Docket Number:	04-30374-CON
Project Title:	Establish Elective Angioplasty and Open Heart Surgery Program at The Stamford Hospital
Statutory Reference:	Sections 19a-638 & 639, Connecticut General Statutes
Filing Date:	August 15, 2005
Hearing Dates:	Public Portion: September 22, 2005 Technical Portion: October 6, 2005 and October 27, 2005
Commissioner & Presiding Officer:	Cristine A. Vogel
Agreed Settlement Date:	January 4, 2006
Default Date:	Not Applicable
OHCA Staff	Steven W. Lazarus Michael Sabados

Project Description: The Stamford Hospital ("TSH" and "Hospital") and New York Presbyterian Healthcare System, Inc. ("Applicants") propose the establishment of an elective angioplasty ("PCI") and open-heart surgery ("OHS") program, to be located at the Hospital, at a capital expenditure of $5,404,425.

Nature of Proceedings: On August 15, 2005, the Office of Health Care Access ("OHCA") received the Applicants' Certificate of Need ("CON") application seeking authorization to establish an elective angioplasty and open-heart surgery program, to be located at the Hospital, at a capital expenditure of $5,404,425. The Stamford Hospital is organized under the laws of Connecticut, and New York Presbyterian Healthcare System, Inc. is a corporation organized under the laws of the State of New York. The Hospital is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

Public hearings regarding the CON Application were held on September 22, 2005, October 6, 2005 and October 27, 2005. The Hospital was notified of the date, time, and place of the hearings and notices to the public were published prior to the hearings in *The Advocate* (Stamford) by OHCA. The hearings were conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the Connecticut General Statutes) and Sections 19a-638 and 19a-639, C.G.S.

Yale-New Haven Hospital, Bridgeport Hospital, and Greenwich Hospital collectively known as Yale-New Haven Heart Health Institute were granted Intervenor status with rights to cross-examine. St. Vincent's Medical Center was granted Intervenor status with the rights to cross-examine.

The Presiding Officer heard testimony from the general public, legislators, local officials and witnesses for the Hospital and Intervenors. In rendering this decision, the presiding officer has considered the entire record of the proceeding. OHCA's authority to review, approve, modify or deny this proposal is established by Sections 19a-638 and 19a-639, C.G.S. The provisions of these sections, as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were considered by OHCA in its review.

Findings of Fact

Clear Public Need
Impact on The Hospital's Current Utilization Statistics
Proposal's Contribution to Accessibility and Quality of Health Care Delivery in the Region

1. The Stamford Hospital ("TSH" and "Hospital") is a not-for-profit, 305-bed acute care hospital located in Stamford, Connecticut. TSH, as an affiliate member of the New York Presbyterian Healthcare System ("System"). TSH provides a comprehensive array of services including: Medicine, Surgery, Obstetrics/Gynecology, Psychiatry as well as Medical and Surgical critical care units. *(Completeness Responses, Proposed Resolution, August 15, 2005, Exhibit 3 and Certificate of Need Application, August 15, 2005, page 1-3)*

2. The New York Presbyterian Healthcare System, Inc ("NYPHS") coordinates a system of hospitals and other healthcare institutions throughout the tri-state area, including The Stamford Hospital ("TSH") and New-York Presbyterian Hospital ("NYPH"). NYPH operates New York-Presbyterian Hospital/Columbia University Medical Center ("NYP/C") in affiliation with Columbia University College of Physicians and Surgeons ("CU"). *(Certificate of Need Application, August 15, 2005, pages 2-3)*

3. TSH and NYPHS ("Applicants") propose the establishment of an elective percutaneous coronary angioplasty[a] ("PCI") and open-heart surgery[b] ("OHS") program, to be located at the Hospital. *(Certificate of Need Application, August 15, 2005, page 2)*

4. TSH's proposal is for a full-service cardiovascular services program in the lower Fairfield County. TSH is located in the region's largest population center. *(Prefiled Testimony of Brian Grissler, September 19, 2005,)*

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[a] Elective (Scheduled) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure performed in a catheterization laboratory whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a previously diagnosed blockage in the heart. An expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow.

[b] Open-heart surgery is a surgical intervention performed on the opened heart while the bloodstream is diverted through a heart-lung machine. Cardiac Surgery includes Coronary Artery Bypass Graft (CABG), Valvuloplasty, and Valve Replacement. CABG is where a vein from the chest or leg, or a prosthesis, is grafted onto either side of a blockage in the coronary artery. This reroutes blood flow around the blockage to the heart muscle. Valvuloplasty is where a balloon tipped catheter is inserted into plaque-blocked heart valves to widen and separate them through repeated balloon inflation. A Valve Replacement is a replacement of plaque-blocked heart valves with prosthetic or tissue graft.

5. On August 25, 2004, TSH received CON authorization from OHCA to perform primary[c] PCI services. *(Certificate of Need Application, August 15, 2005, page 2)*

6. The proposed program will augment existing cardiovascular services at the Hospital. The Hospital currently offers:

Primary Angioplasty	Electrocardiogram
Interventional electrophysiology (ablations)	Electrophysiology
Diagnostic cardiac catheterization	Holter monitoring
Coronary care unit	Intra-aortic balloon pump
Telemetry inpatient care	Nuclear stress testing
Cardiac imaging	Pulmonary function testing
Cardiac rehabilitation	Stress testing
Cardiac ultrasound	Tilt table testing
Cardiopulmonary testing	Vascular and thoracic surgical services

(Certificate of Need Application, August 15, 2005, pages 8-9)

7. TSH's cardiology primary and secondary service areas consist of the following Connecticut towns:

Table 1: Stamford Hospital's Proposed Service Area for this Proposal for FYs 2002 – 2005 (1st Two Quarters)

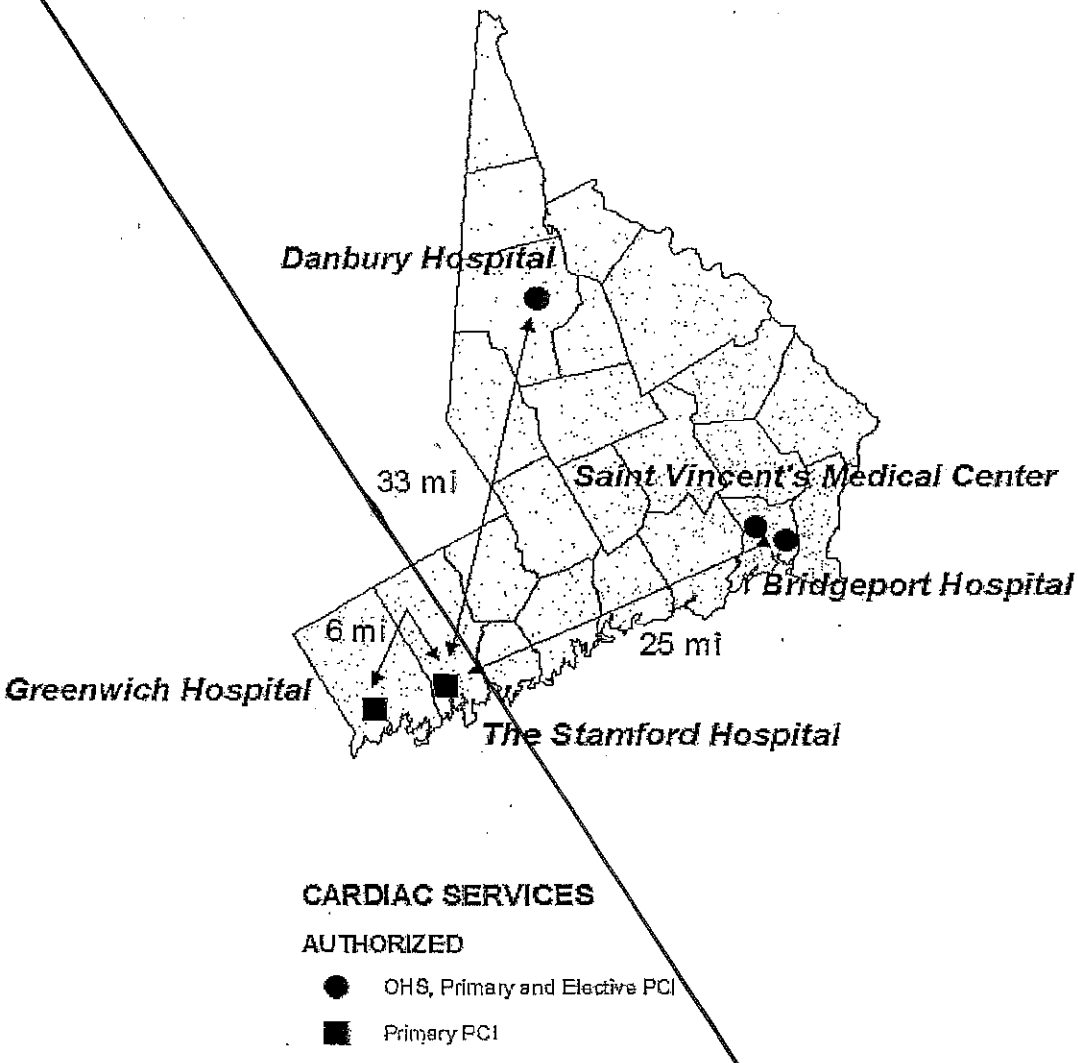
Towns	Primary	Secondary	Total Service Area
	Darien	Greenwich	Darien
	Stamford	New Canaan	Greenwich
		Norwalk	New Canaan
		Weston	Norwalk
		Westport	Stamford
		Wilton	Weston
			Westport
			Wilton
TSH's Share of Service Area's Inpatient Cardiac Catheterizations	57.4%	4.2%	26.1%
Service Area's share of TSH's Inpatient Cardiac Catheterizations	84.6%	8.7%	93.3%

(Source: Cardiac catheterization volume from *OHCA's Acute Care Hospital Inpatient Discharge Database. Service Area from Certificate of Need Application August 15, 2005, page 22)*

[c] Primary (Emergent) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure performed in a catheterization laboratory whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a previously diagnosed blockage in the heart. An expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow. Non-ST Segment elevation MI (NSTEMI or high-risk) patients consist of 80% of all MIs and are considered for angioplasty on an elective basis within 72 hours. Performance of elective angioplasty without cardiac surgery back up is not recommended by the American College of Cardiology or the American Heart Association.

8. Providers of interventional cardiac services in the Hospital's total service area ("TSA") are as follows

Map 1: Area Providers of Interventional Cardiac Services



Danbury Hospital began performing open heart surgery in January 2005.
Greenwich Hospital began performing Primary PCI in February 2005.
Stamford Hospital began performing Primary PCI in August 2005.

(Connecticut Acute Care Hospital Inpatient Discharge Database and Travel Distances from Yahoo Maps)

9. The Applicants based the need for the proposed Elective PCI and OHS program on the following:
   - Improved accessibility for patients;
   - Improved continuity of care;
   - Historical/Existing cardiac volume;
   - Adopting a standard of care that exists in the other large urban area; and
   - Improved quality of cardiac services.

   (Certificate of Need Application, August 15, 2005, pages 2-55)

10. TSH stated that the establishment of a full-service cardiac program in Stamford will provide timely access and local availability of these services in keeping with trends that have been already established nationally.
    (Prefiled Testimony of Kathleen Silard, Senior Vice President for Operations at TSH, September 19, 2005)

11. TSH's cardiac catheterization volume for FYs 2000 through 2005 are as follows:

Table 2: TSH's Historical Cardiac Catheterization Volume, FYs 2002 – 2005 1st Two Quarters

CT Service Area	2002	2003	2004	2005
Inpatient	354	352	296	147
Outpatient	321	283	332	-
Total	**675**	**635**	**628**	**147**

(Inpatient catheterization figures from OHCA's Acute Care Hospital Inpatient Discharge Database and outpatient volume from August 15, 2005, Responses to OHCA Completeness Letter, pages 1-2)

12. The following is a table of the average annual historical and projected Total PCI volumes (Primary & Elective) in TSH's service area:

Table 3: Average Annual Historical and Projected Total PCI Volumes in TSH's Service Area, FYs 2002 – 2005

	FYs 2002–2005 1st Two Quarters		Year One		Year Two		Year Three	
TSH Service Area	**Average PCIs**	**Adult Use Rate**	**Market Share (%)**	**Projected PCIs**	**Market Share (%)**	**Projected PCIs**	**Market Share (%)**	**Projected PCIs**
Primary	277	2.55	78%	216	83.5%	231	83.4%	231
Secondary	418	2.48	6.8%	28	11.0%	46	20.3%	85
Total Service Area	695	2.51	36.3%	244	40.6%	276	45.7%	316
Connecticut	**8,024**	**2.98**	-	-	-	-	-	-

Note: "Adult" refers to those 15 years and older. Adult use rate per 1,000 population.
Projected PCI volumes were calculated by applying the applicant's projected capture rate to the current PCI volume in the service area. For example, in Year One in the primary service area: 277 (average volume) * .78 (market share) = 216 PCIs.
(OHCA Acute Care Hospital Inpatient Discharge Database; MA, NY, and RI Hospital Discharge Databases; Census 2000 for population figures, and August 15, 2005 CON Application, *pages 45 & 23)*

13. The following table is the annual average historical and projected OHS for TSH in the proposed service area for FYs 2002-2005:

Table 4: Historical and Projected, Average Annual OHS Volumes in TSH's Service Area, FYs 2002–2005

	FYs 2000 – 2005 1st Two Quarters		Year One		Year Two		Year Three	
TSH Service Area	**Average OHS**	**Adult Use Rate**	**Market Share (%)**	**Projected OHS**	**Market Share (%)**	**Projected OHS**	**Market Share (%)**	**Projected OHS**
Primary	112	1.03	78.1%	88	83.5%	94	83.5%	94
Secondary	213	1.27	6.7%	14	10.9%	23	20.3%	43
Total Service Area	325	1.17	32.9%	102	38.8%	117	45.7%	137
Connecticut	**4,640**	**1.72**	-	-	-	-	-	-

Note: FY 2005 is First two quarters only.
"Adult" refers to those 15 years and older. Adult use rate per 1,000 population
Projected OHS volumes were calculated by applying the Applicant's projected capture rate to the current PCI volume in the service area. For example, in Year One in the primary service area: 112 (average volume) * .781 (market share) = 88 open-heart surgeries.
(OHCA Acute Care Hospital Inpatient Discharge Database; MA, NY, and RI Hospital Discharge Databases; Census 2000 for population figures; and August 15, 2005, CON Application, pages 46&23).

14. TSH projects the following number of elective PCIs procedures and OHS for its service area.

Table 5: Projected Cardiac Volume for TSH's Service Area

Service	FY 2007	FY 2008	FY 2009
Angioplasties (Elective only)	193	324	417
Open-heart surgeries	86	150	197

Note: TSH based the projected volumes on historical utilization and population data. The use-rates utilized are based on Claritas data. OHCA can not verify any of the above claimed data. *(Responses to the Interrogatories, September 28, 2005, Updated Financial Attachment and CON Application)*

15. The 2001 American College of Cardiology ("ACC") and the American Heart Association ("AHA") Guidelines for Percutaneous Coronary Intervention ("PCI") recommend that PCI be performed by higher volume operators (>75 cases/year) with advanced technical skills (e.g. subspecialty certification) at institutions with fully equipped interventional laboratories and experienced support staff. This setting will most often be in a high-volume center (>400 cases/year) associated with an on-site cardiovascular surgical program. Therefore, PCI is best done by high-volume operators in high-volume institutions. *(JACC, 2001, Vol. 37, No.8, page 2239)*

16. The ACC/AHA Guidelines for CABG Surgery (1999) state the following:
    - Studies suggest that survival after CABG is negatively affected when carried out in institutions that perform fewer than a threshold number of cases annually. Similar conclusions have been drawn regarding individual surgeon volumes.
    - The ACC/AHA are supportive of a posture of close monitoring of institutions or individuals that perform <100 cases annually.

17. TSH states that it will utilize the existing guidelines published by the ACC and AHA as a basis for the development of standards for the proposed services, as specified in **Attachment I.** *(Certificate of Need Application, August 15, 2005, page 11)*

18. The Guidelines for Standards in Cardiac Surgery by the Advisory Council for Cardiothoracic Surgery ("ACCS") and the American College of Surgeons ("ACS") (1996) state the following:
    - An annual volume of at least 100 to 125 open-heart procedures per hospital is necessary from a quality standpoint and there is a greater variation in adjusted mortality rates for teams doing lower volumes of procedures as compared with those doing a high volume.
    - At least 200 procedures per year as previously recommended in the 1975 report of the Inter-Society Commission on Heart Disease Resources are necessary in order for a program to function efficiently.
    - A team approach with a minimum of two qualified cardiac surgeons is recommended to provide adequate and continuous perioperative care as well as assistance in the operating room.

19. Dr. Steven F. Horowitz testified to the following at the public hearing:
    - TSH can sustain a full-service cardiac program due to the increase in the size of the minority population.
    - Numerous studies have confirmed that the cardiovascular risk profile for both Hispanics and African Americans has been worsening in recent years as obesity and diabetes continue to rise exponentially within these populations.
    (Prefiled Testimony of Steven F. Horowitz, M.D. Chief of Cardiology at TSH, September 19, 2005)

20. Kathleen Silard testified to the following at the public hearing:
    - TSH has examined the significant disparity in utilization rates for PCI and OHS that exists for African Americans in TSH service area as well as other regions of the state when compared to the Caucasian population. TSH has seen how some of the major precursors of heart disease, such as diabetes and obesity, can disproportionately effect minority populations as well as the economically disadvantaged.
    - One of the primary goals of TSH's proposed program will be to address and hopefully eradicate some of those disparities by improving access to PCI and OHS to these high-risk groups.
    (Prefiled Testimony of Kathleen Silard, Senior Vice President for Operations at TSH, September 19, 2005)

21. The demographic characteristics by Race for TSH's TSA are as follows:

Table 6: TSH Demographics by Race

Service Area	Caucasian	African American	Native American	Asian	Other	Total
Primary	73.6%	13.2%	0.2%	4.6%	8.4%	100%
Secondary	85.7%	6.6%	0.1%	3.5%	4.1%	100%
Total Service Area	81.0%	9.2%	0.2%	3.9%	5.7	100%
Connecticut	81.6%	9.1%	0.3%	2.4%	6.6%	100%

Source: Census 2000.

22. The demographic characteristics by Hispanic ethnicity for the proposed TSA:

Table 7: Hispanic Ethnicity of TSH Service Areas

Service Area	Hispanic or Latino	Non-Hispanic	Total
Primary	14.7%	85.3%	**100%**
Secondary	8.4%	91.6%	**100%**
Total Service Area	10.8%	89.2%	**100%**
Connecticut	**9.4%**	**90.6%**	**100%**

Source: Census 2000.

23. The AMI discharges for the TSH TSA are as follows:

Table 8: Share of AMI by Race and Hispanic Ethnicity, FYs 2002 – 2005 (First 2 Quarters)

Service Area	Caucasian	African American	Hispanic	Asian	Native American	Other	Total
Primary	84.7%	7.0%	4.2%	0.1%	0.0%	4.0%	**100%**
Secondary	85.1%	7.1%	3.4%	1.0%	0.1%	3.3%	**100%**
Total Service Area	84.9%	7.0%	3.7%	0.6%	0.1%	3.6%	**100%**
Connecticut	**87.1%**	**4.7%**	**4.0%**	**0.3%**	**0.1%**	**3.8%**	**100%**

(Discharges from OHCA Acute Care Hospital Inpatient Discharge Database and MA, NY, and RI Hospital Discharge Databases. "White," "Black," "Asian," "Native American," and "Other" are non-Hispanic categories.)

24. NYPH has one of the largest cardiac surgery and cardiac catheterization[d] programs in New York State with its physicians performing over 3,000 PCIs and close to 2,000 OHS in calendar year 2004. *(Prefiled Testimony of Arthur A. Klein, M.D., September 19, 2005)*

[d] Diagnostic Cardiac Catheterization is a diagnostic procedure in which a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to the heart to measure electrical activity, blood pressure, and locate blockages.

25. Dr. Steven Horowitz, testified on behalf of TSH to the following:
    - Diabetes is a leading cause of hospitalization among Connecticut's African American and Hispanic populations which are 3.8 and 2.2 times more likely to be hospitalized directly due to the disease as compared to the Caucasian Connecticut residents.
    - The percent difference for the African American utilization rates in the TSH's TSA versus those statewide is nearly 26% and 62% for PCI and cardiac surgery respectively. The same numbers skyrocket to 41% and 95% when the focus is placed solely on the City of Stamford.
    - TSH can target the African American and Hispanic population and relieve some of these barriers to access through the comprehensive preventive and medical outreach program.

    (Prefiled Testimony of Steven F. Horowitz, M.D., Chief of Cardiology Department at TSH, September 19, 2005)

26. Dr. Arthur Klein testified to the following at the public hearing:
    - NYPH and NYPHS have developed a number of strong and effective partnerships with affiliated hospitals to elevate the scope of and quality of cardiac care in the tri-state region.
    - NYPHS assists in the operation of nine (9) diagnostic cardiac catheterization programs through out the tri-state area, four elective angioplasty programs and one primary angioplasty program.
    - In this proposal, the cardiac surgery professional services will be provided exclusively by full-time faculty of the Division of Cardiothoracic Surgery, Department of Surgery of Columbia College of Physicians and Surgeons.
    - Oversight of elective angioplasty shall be through a joint committee co-chaired by Drs. Moses and Stone, senior faculty from Columbia University's Division of Cardiology and Stamford Hospital's cardiology leadership.

    (Prefiled Testimony of Arthur A. Klein, M.D., September 19, 2005)

27. Dr. Eric A. Rose testified at the public hearing that Columbia University Department of Surgery's professional expertise in cardiothoracic research, its strategic network of partnerships and its vast clinical experience will help support TSH in their cardiac health services. *(Prefiled Testimony of Eric A. Rose, M.D., Chairman for the Dept. of Surgery at NYP/C, September 19, 2005)*

28. TSH submitted a signed Draft Agreement with NYPHS. NYPHS' role is defined as follows:
    - Arrange consultative assistance to the Hospital in the following areas:
        - Preparation of the CON Application;
        - Clinical training of nursing and technical staff;
        - Development of the Hospital's standards of care, risk stratification criteria and operational policies;
        - Development of clinical guidelines and protocols;
        - Collection and analysis of quality data for clinical outcomes and performance monitoring;
        - Recruiting procedures; and

- Adoption by the Hospital of policies, procedures and protocols, including developing practice guidelines and requirements related to the proposed program.

- Recommend CPC standards and/or the standards of NYPHS-affiliated Connecticut institutions for physician, nursing and technical staff protocols to foster a high-quality credentialing program; and
- Advise the Hospital with respect to quality assurance and utilization management functions related to the proposed program.

(Completeness Responses, August 15, 2005, Draft Agreement between the Applicants, Exhibit 4, page 4)

29. TSH proposes to provide elective PCI utilizing five (5) interventional cardiologists, who are currently providing primary PCI services at TSH. *(Certificate of Need Application, August 15, 2005, page 11)*.

30. The PCI volumes for the proposed interventionalists for FYs 2002-2005 1st two quarters are as follows:

Table 9: Volume of Proposed Program Interventionalists (FYs 2002 – FY 2005 1st Two Quarters)

Physician	Hospital Affiliation	Office/Home	Average Annual PTCA Volume
Alcan[1]	St. Vincent's & TSH	Norwalk	347
Jumper[2]	St. Vincent's & TSH	Valhalla, NY	119[3]
Charney	NY Presbyterian, Greenwich, & TSH	New Rochelle	X[4]
Messinger	NY Presbyterian, Greenwich, & TSH	New Rochelle	X[4]
Stone	NY Presbyterian, TSH (pending)	Greenwich	-

[1]Member of Cardiology Associates of Fairfield County
[2]In training
[3]Dr. Jumper performed 57 in FY 2004 and 122 in the first two quarters of FY 2005.
[4] TSH reported volume (FYs 2003 & 2004 – NYP physicians not specifically identified)
Physician C: 156 & 145 and Physician D: 108 & 126
(OHCA Acute Care Hospital Inpatient Discharge Database and CON Application, August 15, 2005, page 11&58 and Completeness Responses, August 15, 2005, page 8)

31. TSH stated that three additional cardiac interventionalists, Drs. Portnay, Lorenz and Corvaja will be added to the proposed program to perform PCIs at TSH. *(CON Application, August 15, 2005, pages 11&58 and Completeness Responses, August 15, 2005, page 8)*

32. TSH proposes to staff the proposed OHS program with two (2) board-certified cardiac surgeons, who will practice full-time at TSH and be credentialed at both TSH and at NYP/C. These two surgeons will be recruited through the formation of a three (3) person committee which will include as its members, Dr. Craig Smith, Dr. Mehmet Oz and Dr. Eric Rose, Chair of the Surgery Department at NYP/C. *(Certificate of Need Application, August 15, 2005, page 11)*

38. The average annual PCI and OHS volumes in TSH's TSA by hospital provider for FYs 2000-2005 (1st two quarters) are as follows:

Table 10: Average Annual PCI and Open-Heart Surgery Volumes by Provider in TSH's TSA by Provider, (FYs 2002 – 2005 1st Two Quarters)

	PCIs			Open-Heart Surgeries		
Hospital	Procedures	Market Share	Area Volume as Share of Total Provider Volume (%)	Procedures	Market Share	Area Volume as Share of Total Provider Volume (%)
Bridgeport	154	22.2%	12.3%	75	23.1%	24.3%
Danbury	0	0.0%	-	0	0.0%	-
Greenwich	1*	0.1%	100%	-	0.0%	-
Hartford	0	0.0%	-	0	0.0%	-
John Dempsey	1	0.1%	0.2%	0	0.0%	-
Saint Francis	0	0.0%	-	1	.3%	.1%
Saint Raphael's	4	0.5%	0.4%	3	.9%	.4%
Saint Vincent's	392	56.4%	34.9%	119	36.6%	39.7%
Yale	78	11.2%	4.8%	57	17.5%	6.4%
Out of State	65	9.3%	-	70	21.6%	-
Totals	**695**	**100%**	**-**	**325**	**100%**	**-**

*Greenwich Hospital began providing primary PCI in February 2005.
(OHCA Acute Care Hospital Inpatient Discharge Database and MA, NY, and RI Hospital Discharge Databases)

34. Danbury Hospital, along with Waterbury Hospital and St. Mary's Hospital (one program, two sites in Waterbury) were authorized by OHCA to offer full-service cardiac programs in 2003. *(Certificate of Need Applications, Final Decision Docket Numbers 03-30167 & 03-30143, both dated July 23, 2005)*

35. St. Vincent's Medical Center ("SVMC") testified to the following:
    a. Angioplasty volume is flat nationally and has begun to decline in Connecticut.
    b. If TSH proposal is approved, St. Vincent's Medical Center would not be able to achieve both institutional and surgeon specific minimum volumes for OHS and would put the quality of St. Vincent's Medical Center at significant risk.
    c. SVMC performed 1,097 PCIs and 283 OHS in FY 2005.
    d. The overall risk adjusted mortality rate at SVMC is 1.3%.
    e. Other than volume, SVMC measures quality through independent third party companies (to whom they report data to).
    (Prefiled Testimony of Jose Missri, M.D. St. Vincent's Medical Center, September 28, 2005 and Public Hearing Testimony, October 6&27, 2005)

36. Bridgeport Hospital ("BH"), as part of Yale-New Haven Health Heart Institute, testified to the following:
    a. BH performed under 1,200 PCIs and under 250 OHS in FY 2005.
    b. BH could not specify their overall risk adjusted mortality rate, BH simply stated that it was under 2.0%.
    c. Other than volume, BH measures quality through independent third party companies (to whom they report data to).

d. If the proposed CON was to be approved, this would not impact the physician coverage at BH.
(Prefiled Testimony of Stuart .Zarich, M.D., Bridgeport Hospital, September 28, 2005 and Public Hearing Testimony, October 6&27, 2005)

37. Yale-New Haven Hospital ("YNHH"), as part of Yale-New Haven Health Heart Institute, testified to the following:
    a. There is a statewide decline in the number of OHS cases,
    b. There is a flattening of PCI volumes,
    c. Proliferation of full-service cardiac program will place additional stress on the state's staffing infrastructure,
    d. Additional cardiac programs will not improve mortality rates,
    e. The residents of Fairfield County have a wide range of options for their full-service cardiac care needs,
    f. There is a direct correlation between physician and institutional case volumes and quality outcomes, and
    g. In FY 2004, YNHH had 64 PCI discharges (4.3% of YNHH's total PCI) and 52 OHS discharges (6.2% of YNHH's total OHS) from the Stamford service area.
    (Prefiled Testimony of Kyle Kramer, Executive Director of the Yale-New Haven Health Heart Institute, September 28, 2005 and Public Hearing Testimony, October 6&27, 2005)

38. In order to implement the proposed project, TSH will require a series of facility renovations. The renovations will include an expansion of surgical facilities on Level 2 of TSH's North building to allow for the creation of two new, state-of-the-art operating rooms that will be the primary operating suites for the proposed program as well as enlarged perioperative and other surgical support areas.
(Certificate of Need Application, August 15, 2005, page 13)

Financial Feasibility of the Proposal and its Impact on the Hospital's Rates and Financial Condition
Impact of the Proposal on the Interests of Consumers and Payers of Health Care Services
Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines

39. The proposal has a total expenditure cost of $5,404,425 which consists of the following:

Table 11: Total Capital Expenditure

Description	Cost
Medical Equipment	3,109,345
Construction/Renovation	1,590,065
Project Contingency	704,925
Total Capital Expenditure	**$5,404,425**

(Certificate of Need, August 15, 2005, page 63)

40. The proposal will be financed from the TSH's equity through operations. *(Certificate of Need, August 15, 2005, page 64)*

41. TSH will pay NYPHS a fee for expenses related to training and oversight of TSH's proposed program. This arrangement will be finalized if the proposal is approved by OHCA. *(Arthur S. Klein, Chief Operating Officer of NYPHS, Public Hearing Testimony, October 6&27, 2005)*

42. TSH projects incremental to the project losses from operations for the first two years of operation for FYs 2007 and 2008 of ($1,940,000) and ($294,000), respectively. This is due to program start up. However, TSH is projecting incremental gains from operation of $1,082,000 for the third year of operation, FY 2009. *(Responses to the OHCA Completeness Letter, August 15, 2005, Updated Financial Attachment)*

43. TSH is projecting a gain from operations with the CON project of $10,137,000, $12,327,000 and $14,365,000, for FYs 2007, 2008 and 2009. *(Responses to the OHCA Completeness Letter, August 15, 2005, Updated Financial Attachment)*

44. TSH proposes to hire 26, 34 and 38 Full Time Equivalent employees for FYs 2007, 2008 and 2009, respectively. *(Responses to the OHCA Completeness Letter, August 15, 2005, Updated Financial Attachment)*

45. There is no State Health Plan in existence at this time. *(Certificate of Need Application, August 15, 2005, page 14)*

46. TSH has adduced evidence that this proposal is consistent with TSH's long-range plan. *(Certificate of Need Application, August 15, 2005, page 14)*

47. TSH has improved productivity and contained costs by participating in group purchasing, energy conservation, reengineering and through application of technology. *(Certificate of Need Application, August 15, 2005, page 59)*

48. TSH stated that this proposal will help enhance the existing academic affiliation with Columbia University College of Physicians and Surgeons. *(Certificate of Need Application, August 15, 2005, pages 59&60)*

49. TSH stated that the patient physician mix of TSH is unique as the cardiac patient care is fully integrated across all medical disciplines and is managed through a state-of-the-art multi-modality data management system. *(Certificate of Need Application, August 15, 2005, page 60)*

50. TSH's rates are sufficient to cover the proposed capital expenditure and operating costs associated with this proposal. *(Responses to Interrogatories, September 28, 2005, Updated Financial Attachment)*

Rationale

The Office of Health Care Access ("OHCA") approaches community and regional need for proposed services on a case-by-case basis. Certificate of Need ("CON") applications for cardiac services do not lend themselves to general applicability due to the variety and complexity of factors, which may affect any given proposal; e.g., the characteristics of the population to be served, the nature of the existing services, the specific services proposed to be offered, the current utilization of services, and the financial feasibility of the proposed service. In considering this application, OHCA determined that TSH's current cardiac utilization, population served, quality of providers and physicians and geographic accessibility were significant factors in determining need.

The Stamford Hospital ("TSH") and New York Presbyterian Healthcare System, Inc. ("NYPHS") (collectively known as "Applicants"), propose to expand the cardiac services delivered at TSH to include elective angioplasty services and open heart surgery. The Applicants based the need for the elective PCI and open heart surgery programs on improved accessibility for patients, improved continuity of care, historical and existing cardiac volume, adopting a standard of care that exists in the other large urban areas and improved quality of care.

TSH's primary and secondary service area ("TSA") consists of eight (8) towns. There are no providers of elective PCI or OHS in TSH's TSA. The Hospital's service area is comprised of a higher proportion of African American and Hispanic population when compared to the rest of the state overall. The primary service area has experienced higher adult per capita rates of AMI discharges for African American and Hispanic as compared to the state as a whole. In addition, there appears to be a disparity in the utilization rates for PCI and OHS for Hispanics and African Americans in the service area when compared to the Caucasian population. This proposed cardiac program will enhance the access for the African American and Hispanic population in TSH's TSA. OHCA concludes that the Applicants proposal will provide the residents of lower Fairfield County with improved access to the full continuum of cardiac care.

TSH's historical cardiac catheterizations volumes for FYs 2002, 2003, 2004, and 2005 (1st 2 quarters) were 675, 635, 628 and 147, respectively. OHCA determined that TSH could potentially perform a minimum of 244 annual total PCIs (primary & elective) and 102 OHS cases on residents of TSH's TSA in the first full year of operation of the proposal based upon historical catheterization volume and its market share. This volume increases to 276 total PCI procedures and 117 OHS cases for the second year of operation, and 316 total PCI procedures and 137 OHS cases for the third of operation. Based on historical inpatient diagnostic cardiac catheterization volume and market share, the proposed full-service cardiac program at TSH would exceed institutional minimum volumes recommended by the ACC/AHA for PCI (200) and the American College of Surgeons–Advisory Council for Cardiothoracic Surgery for open-heart surgery (100–125 surgeries per year).

The proposal involves offering of elective Percutaneous Coronary Intervention ("PCI") through the use of five (5) interventional cardiologists, who are currently providing primary PCI services at TSH. TSH also proposes to provide OHS utilizing two (2) surgeons will be recruited from outside of Connecticut, through the formation of a three (3) person committee comprised of TSH and Columbia physicians. Therefore this program will not impact coverage at any of the existing cardiac programs in Connecticut. In addition, OHCA concludes that even though the PCI and OHS volumes may decline at the existing providers, the PCI and OHS volumes will not fall below the institutional minimum volumes recommended by ACC/AHA for PCI and American College of Surgeons-Advisory Council for Cardiothoracic Surgery for OHS.

TSH's proposal will increase the availability of quality PCI and OHS services for residents of TSH's TSA. The proposed elective PCI and OHS program will be developed in collaboration with NYPHS. NYPHS will provide or arrange for TSH consulting in the areas of clinical training for staff, development of TSH's standards of care, development of clinical guidelines, collection and analysis of data and recruiting procedures. NYPHS expects the initial training to continue over an eighteen month period. NYPHS will also advise TSH with respect to quality assurances and utilization management and provide assistance to TSH concerning the adoption of policies, procedures and protocols, including developing practice guidelines and program requirements. This proposal will improve the quality of care and continuity of TSH's cardiac services.

Finally, the CON proposal is financially feasible. The proposal has a total capital expenditure of $5,404,425, which consists $3,109,345 for medical equipment, $1,590,065 for construction/renovations and $704,925 for contingency costs. TSH proposes to fund the proposed total capital expenditure through TSH's equity, specifically through operations. TSH will pay NYPHS a fee for expenses related to training and oversight of TSH's proposed program; however, the details have not yet been finalized. TSH projects incremental losses from project operations for the first two years of operation of ($1,940,000), and ($294,000), respectively. However, TSH is projecting an incremental gain from operation of $1,082,000 by the third year of operation. Further, TSH is projecting gains from total Hospital operations with the CON project of $10,137,000, $12,327,000 and $14,365,000 for the first three years of operations. The projected utilization and financials of this proposal appear to be reasonable, financially feasible and cost-effective and will not adversely impact the interests of consumers and payers of such services.

TSH's proposed elective angioplasty and open heart surgery program is differentiated from other cardiac-related proposals in the following ways. TSH currently operates a high volume diagnostic cardiac catheterization program and recently initiated a primary angioplasty program. The Hospital's service area is comprised of a higher proportion of African American and Hispanic population than the rest of the state. The implementation of the proposed program should address some of the disparities in utilization of cardiac services by this population. Additionally, the proposed program is not expected to impact the physician coverage at any of the existing cardiac programs in Connecticut because the interventionalists are already on staff at TSH and the cardiac surgeons will be

recruited from out of state. TSH's strong collaborative relationship with the NYPHS will enhance the accessibility of high-quality, community-based medical services offered by TSH. TSH will utilize the resources of NYPHS to further enhance provision of quality care including access to the expertise, information, and consultative support of a nationally recognized academic healthcare center renowned for the diagnosis and treatment of cardiac disease. Finally, implementation of TSH's proposal will bring appropriate access to high quality cardiac services to the residents of the proposal's TSA. In summary, the proposal will result in enhanced cardiac services in the Stamford region.

Order

NOW, THEREFORE, the Office of Health Care Access ("OHCA") and The Stamford Hospital ("TSH") and New York Presbyterian Healthcare System, Inc. ("NYPHS") (together referred to as "Applicants") hereby stipulate and agree to the terms of settlement with respect to the Applicants' request to establish elective angioplasty and open heart surgery program to be located at Stamford Hospital at a total capital expenditure of $5,404,425, as follows:

1. The Applicants' request for a CON to establish an elective angioplasty and open-heart surgery program to be located at TSH, a total capital expenditure of $5,404,425, is hereby approved.

2. TSH shall only commence operation of the OHS program at The Stamford Hospital initially. Once the number of OHS procedures exceeds 125, the Hospital may commence operation of the elective angioplasty program. Prior to commencement of the angioplasty services, TSH is required to provide OHCA evidence that it has performed the required 125 OHS.

3. TSH will have at least two cardiac surgeons as part of this proposal, who are in the process of being recruited and shall be identified prior to the beginning of the OHS program. The surgeons must be fully credentialed and have the following qualifications:
   - Board-Certified in cardiac surgery
   - Maintains a Connecticut license and admitting privileges at the Hospital
   - Has performed OHS procedures at a cardiac surgical center that meets or exceeds the annual ACCS/ACS minimum institutional volume standard for cardiac surgery for the past 2 years
   - TSH shall provide the Curriculum Vitae ("CV") of the cardiac surgeons prior to commencement of the OHS program. TSH shall demonstrate that the cardiac surgeons satisfy all requirements specified above. The OHS program shall not commence operation until OHCA acknowledges receipt of the CV and that it complies with this Order.

4. TSH shall provide the CVs of each of the cardiac operating room nurses, Board-certified cardiac anesthesiologists, intensivists and perfusionists for the authorized OHS program prior to commencement of the OHS program. Fifty percent (50%) of each of the core OR staff mentioned above must be trained in OHS prior to commencement of the OHS program. The OHS program shall not commence operation until OHCA acknowledges receipt of the CVs and that they comply with this Order.

5. TSH shall not exceed the approved total capital expenditure of $5,404,425. In the event TSH learns of potential cost increases or expects final project costs will exceed those approved, the Hospital shall file with OHCA a request for approval of

the revised CON project budget. The source of funding for the project will be The Stamford Hospital's operations and owner equity.

6. TSH shall complete and submit to OHCA on a quarterly basis the data elements in the Connecticut Cardiac Data Registry (**Attachment II**). Data should be submitted to OHCA on a computer disk in either an excel workbook or comma-delimited text file in a format specified by OHCA. The most current version of the Connecticut Cardiac Data Registry includes, but may not be limited to, the elements listed in **Attachment II**. Data must be reported to OHCA thirty (30) calendar days following the end of the quarter. Fiscal Year quarters end December 31st, March 31st, June 30th, and September 30th. Upon receipt, OHCA will check the data's conformance to the required specifications and within ten (10) business days notify TSH in writing of its evaluation. If OHCA finds questionable material, TSH will have fifteen (15) business days from notification by OHCA to submit a revised dataset for evaluation. All patient-level data submitted to OHCA to satisfy this requirement will be subject to the laws and regulations of the state of Connecticut and the Office of Health Care Access regarding its collection, use and confidentiality. If TSH does not submit the data elements in the Connecticut Cardiac Data Registry on a quarterly basis, the programs may be terminated. In the event of such a termination, TSH shall file a CON for reinstitution of the programs.

7. TSH shall submit on an annual basis to OHCA the following reports which must be reported to OHCA thirty (30) calendar days following the end the year, for the first three (3) years of operation:
   a. A report of all elective PCIs and OHS performed each year by ethnicity and race, in a format to be specified.
   b. A report which illustrates that this CON proposal helped relieve the barriers to access through comprehensive preventive and medical out-reach programs for the African American and Hispanic population within TSH's TSA.

8. If TSH does not perform 125 OHS procedures within twelve months of the initiation of the OHS program, TSH shall submit monthly reports of OHS arrayed by physician to OHCA until such time as these volumes are met by TSH. If these volumes are not met for a period of two consecutive 12-month periods, TSH's OHS program shall be terminated. In the event of such a termination, TSH shall file a CON for reinstitution of the OHS program.

9. If TSH does not perform 200 elective PCIs within twelve months of the initiation of the PCI program, TSH shall submit monthly reports of elective PCIs arrayed by physician to OHCA until such time as these volumes are met by TSH.

10. TSH shall participate in the Society of Thoracic Surgeons Database (STS-DB) database and the ACC National Cardiovascular Database Registry (ACC-NCDR) and report all data including the optional follow-up section. TSH shall provide OHCA quarterly data reports from STS-DB and ACC-NCDR. Data must be

reported to OHCA thirty (30) calendar days subsequent to TSH receiving the reports from the STS and ACC. TSH is required to comply with the STS and ACC/AHA criteria and standards. If TSH determines not to participate in the STS-DB or ACC-NCDR, TSH shall notify OHCA immediately, and continue to comply with the STS and ACC/AHA criteria and standards set forth in Attachment III.

11. TSH shall provide OHCA with a copy of a dated and signed Consulting Services Agreement with NYPHS or its Affiliates prior to commencement of operation of the OHS program. This contract shall be renewed annually for a period of three years.

12. OHCA and TSH agree that this Agreed Settlement represents a final agreement between OHCA and TSH with respect to this request. The signing of this Agreed Settlement resolves all objections, claims and disputes, which may have been raised by the Hospital with regard to Docket Number 04-30374.

13. This authorization for the OHS program shall expire on December 31, 2008. Should the TSH's open-heart surgery program not commence operation by that date, TSH must seek further approval from OHCA to complete the project beyond that date.

14. This Agreed Settlement is an order of the Office of Health Care Access with all the rights and obligations attendant thereto, and the Office of Health Care Access may enforce this Agreed Settlement pursuant to the provisions of Sections 19a-642 and 19a-653 of the Connecticut General Statutes at TSH's expense, if TSH fails to comply with its terms.

January 4, 2006

Brian G. Grissler
Duly Authorized Agent for
The Stamford Hospital

December 28, 2005

Arthur A. Klein, M.D.
Duly Authorized Agent for
New York Presbyterian Health System, Inc.

The above Agreed Settlement is hereby accepted and so ordered by the Office of Health Care Access on January 4, 2006.

January 4, 2006

Cristine A. Vogel
Commissioner & Presiding Officer

CAV:sl

ATTACHMENT III

Table 1A: Inpatient cardiac catheterization discharges by provider, FFYs 2002-2010

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	FFY 06-10 (5-yr) % Change	FFY 08-10 (3-yr) % Change	FFY 09-10 (1-yr) % Change
Backus	156	210	200	170	116	53	106	135	115	-1%	8%	-15%
Bridgeport	1,148	1,185	1,274	1,129	902	809	817	632	626	-31%	-23%	-1%
CT Children's								10	5	n/a	n/a	-50%
Danbury	263	299	260	327	748	533	475	452	418	-44%	-12%	-8%
Dempsey	519	564	633	640	487	439	480	419	462	-5%	-4%	10%
Greenwich	100	42	35	106	167	158	163	177	166	-1%	2%	-6%
Hartford	2,546	2,405	2,241	2,128	2,135	2,032	2,008	1,833	1,892	-11%	-6%	3%
Hospital of Central CT	448	465	409	411	436	401	319	344	269	-38%	-16%	-22%
Lawrence & Memorial	420	473	466	393	414	303	337	440	503	21%	49%	14%
Middlesex	28	169	168	150	182	142	161	138	138	-24%	-14%	0%
New Milford	0	0	0	22	37	38	65	37	0	-100%	-100%	-100%
Norwalk	247	203	195	182	128	67	77	104	126	-2%	64%	21%
Rockville	0	79	99	24	4	3	0	0	0	-100%	n/a	n/a
St. Francis	2,742	2,802	2,800	2,656	2,421	2,543	2,431	2,292	2,206	-9%	-9%	-4%
St. Mary's	291	299	260	307	519	469	455	480	469	-10%	3%	-2%
St. Raphael	1,744	1,878	1,833	1,496	1,383	1,200	1,113	1,062	1,098	-21%	-1%	3%
St. Vincent's	1,276	1,259	1,324	1,432	1,554	1,540	1,562	1,375	1,267	-18%	-19%	-8%
Stamford	354	352	296	299	311	297	293	358	321	3%	10%	-10%
Waterbury	451	477	367	412	658	622	611	675	608	-8%	0%	-10%
Yale	2,549	2,587	2,330	2,200	2,021	1,939	1,954	2,135	2,129	5%	9%	0%
Total	**15,282**	**15,748**	**15,190**	**14,484**	**14,623**	**13,588**	**13,427**	**13,098**	**12,818**	**-12%**	**-5%**	**-2%**

***Source** : CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database.*

ICD-9-CM Procedure Codes: 37.21-37.23

Please note: unduplicated counts utilizing all procedure codes

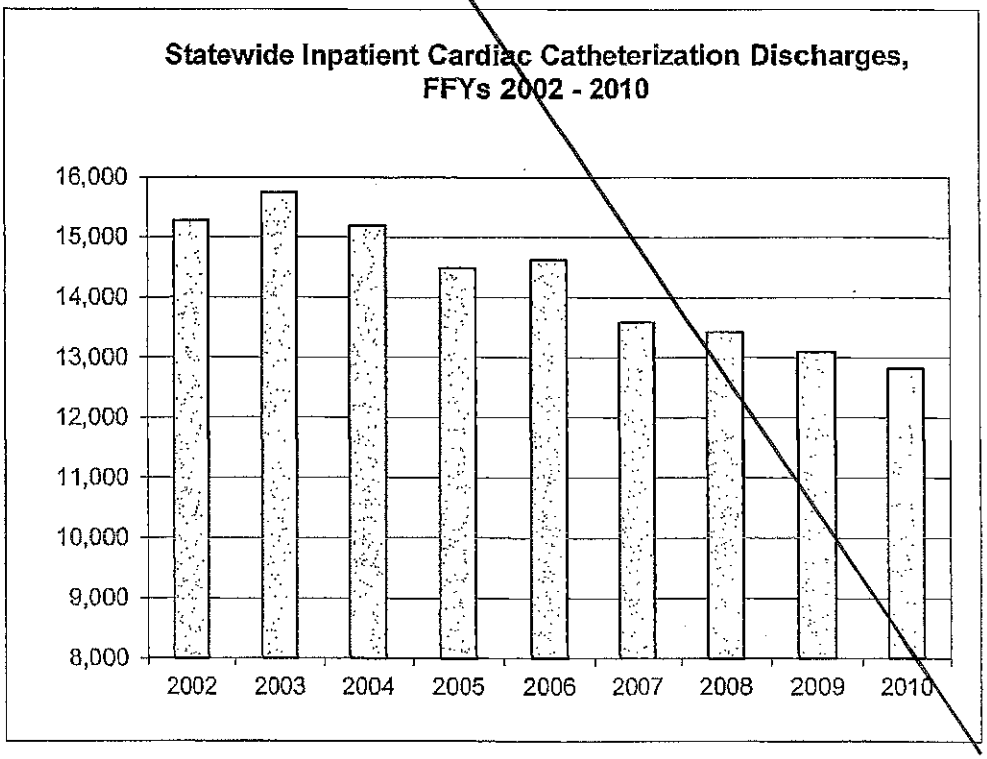


Table 2A: PCI discharges by provider, FFYs 2002-2010

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	FFY 06-10 (5-yr) % Change	FFY 08-10 (3-yr) % Change	FFY 09-10 (1-yr) % Change
Bridgeport	1,191	1,249	1,288	1,052	692	560	580	428	379	-45%	-35%	-11%
CT Children's								2	0	n/a	n/a	n/a
Danbury	0	0	0	0	453	409	330	326	277	-39%	-16%	-15%
Dempsey	452	464	453	519	401	353	376	334	368	-8%	-2%	10%
Greenwich	0	0	0	20	38	32	40	40	32	-16%	-20%	-20%
Hartford	1,312	1,483	1,321	1,282	1,246	1,206	1,093	1,031	1,122	-10%	3%	9%
Hospital of Central CT	0	0	0	26	61	70	60	74	69	13%	15%	-7%
Lawrence & Memorial	0	0	0	0	41	-	29	74	74	80%	155%	0%
New Milford	0	0	0	0	0	6	11	11	0	n/a	-100%	-100%
Norwalk								14	57	n/a	n/a	307%
St. Francis	1,192	1,253	1,349	1,223	1,170	1,188	1,171	1,232	1,030	-12%	-12%	-16%
St. Mary's	0	0	0	59	297	246	251	255	291	-2%	16%	14%
St. Raphael	715	970	924	708	680	632	595	534	523	-23%	-12%	-2%
St. Vincent's	1,063	1,035	1,085	1,150	1,181	1,101	1,124	958	925	-22%	-18%	-3%
Stamford	0	0	0	9	39	34	45	159	151	287%	236%	-5%
Waterbury	0	0	0	61	347	373	325	361	361	4%	11%	0%
Yale	1,635	1,715	1,460	1,297	1,218	1,131	1,186	1,352	1,469	21%	24%	9%
Total	7,560	8,169	7,880	7,406	7,864	7,341	7,216	7,185	7,128	-9%	-1%	-1%

Source : CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database

ICD-9-CM Procedure Codes: .66, 36.01, 36.02, 36.05, 36.06 and 36.07

Please note: unduplicated counts utilizing all procedure codes

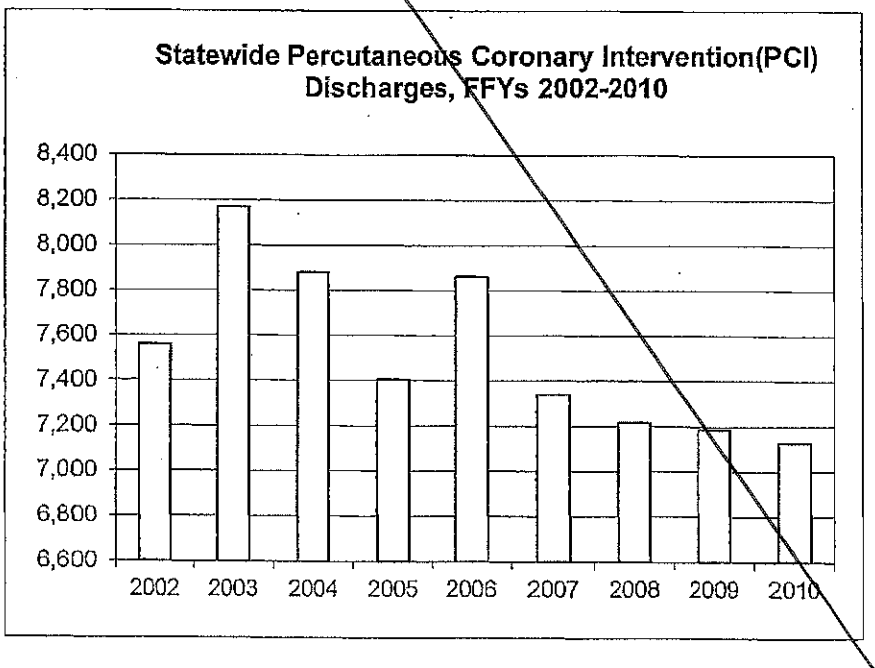


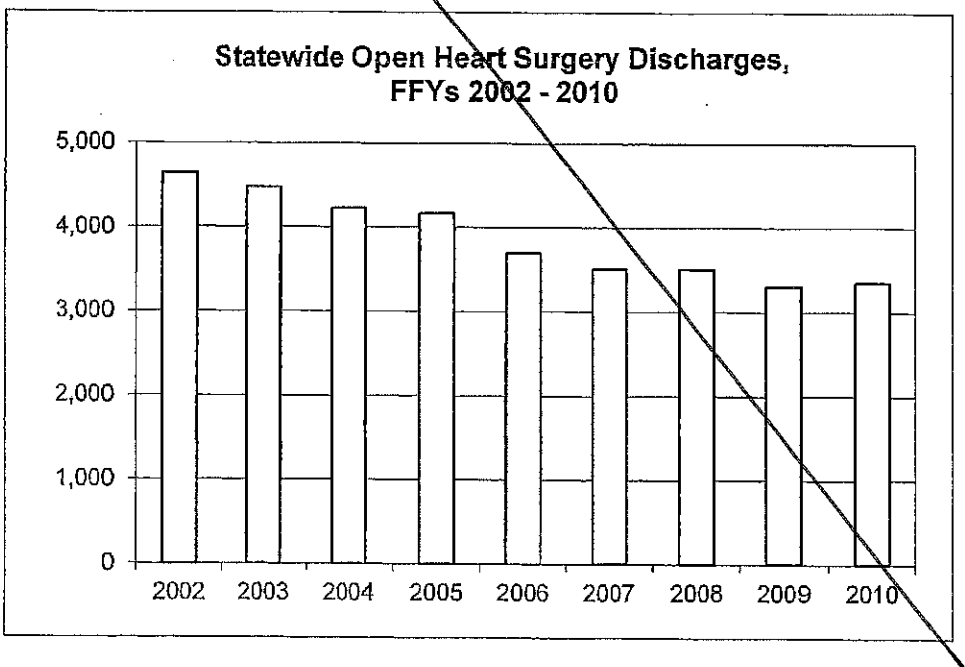
Table 3A: Open heart surgery discharges by provider, FFYs 2002-2010

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	FFY 06-10 (5-yr)% Change	FFY 08-10 (3-yr)% Change	FFY 09-10 (1-yr) % Change
Bridgeport	345	313	268	263	175	194	106	96	136	-22%	28%	42%
CT Children's								6	4	n/a	n/a	na
Danbury	0	0	0	114	177	121	162	148	174	-2%	7%	-9%
Dempsey	115	134	121	174	97	70	84	56	58	-40%	-31%	-33%
Hartford	901	844	756	726	742	685	671	652	695	-6%	4%	-3%
St. Francis	1,239	1,299	1,311	1,188	998	990	912	845	820	-18%	-10%	-7%
St. Mary's	0	0	0	19	72	100	85	114	112	56%	32%	34%
St. Raphael	761	687	617	510	353	342	321	299	318	-10%	-1%	-7%
St. Vincent's	310	296	293	291	259	232	257	219	195	-25%	-24%	-15%
Stamford	0	0	0	0	0	0	75	73	46	n/a	-39%	-3%
Waterbury	0	0	0	20	117	110	134	110	98	-16%	-27%	-18%
Yale	973	905	860	861	704	664	698	691	697	-1%	0%	-1%
Total	**4,644**	**4,478**	**4,226**	**4,166**	**3,694**	**3,508**	**3,505**	**3,309**	**3,353**	**-9%**	**-4%**	**-6%**

Source : CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database.

ICD-9-CM Procedure Codes: 35.10-35.28 and 36.10-36.19

Please note: unduplicated counts utilizing all procedure codes



ATTACHMENT IV

GUIDELINES FOR STANDARDS IN CARDIAC SURGERY

The following statement is an updated version of guidelines that were first published by the American College of Surgeons in 1991. The revised statement was developed by the Advisory Council for Cardiothoracic Surgery and approved by the College's Board of Regents in October 1996.

Preamble

This report provides guidelines to be used by hospital executives and appropriate medical staff only. It places no value judgment on existing successful programs or on the treatment of individual patients.

While current standards of practice form the basis of this report, it is recognized that large programs in cardiac surgery grow from smaller ones. Hospitals and their staffs should exercise their own discretion in approving programs based on local need and the responsibility for achieving a good standard of practice.

While attention is directed primarily to open-heart surgery, the proposed standards should apply to closed-heart operations as well as to operations on the great vessels within the chest.

In borderline situations, in which the number of open-heart operations does not meet the established guidelines, the American College of Surgeons recommends the use of peer review.

Professional team

Specification of the qualifications for cardiac surgeons in an established practice is beyond the scope of these guidelines. Surgeons practicing cardiac surgery should be certified or awaiting certification by the American Board of Thoracic Surgery or its Canadian equivalent within five years after completion of an approved residency program in cardiac surgery. It is recommended that hospital committees for staff accreditation exercise their judgments for privileges based on the nature of the cardiothoracic residency or postresidency experiences of the applicant.

A team approach with a minimum of two qualified cardiac surgeons is recommended to provide adequate and continuous perioperative care as well as assistance in the OR. It is recognized that, depending on the particular setting and situation, the assistant on a particular case may vary in experience and qualification.

Hospital operative volume–Adult cardiac surgery

The 1975 report of the Inter-Society Commission on Heart Disease Resources recommended that cardiac surgical programs in a *hospital* should perform at least 200 procedures annually. This recommendation was based on the premise of a hospital dedicating 1 operating room to cardiac surgery and functioning at 80 percent capacity (4 cases per week x 52 weeks = 200 per year). While there are no presently available data linking an *individual surgeon's* patient volume and hospital mortality rate, there are data to suggest that an annual volume of at least 100 to 125 open heart procedures (including coronary artery bypass procedures, valve replacements, and other operations requiring the use of cardiopulmonary bypass) per *hospital* is necessary from a quality standpoint and that there is a greater variation in adjusted mortality rates for teams doing lower volumes of procedures as compared with those doing a high volume. While 100 to 125 cases per year per *hospital* appears sufficient from a quality standpoint, it is likely that considerably more, and at least 200 procedures per year as previously recommended, are necessary in order for a program to function efficiently.

Congenital heart surgery

Surgery for congenital heart disease, especially in infants, requires a setting that readily meets the complex and special needs

of this group of patients. These requirements include a cardiac surgeon experienced in the operative and perioperative management of such patients. There should be a pediatric cardiologist, an anesthesia team, perfusionists, intensive care nurses, and appropriate intensive care facilities for the treatment of infants and children. At a hospital where congenital heart operations are performed, a total of 100 congenital heart operations (both open and closed, not including neonatal ductus ligations) should be done. The occasional management of an infant or child with congenital heart disease by an otherwise busy and well-functioning adult cardiac surgical team is strongly discouraged.

Hospital facilities and personnel

It is urged that hospital committees for staff accreditation use peer review to determine that adequate standards of practice are maintained in terms of case frequency and results. A registry for the recording of cardiac surgical results is mandatory.

The complex operating room environment required by cardiac surgery in terms of equipment and instruments requires constant improvement in technique and proper indoctrination of personnel. Such educational programs should be under the direction of a clearly designated individual with particular interest and skill in cardiac surgery. Operating room nurses and technicians specializing in cardiac surgery are important. It should be mandatory that operating room nurses and technicians be assigned to cardiac surgery sufficiently often to develop and maintain the skills required for proficient performance in this area.

Anesthesia for cardiac surgical patients encompasses a variety of special problems. To ensure technical competence, frequent changing of the anesthesiologists assigned to cardiac surgery should be avoided.

The operation of a heart-lung machine should be performed by a specially trained nurse or technician under the supervision of the operating surgeon. A perfusionist certified by the American Board of Cardiovascular Perfusion is recommended. Perfusionists who are not certified should have at least two years of experience under supervision in an active clinical program in open-heart surgery and have a thorough background in operating room sterile techniques, perfusion physiology, the use of monitoring equipment, and a general understanding of commonly performed cardiac surgical procedures. The primary responsibility for determining the capability of the perfusionist remains with the cardiac surgeon.

Cardiac surgeons must be primarily responsible for the postoperative care of their patients, including that provided in the intensive care unit. Portions of that care may be shared with others, such as nurses and other physicians. However, only the cardiac surgeon is fully cognizant of all aspects of a given patient's condition and retains the responsibility for the continuity of care, which includes the preoperative status, the operative management, and the postoperative care.

Intensive care nursing of cardiac surgical patients is recognized as a true specialty involving skills in dealing with cardiac and respiratory emergencies. Assignment to cardiac surgical patients should be sufficiently often to maintain competence in this area of nursing. The surgeon should participate in the supervision of cardiac intensive care unit nurses.

The operating room, intensive care unit, and other facilities must conform to standards mandated by the Joint Commission on Accreditation of Health Care Organizations.

The nature of cardiac surgery makes it mandatory that diagnostic facilities be available to the surgical team. A proper cardiac catheterization laboratory must be available for hemodynamic and cine' angiographic studies. This laboratory should be under the direction of a qualified specialist and be accessible for preoperative elective studies, postoperative elective studies, and emergency procedures on a 24-hour basis.

Standard laboratory studies should be available on a 24-hour basis, including blood-gas analysis.

A blood bank facility with full resources under the direction of qualified specialists in this field is mandatory.

An intensive care facility must be available for all patients following cardiac surgery, and in some instances, for patients who are severely ill, preoperatively. This should be a limited-access area that is off limits to nonparticipating personnel and should have facilities for the adequate isolation of septic patients.

Patient follow-up

Proper patient follow-up is an integral part of surgical treatment. An effective follow-up system for patients having open-heart surgery is the responsibility of the surgical team. The team should be able to demonstrate that it has an adequate follow-up system and that patients are seen as often as necessary during the immediate postdischarge period and, subsequently, are followed up at appropriate intervals.

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Guidelines

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sponsor hospitals and OEMS the ability to begin to collect EMS data, creating the potential in the near future to begin to analyze the data and create best practices to elevate the quality of care and delivery of Emergency Medical Services to the residents and visitors of Connecticut.

In late 2008/early 2009 the AHA formed a "STEMI stakeholders group" comprised of three sub-committees (pre-hospital, timely transfers and education) intended to develop and promulgate best practice related to ST segment myocardial infarction (STEMI). The group had a varied composition including physicians (EMS/ED, cardiology, and interventional cardiology), nurses, pre-hospital providers and health care administrators/regulators. This group drafted a document outlining recommendations to improve care in relation to pre-hospital triage of STEMI patients, timely transfers of patients between facilities and issues of education for pre-hospital providers. A "STEMI Protocol" was also drafted that was intended to offer state-wide guidance for best practice regarding patients experiencing chest pain and subsequently diagnosed with a STEMI by pre-hospital EKG (including bypass for more timely cardiac catheterization).

The "STEMI Protocol" was reviewed by the CT EMS Medical Advisory Committee (CEMSMAC) beginning in 2010. In 2011, after a significant amount of thoughtful work by the CEMSMAC, a revised version of the document entitled "CT EMS STEMI Guideline" was completed and submitted to the Commissioner of Public Health for review; it was approved in January 2012.

OHCA would encourage the adherence of the "CT EMS STEMI Guideline." The foremost goal is for authorized EMS personnel to obtain a 12-lead electrocardiogram in the field for all patients suspected of myocardial infarction, thereby increasing the likelihood for percutaneous coronary intervention (PCI) within 90 minutes of first medical contact. Please see link below for the complete "CT EMS STEMI Guideline" document:

http://www.ct.gov/dph/lib/dph/ems/pdf/stemi_patients.pdf

CARDIAC SERVICES

Heart disease is the leading cause of death for both men and women in the United States.[53] In 2010, coronary heart disease alone was projected to cost the United States approximately $108.9 billion in health care services, medications, and lost productivity.[54] In Connecticut, cardiovascular disease (CVD) is also a significant public health concern and contributor of resident deaths. In fact, about one third of Connecticut resident deaths are due to CVD; coronary heart disease (48%), cerebrovascular disease (15%) also known as stroke and heart failure (8%) account form the majority of CVD deaths.[55]

Existing Connecticut statute requires CON authorization for the establishment of cardiac services, including inpatient and outpatient cardiac catheterization, interventional cardiology and cardiovascular surgery. According to OHCA's Policies and Procedures, "interventional cardiology" is defined as non-

surgical procedures performed in the cardiac catheterization laboratory for the treatment of coronary artery and peripheral vascular disease. Procedures include, but are not limited to, angioplasty, valvuloplasty, cardiac ablation, coronary thrombectomy, and congenital heart defect correction. Only those procedures authorized pursuant to CON may be performed by a health care facility or provider. Multiple cardiac services may be authorized under one CON decision. A facility that is authorized to provide open heart surgery is also authorized to provide the full range of cardiac procedures mentioned above.

CARDIAC CATHETERIZATION

Cardiac catheterization is defined as a medical procedure requiring the passage of a catheter into one or more cardiac chambers of the left and right heart, with or without coronary arteriograms, for the purpose of diagnosing congenital or acquired cardiovascular disease, or for determining measurement of blood pressure flow.

ANGIOPLASTY/PERCUTANEOUS CORONARY INTERVENTION

Primary (emergent) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a previously diagnosed blockage in the heart. An expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow

Elective (scheduled) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure performed in a catheterization lab whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a previously diagnosed blockage in the heart. An expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow.

PCI and Elective PCI are often combined with the permanent placement of a small wire mesh tube called a stent to help prop the artery open and decrease the chance of it narrowing again. Some stents are coated with medication to help keep the artery open (drug-eluting stents), while others are not (bare-metal stents).

OPEN HEART SURGERY

Open heart surgery refers to a therapeutic operative procedure performed on the heart and/or its coronary arteries in order to correct anomalous conditions (for example, coronary artery bypass surgery, heart valve replacement), often using a heart-lung by-pass machine to perform the functions of circulation during surgery.

Authorization for Connecticut hospitals to perform elective catheter-based interventions for coronary artery disease has been limited in the past to hospitals with the ability to perform cardiac surgery onsite. However, increasing operator experience, improvements in surgical technique and major advances in technology and pharmacology have contributed to a progressive trend to allow PCI without on-site surgical backup. New evidence gives support to the positive effects that these medical advances have contributed to the significant reduction in emergency surgery following PCI[56]. Elective PCI without on-site surgical backup was, until recently, recommended as class III (not recommended, potentially harmful). However, an important change occurred in 2011, when the ACCF-AHA-SCAI PCI guidelines were modified to a class IIb (Level of evidence B) recommendation. CPORT-E trial findings conclude that patients have no greater risk of death or complications when they have Elective PCI at a hospital without cardiac surgery backup. However, similar to the 2007 SCAI Expert Consensus document, the revised guidelines also recommend stringent criteria for such programs. Connecticut hospitals seeking authorization to initiate an Elective PCI program without on-site cardiac surgery capabilities will be required to meet the SCAI conditions required in guidelines as well as demonstrate clear public need for the program.

DESCRIPTION OF DATA SOURCES

The primary source to be used for Acute Care utilization will be the CT Office of Health Care Access Acute Care Hospital Inpatient Discharge Database.

MAP OF CURRENT SERVICE LOCATIONS

Table 3.10: Adult Cardiac Services in Connecticut[57]

Hospital	Cardiac Cath	Primary PCI	Elective PCI	Open Heart
William. W. Backus	X			
Bridgeport Hospital	X	X	X	X
Danbury Hospital	X	X	X	X
John Dempsey Hospital	X	X	X	X
Greenwich Hospital	X	X		
Hartford Hospital	X	X	X	X
Lawrence & Memorial Hospital	X	X		
Middlesex Hospital	X			
Hospital of Central CT	X	X		
Norwalk Hospital	X	X		
Rockville General[1]	X			
St. Francis Hospital	X	X	X	X
HCGW (Saint Mary/Waterbury)	X	X	X	X

Hospital of Saint Raphael	X	X	X	X
St. Vincent's Medical Center	X	X	X	X
Stamford Hospital	X	X	X	X
Yale-New Haven Hospital	X	X	X	X

[1]Although allowed to provide the service, the hospital has not provided the cardiac services.
Source: CT DPH-OHCA Acute Care Hospital Service Line Survey, 2012

STANDARDS/GUIDELINES

Connecticut General Statutes Section 19a-638 specifies that at CON is required for: the establishment of cardiac services, including inpatient and outpatient cardiac catheterization, interventional cardiology and cardiovascular surgery.

The Office of Health Care Access has historically utilized Professional Societies and Organizations held to be the experts for establishing standards and guidelines for cardiac care and will continue to make appropriate use of their recommendations in the future review and determination of CON applications. Examples of expert sources to be used in determining standards and guidelines include: the American College of Cardiology, the American Heart Association and the Advisory Council for Cardiothoracic Surgery.

PERCUTANEOUS CORONARY INTERVENTION (PCI)

Primary PCI

1. Based on ACC and AHA, Primary PCI for STEMI should be performed by experienced operators who perform more than 75 elective PCIs per year and, ideally, at least 11 PCI procedures for STEMI per year. Ideally, these procedures should be performed in institutions that perform more than 400 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year.
2. A report by the American College of Cardiology/American Heart Association Task Force on practice guidelines, referring to Class II b, suggests that Primary PCI for patients with STEMI might be considered in hospitals without on-site cardiac surgery provided that appropriate planning for program development has been accomplished and includes: appropriately experienced physician operators (more than 75 total PCIs and, ideally, at least 11 primary PCIs per year for STEMI); an experienced catheterization team on a 24 hours per day; a 7 day per week call schedule; a well-equipped catheterization lab with digital imaging equipment; a full array of interventional equipment; intra-aortic balloon pump capability; and a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital with appropriate hemodynamic support capability for transfer. Primary PCI should be limited to patients with STEMI or MI with new or presumably new LBBB on ECG and should be performed in a timely fashion (goal of balloon inflation within 90 minutes of presentation) by persons skilled in the procedure (at least 75 PCIs per year) and at hospitals that perform a minimum of 36 Primary PCI procedures per year. (Level of Evidence: B - Limited populations evaluated. Data derived from a single randomized trial or nonrandomized studies).

Elective PCI

1. Elective/urgent PCI should be performed by operators with an acceptable annual volume (>75 procedures) at high volume centers (> 400 procedures) with on-site cardiac surgery (Level of Evidence: C)
2. Elective/urgent PCI should be performed by operators and institutions whose current risk-adjusted outcome statistics are comparable to those reported in contemporary national data registries, (Level of Evidence: C)
3. It is reasonable that low volume operators (< 75 PCI procedures per year) perform elective/urgent PCI at high volume centers (> 400 PCI procedures per year) with on-site cardiac surgery. Ideally, operators with an annual procedure volume of fewer than 75 procedures per year should only work at institutions with an activity level of more than 600 procedures per year. Operators who perform fewer than 75 procedures per year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume of at least 150 procedures per year. (Level of Evidence C)
4. It is not recommended that elective/urgent PCI be performed by low volume operators (< 75 PCI procedures per year) at low volume centers (200 to 400 procedures per year) with or without on-site cardiac surgery. An institution with a volume of fewer than 200 procedures per year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer this service. (Level of Evidence: C)
5. The 2005 PCI Guideline does not establish an explicit minimum hospital volume threshold for elective PCI; there are multiple references in the context of operator and institutional competency to "centers" performing 200 – 400 elective PCI procedures per year.
6. The 2011 PCI Guideline states that operator and hospital volume recommendations have been carried over from the ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention.

   a. PCI in Hospitals without On-Site Surgical Back-up is in the Class IIb category.

      Class IIb: Elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection (Level of Evidence: B)

      Any hospital considering elective PCI without on-site-cardiac surgery must meet the criteria set forth in the 2011 ACCF/ANA/SCAI PCI Guideline, Section 4.8., PCI in Hospitals Without On-Site Surgical Backup: Recommendations (see link below):

      http://content.onlinejacc.org/cgi/reprint/58/24/e44.pdf

      Any hospital not meeting the 2011 ACCF/ANA/SCAI PCI Guideline criteria will be considered to be in Class III.

Class III–Harm: Primary and elective PCI should not be performed in hospitals without on-site cardiac surgery capabilities without a proven plan for rapid transport to a surgery operating room in a nearby hospital or without appropriate hemodynamic support capability for transfer. (Level of Evidence: C)

Quality and Performance Considerations for PCI Programs

Based on the 2011 American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions Guidelines for Percutaneous Coronary Intervention:

1. Every PCI program should operate a quality improvement program that routinely:
   a) reviews quality and outcomes of the entire program;
   b) reviews results of individual operators;
   c) includes risk adjustment;
   d) provides peer review of difficult or complicated cases; and
   e) performs random case reviews (Level of Evidence: C)
2. Every PCI program should participate in a regional or national PCI registry for the purpose of benchmarking its outcomes against national norms. (Level of Evidence: C)

PCI quality and performance considerations are defined by attributes related to structure, processes, and risk adjusted outcomes. Structural elements include, for example, staffing, equipment, supplies, operator and institutional volumes, and the availability of electronic medical records. Processes include strategies for the appropriate patient, protocols for pre- and post-procedural care, appropriate procedural execution and management of complications, and participation in databases and registries for benchmarking program and individual operator performance. The end result of these structures and processes of care are risk-adjusted outcomes, and when available, are more reliable measures of quality than the institutional and individual operator volumes.[58]

CARDIAC SURGERY/OPEN HEART SURGERY[59]

1. Guidelines for Standards in Cardiac Surgery developed by the Advisory Council for Cardiothoracic Surgery and approved by the American College of Surgeons' Board of Regents in October 1996 – Bulletin of the American College of Surgeons, Vol. 82, No. 2, February 1997
   a. An annual volume of at least 100 to 125 open heart procedures per hospital is necessary from a quality standpoint and there is a greater variation in adjusted mortality rates for teams doing lower volumes as compared with those doing a high volume.
   b. At least 200 procedures per year are necessary in order for a program to function efficiently
   c. A team approach with a minimum of 2 qualified cardiac surgeons is recommended to provide adequate and continuous perioperative care as well as assistance in the OR.
2. The following conditions must be met to initiate a new OHS program:

a. The annual caseload of other programs w/in the proposed PSA shall not drop below 350 procedures.
b. Epidemiological evidence of conditions for which OHS is appropriate w/in the PSA or demonstrates a significant unmet need in the PSA for these procedures.
c. Existing program(s) in the service area are performing at least 350 open heart surgeries annually.
d. Evidence demonstrating the performance of a minimum of 200 open heart surgeries annually within the first three years of the start of the new Open Heart Surgery program.

CARDIAC UTILIZATION

Based on hospital discharge data, inpatient cardiac care is declining both in patient volume and overall patient days (see Table 4.7 and Chart 4.3). From FY 2008 to FY 2011, Cardiac Care-Medical discharges dropped 6%, while the corresponding patient days declined by 3%. During the same time period, Cardiac Care-Surgical care declined even more significantly, with both discharges (11%) and patient days (8%) falling.

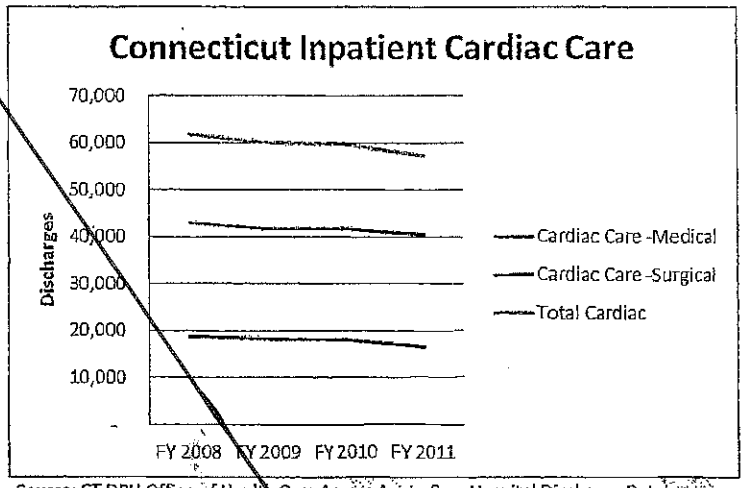
Table 3.11: Statewide Cardiac Inpatient Data

Discharges	FY 2008	FY 2009	FY 2010	FY 2011	chg 08-11	chg 10-11
Cardiac Care -Medical	43,072	41,747	41,795	40,542	-6%	-3%
Cardiac Care -Surgical	18,681	18,299	18,104	16,710	-11%	-8%
Total Cardiac	**61,753**	**60,046**	**59,899**	**57,252**	**-7%**	**-4%**

Patient Days	FY 2008	FY 2009	FY 2010	FY 2011	chg 08-11	chg 10-11
Cardiac Care -Medical	159,087	156,890	155,239	153,817	-3%	-1%
Cardiac Care -Surgical	95,344	93,054	90,455	87,361	-8%	-3%
Total Cardiac	**254,431**	**249,944**	**245,694**	**241,178**	**-5%**	**-2%**

Source: CT DPH Office of Health Care Access Acute Care Hospital Discharge Database

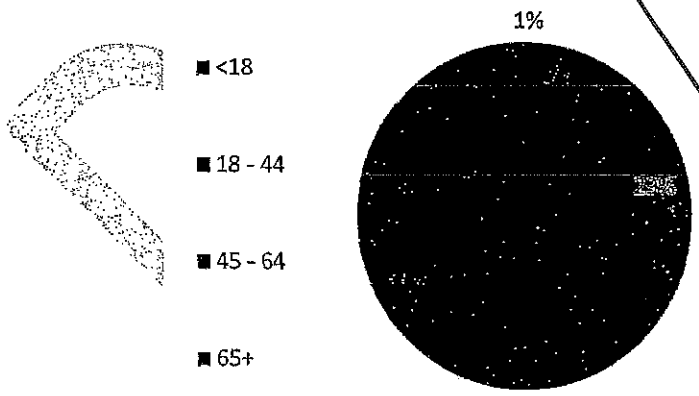
Chart 3.4: Connecticut Inpatient Cardiac Care



Source: CT DPH Office of Health Care Access Acute Care Hospital Discharge Database

Cardiac discharges are highly prevalent among the elderly. As seen in Chart 4.3, sixty-four percent of inpatient cardiac discharges in FY 2011 were for patients age 65 and older.

Chart 3.5: Cardiac Discharges by Age (FY 2011)



Source: CT DPH Office of Health Care Access Acute Care Hospital Discharge Database

DISCUSSION OF UNMET NEED AND GAPS IN SERVICES, CAPACITY ISSUES, ETC.

The tables below provide an initial step toward the identification of potential areas of unmet need for cardiac care in the state. The tables below provide information that compares the number of residents from a given region that received treatment for cardiac medical services or surgery in a given year (patient demand). This patient demand is compared to the overall volume of cardiac patients served by hospitals in the same region. If hospital volumes are lower than patient demand in the region, it may indicate the need for additional capacity and warrants additional study to examine patient migration patterns to confirm or refute this assertion.

Table 3.12: Bed Need for Inpatient Cardiac Services

Hospitals	DEMHS Region	Service		Discharges				Patient Days			
				2007	2008	2009	2010	2007	2008	2009	2010
Bridgeport, Norwalk, Greenwich, Stamford, St Vincent's	1	Medical	Demand	7,580	7,249	7,242	7,060	29,191	28,470	27,682	27,702
			Served	6,842	6,345	6,412	6,230	32,392	32,060	31,436	31,124
			Surplus (-) or Deficit (+)	(1,053)	(1,096)	(1,170)	(1,170)	(3,201)	(3,590)	(3,554)	(3,422)
		Surgical	Demand	3,418	3,340	3,031	2,926	17,610	16,340	15,777	14,429
			Served	3,850	3,728	3,263	3,205	18,593	17,724	16,198	15,181
			Surplus (-) or Deficit (+)	(432)	(388)	(232)	(279)	(1,883)	(1,384)	(421)	(752)

Hospitals	DEMHS Region	Service		Discharges				Patient Days			
				2007	2008	2009	2010	2007	2008	2009	2010
Yale, Griffin, Milford, St Raphael, MidState	2	Medical	Demand	10,202	10,650	9,967	10,664	36,304	37,046	36,740	38,338
			Served	10,000	9,936	9,745	10,539	35,660	37,066	36,198	38,379
			Surplus (-) or Deficit (+)	202	314	222	125	644	580	542	(41)
		Surgical	Demand	4,243	4,119	4,088	4,176	21,406	21,045	20,569	20,451
			Served	5,117	5,118	5,323	5,441	25,969	26,043	26,568	25,675
			Surplus (-) or Deficit (+)	(874)	(999)	(1,235)	(1,265)	(4,563)	(4,998)	(5,975)	(5,224)

Hospitals	DEMHS Region	Service		Discharges				Patient Days			
				2007	2008	2009	2010	2007	2008	2009	2010
Dempsey, Saint Francis, Bristol, HOCCT, Manchester, Hartford, CTGMC, Middlesex, Rockville, Johnson	3	Medical	Demand	12,700	12,162	11,646	10,991	45,821	47,067	46,730	44,209
			Served	14,235	13,846	13,164	12,561	51,503	53,644	53,461	50,997
			Surplus (-) or Deficit (+)	(1,535)	(1,684)	(1,518)	(1,570)	(5,682)	(6,577)	(6,731)	(6,788)
		Surgical	Demand	5,902	5,599	5,600	5,357	33,546	29,771	30,034	28,483
			Served	7,704	7,280	7,172	6,951	43,656	39,799	39,143	38,204
			Surplus (-) or Deficit (+)	(1,802)	(1,681)	(1,572)	(1,594)	(10,109)	(10,028)	(9,109)	(9,721)

Hospitals	DEMHS Region	Service		Discharges				Patient Days			
				2007	2008	2009	2010	2007	2008	2009	2010
Backus, L&M, Day Kimball, Windham	4	Medical	Demand	5,252	5,773	5,422	5,451	17,269	19,042	18,659	17,806
			Served	4,772	5,187	4,904	4,926	14,865	16,203	15,676	15,085
			Surplus (-) or Deficit (+)	480	586	518	525	2,404	2,839	2,983	2,721
		Surgical	Demand	1,948	2,051	1,980	2,120	10,852	10,340	9,556	10,656
			Served	362	426	356	414	2,227	1,982	1,923	2,052
			Surplus (-) or Deficit (+)	1,586	1,625	1,664	1,706	8,425	8,358	7,633	8,604

Hospitals	DEMHS Region	Service		Discharges 2007	Discharges 2008	Discharges 2009	Discharges 2010	Patient Days 2007	Patient Days 2008	Patient Days 2009	Patient Days 2010
Danbury, New Milford, Hinggerford, Sharon, St Mary's, Waterbury	5	Medical	Demand	6,454	6,026	5,884	5,864	22,071	21,794	21,988	21,740
			Served	6,183	5,756	5,522	5,539	20,718	20,114	20,119	20,254
			Surplus (-) or Deficit (+)	271	269	362	325	1,353	1,680	1,869	1,486
		Surgical	Demand	3,001	2,864	2,901	2,811	14,999	14,367	13,705	12,906
			Served	2,164	2,129	2,145	2,093	10,302	9,796	9,232	8,343
			Surplus (-) or Deficit (+)	837	735	756	718	4,697	4,571	4,473	3,563

Hospitals		Service		Discharges 2007	Discharges 2008	Discharges 2009	Discharges 2010	Patient Days 2007	Patient Days 2008	Patient Days 2009	Patient Days 2010
Distributed among several hospitals	Out of State, Unk Address	Medical	Demand	1,635	1,612	1,586	1,765	4,682	5,068	4,891	5,444
			Served								
			Surplus (-) or Deficit (+)								
		Surgical	Demand	705	708	699	714	3,433	3,481	3,399	3,529
			Served								
			Surplus (-) or Deficit (+)								

RECOMMENDATIONS

1. Examine volume as indicator of quality, as well as other indicators, by examining institutional and operator performance.
2. Continue to review and update Connecticut's cardiac guidelines to reflect updated information and recommendations provided by Professional Societies and Organizations with expert knowledge of cardiac care.

CANCER TREATMENT

Oncology is the branch of medicine concerned with the study and treatment of cancer, including screening, diagnosis, therapy, follow-up and palliative care. It includes various sub specialties such as radiation oncology (medical use of high-energy radiation to kill malignant cells), surgical oncology, and pediatric oncology. Chemotherapy, most generally the treatment of disease by chemicals, can be used for a range of diseases but most frequently refers to antineoplastic drugs to treat cancer.

In Connecticut, there is no unique licensure category for cancer treatment. The Commission on Cancer (CoC), a consortium of professional organizations dedicated to improving cancer patients' lives, administers an accreditation program that encourages hospitals, treatment centers, and other facilities to improve the quality of patient care by focusing on prevention, early diagnosis, pretreatment evaluation, staging, optimal treatment, rehabilitation, surveillance for recurrent disease, support services, and end-of-life care. A broad range of available medical services combined with a multidisciplinary team approach has resulted in 80 percent of all newly diagnosed cancer patients in the US being treated in CoC-accredited cancer programs.[60] According to the CT Cancer Partnership, 67% of acute care hospitals in Connecticut are ACoS accredited.[61].

The change in the 2011 ACCF/AHA/SCAI guidelines for elective angioplasty without onsite cardiac surgery from a Class III to a Class IIb is significant. Dr. Gray states this change is only "incremental", but my opinion is to move from a Class III which indicates harm to a Class IIb which states such a program might be considered as long as there is appropriate program development and rigorous criteria for proper patient selection is beyond "incremental". ~~OHCA has recognized this significant change and incorporated in their Cardiac Services section of the new State Health Plan (draft form) the following statement:~~

~~"...an important change occurred in 2011, when the ACCF-AHA-SCAI PCI guidelines were modified to a class IIb (Level of evidence B) recommendation".~~

- Dr. Gray discusses the results of the CPORT-E study recently published in the New England Journal of Medicine and suggests that our CON application included the position that elective angioplasty without onsite cardiac surgery is preferred over sites with onsite surgery. Our application never included any such suggestion. But the CPORT-E study, along with others noted in Dr. Cabin's prefiled testimony, and the shift from a Class III to a Class IIb assignment by the ACCF/AHA/SCAI Angioplasty Guidelines all support the reasonableness of offering elective angioplasty without onsite cardiac surgery as long as number of criteria are met which we have already addressed in our CON application. Dr. Gray's skepticism and criticism of angioplasty without onsite cardiac surgery is puzzling given his institution's (NYP) support of White Plains Hospital's program as well as support of a similar program by another NYP affiliate, Holy Name Hospital in Teaneck, New Jersey.

- Dr. Gray also highlights the statement in the 2011 ACCF/AHA/SCAI Guidelines which discusses competition with another angioplasty program in the same geographic area, particularly an established program with surgical back-up and that such competition MAY not be in the best interests of the community. The data we included in our prefiled testimony clearly shows that Greenwich and Stamford Hospitals are overwhelmingly serving residents of different communities. I would go so far as to say that we do not compete in the area of cardiology, despite our close geography. Our medical staff in

cardiovascular services does not overlap to any measurable degree and referral patterns to the interventional cardiologists are different. We have offered emergency angioplasty for approximately 8 years and despite the entrance of Stamford Hospital's program, we have maintained our emergency and elective transfer volume because patients want their care from Greenwich Hospital and the YNHHVC. In this case, a program at Greenwich Hospital IS in the best interest of the community because the Greenwich Hospital community has demonstrated that is where they want their care.

- Dr. Gray states that if the program at Greenwich Hospital is approved there is a risk that Stamford and Greenwich Hospital's angioplasty programs may perform less than 200 PCIs per year. For the reasons I have outlined above, we do not believe our program will impact Stamford's program due to the lack of patient and physician crossover. It is worthy to note that since the opening of White Plains Hospital's program, Stamford Hospital has not seen any decline in their angioplasty volume. According to Stamford Hospital's Petition, Stamford Hospital "...is on track to perform 277 PCIs in FY 2012" which represents a 25% increase from its 2011 volume as noted on Dr. Kiely's testimony page 32 (PCR data). Clearly, the presence of the White Plains Hospital program, which is located only 15 miles from Stamford Hospital and performed as many as 290 PCIs last year, has not had any impact on Stamford Hospital's angioplasty volumes.

- I must comment on Dr. Gray's suggestion that approval of the proposed program at Greenwich Hospital would in some way encourage physicians to feel "...pressure to refer patients for procedures to keep institutional volumes up. Occurrences like these will only drive up healthcare costs for payers and patients." ~~Dr. Gray is suggesting that physicians may send a patient for an unnecessary procedure just to increase institutional volumes. This may be the practice at New York Presbyterian, but I can assure you that this is NOT the practice of YNHHVC physicians nor would it ever be condoned or permitted~~.

BEFORE THE OFFICE OF HEALTH CARE ACCESS DIVISION OF THE DEPARTMENT OF PUBLIC HEALTH	:	Docket No. 12-31748-CON
IN RE APPLICATION OF YALE-NEW HAVEN HOSPITAL AND GREENWICH HOSPITAL TO ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM AT GREENWICH HOSPITAL	:	July 17, 2012

RESPONSE TO GREENWICH AND YALE-NEW HAVEN HOSPITALS' OBJECTION TO INTERVENOR'S REBUTTAL TESTIMONY AND MOTION TO STRIKE TESTIMONY

Rebuttal Testimony

The Stamford Hospital ("TSH") hereby responds to Greenwich Hospital's ("GH") and Yale-New Haven Hospital's ("YNHH," and, together with GH, the "Applicants") request that the Office of Health Care Access ("OHCA") preclude TSH's submission of rebuttal testimony. Applicants cite absolutely no legal or equitable rationale for precluding such submission. OHCA's Ruling issued on July 16, 2012 regarding TSH's petition to be granted intervenor status does not expressly address Applicants' request to preclude TSH from submitting rebuttal testimony, but such ruling grants TSH intervenor status, including the right "to introduce evidence." Since there is no limitation on such right in OHCA's Ruling – and no possible reason to grant Applicants' unusual request – TSH has submitted herewith written rebuttal testimony. For the record, however, TSH wishes to make the following points.

By granting TSH intervenor status, OHCA has determined that TSH can assist OHCA in resolving the issues raised by Applicants' application. *See* Regs. Conn. State Agencies § 19a-9-27. To place unnecessary and unjustified limits on the submission of evidence by TSH would fly in the face of OHCA's determination. As stated in TSH's Petition for Intervenor Status, its position as an existing provider of elective angioplasty in the same geographic area which would

be served by Applicants' proposed program makes it uniquely qualified to offer evidence and information that would otherwise not be available to OHCA to assist in evaluating Applicants' proposal. Both parties submitted their written testimony on June 12, 2012. Applicants have filed their rebuttal to the testimony submitted by TSH, and in the interest of justice and the public good, TSH must have the same opportunity.

This opportunity, which TSH assumed it would have in addition to full intervenor status, is even more critical now that OHCA has granted TSH only limited intervenor status, precluding TSH from conducting cross-examination of Applicants' witnesses. OHCA's decision to limit TSH's rights as an intervenor is virtually unprecedented in the context of cardiac Certificate of Need applications. To TSH's knowledge, in every such application filed in recent memory, each intervenor has been permitted to cross-examine witnesses. More importantly, when Applicants filed a nearly identical application three (3) years ago seeking permission to provide elective angioplasty, TSH was granted full intervenor status, including the right to cross-examine witnesses. *See* Docket No. 08-31210-CON.

TSH believes that OHCA's decision to deny TSH the right to cross-examine witnesses is not justified by law or precedent and does not serve the interests of OHCA or the public. In addition, as a provider of cardiac services, including elective angioplasty, in the very geographic area which is the subject of Applicants' proposal, TSH's interests are profoundly implicated here – providing yet another reason to have granted TSH full procedural rights as an intervenor. Still, OHCA has denied TSH such rights.

In their motion, Applicants attempt to justify precluding TSH from submitting additional useful information to OHCA via rebuttal testimony by arguing that "*if OHCA grants TSH full procedural rights, TSH will have an opportunity to rebut any information contained in*

Applicants' pre-hearing submissions through cross-examination of Applicants' witnesses." Applicants' Objection to The Stamford Hospital's Petition for Intervenor Status and Motion to Strike Testimony at p. 768. Since OHCA has now denied TSH the right to cross-examine witnesses, without the submission of rebuttal testimony, inaccuracies or distortions in the record which only TSH may be in a position to correct would otherwise go unaddressed.

Unlike a private lawsuit between two parties where a judge's decision will affect only those parties, here, OHCA's decision will affect not only TSH and other health care providers, but the public as well. In Certificate of Need proceedings, OHCA is charged with determining the need for the proposed new service, taking into account services already available and all other information relevant to determining such need, including, without limitation, how the proposed services will impact the financial strength of the state's health care system and whether the proposed services will result in unnecessary duplication of existing health care services. Conn. Gen. Stat. § 19a-639. To fulfill this responsibility, OHCA's decision to accept evidence from TSH, including written rebuttal testimony, is clearly necessary and appropriate.

TSH's rebuttal testimony is not voluminous and will not disrupt the orderly conduct of the proceedings. *See* Conn. Gen. Stat. § 4-177a(b). Applicants have provided no rationale for precluding the acceptance of such testimony, while the benefit of receiving it is obvious – more relevant information is available to OHCA. Moreover, since Applicants' counsel has the right to cross-examine TSH's witnesses with respect to such testimony, Applicants are not at all prejudiced by its submission.

Motion to Strike

Applicants move to strike all references to Lawrence & Memorial Hospital's ("L&M") CON application. The references to that application in TSH's testimony are included simply to

contrast certain elements that are present in the L&M situation which are clearly lacking in Applicants' proposal. On this basis, TSH believes that the inclusion of such information is appropriate.

For the reasons stated above, OHCA's decision to permit the submission of evidence, including rebuttal evidence, from TSH is justified and appropriate and OHCA should deny Applicants' motion to strike testimony relating to L&M's CON application.

Respectfully submitted,

THE STAMFORD HOSPITAL

BY _____

Carolyn R. Linsey
Stephen M. Cowherd
Jeffers Cowherd P.C.
55 Walls Drive
Fairfield, CT 06824
Tel.: 203-259-7900
Fax: 203-259-1070
clinsey@jeffers-law.com
scowherd@jeffers-law.com
Its Attorneys

CERTIFICATE OF SERVICE

This is to certify that a true and accurate copy of the foregoing was sent by electronic mail this 17th day of July 2012 to:

Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.
265 Church Street
New Haven, CT 06510
jgroves@uks.com

Jean Ahn
System Director
Yale-New Haven Hospital
Planning & Business Development
20 York Street (Howe 3)
New Haven, CT 06504
jean.ahn@ynhh.org

Carolyn R. Linsey

BEFORE THE OFFICE OF HEALTH CARE ACCESS DIVISION OF THE DEPARTMENT OF PUBLIC HEALTH	:	Docket No. 12-31748
PROPOSAL TO ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM WITHOUT ONSITE SURGICAL BACKUP AT GREENWICH HOSPITAL	:	July 17, 2012

Rebuttal of Sharon Kiely, M.D. to Testimony of
Marna Borgstrom, Christopher Howes, M.D. and Frank Corvino

I am submitting this testimony in rebuttal to various statements made in the July 12, 2012 pre-filed testimonies of Marna Borgstrom, Frank Corvino and Dr. Christopher Howes.

Rebuttal of Ms. Borgstrom's Testimony

With regard to Ms. Borgstrom's testimony, beginning at page 629 she discusses at considerable length the credentials of the Yale New Haven Heart and Vascular Center (YNHHVC) and its personnel, and its ranking for cardiac services in U.S. News and World Report. We agree that YNHHVC, YNHH and their cardiology specialists have the requisite capabilities and experience to assist its affiliate, Greenwich Hospital, with the development of the proposed satellite elective angioplasty program.

However, just because something can be done does not mean that it should be done. YNHH and YNHHVC will not bring a superior level of expertise or experience to the service area. The region's two existing elective angioplasty providers, The Stamford Hospital (TSH) and White Plains Hospital (White Plains) are affiliated with the New York Presbyterian Hospital of Columbia and Cornell (NY Presbyterian), a world-renowned academic medical center which was ranked substantially higher than YNHH in the most recent U.S. News and World Report rankings of cardiac hospitals (NY Presbyterian was #6 and YNHH was #26).

Ms. Borgstrom's testimony also suggests that the need for another elective angioplasty program in Southwestern Connecticut is established, in large part, by the "telephone survey" conducted by Ms. Hamson. This is indeed a flawed methodology as there is a conspicuous lack of information regarding the nature of this purported survey, the underlying assumptions of respondents or statistical controls. This leaves little doubt of its self-serving nature and the level of credibility it should be accorded.

Finally, Ms. Borgstrom, through her rebuttal testimony, references the discussions between TSH and YNHHVC/Greenwich Hospital regarding a possible collaboration. It is true that there were discussions and that a collaboration ultimately did not come to fruition. However, Ms. Borgstrom misstates the series of events leading up to the termination of discussions and the reason why TSH did not continue to pursue the collaboration.

It should be noted that TSH regularly assesses opportunities to collaborate with other providers to improve the delivery and coordination of care in its service area. In fact, there is a Board-designated task force that meets regularly to assess the market and identify potential opportunities. Greenwich Hospital asked TSH to support its CON application for an elective angioplasty program. TSH responded that this could only be considered within the context of a regional collaboration.

Subsequently, TSH, Greenwich Hospital, and Yale New Haven Health began exploring potential collaboration opportunities to better coordinate heart and vascular care in the region. After a series of discussions, an outline of principles and draft letter of intent were prepared by YNNH for review by TSH in order to conceptualize what a collaboration might look like. As set forth in the letter of intent, the parties were to keep any information furnished to one another

confidential and not make any public statement or comment regarding their discussions without mutual consent.

Contrary to Ms. Borgstrom's assertion, David Smith never told the parties that the terms of the draft letter of intent were acceptable to TSH. Mr. Smith did tell the parties that the draft addressed TSH's initial concerns regarding the collaboration, but he was clear that TSH felt an obligation to continue to explore opportunities with its current partner, New York Presbyterian Health Care System, to improve delivery and coordination of care. He also informed Yale's representative that time did not permit TSH to evaluate the preliminary conceptual framework as well as hold the necessary discussions with NY Presbyterian to see if its existing partnership could be enhanced prior to Greenwich/Yale proceeding with the hearings on this CON Application. TSH asked the Applicants to withdraw this CON Application. The Applicants declined and TSH informed them that it would oppose the proposed competing program.

Rebuttal of Dr. Howes' Testimony

Dr. Howes concludes his testimony by stating that "[w]*e have reached the point in time where the proposal can and should be approved. Earlier barriers have been removed and patients and physicians seek these services at Greenwich Hospital.*" Notwithstanding this proclamation, Dr. Howes has clearly chosen to ignore the largest and most important barrier, which existed in 2009 when Greenwich Hospital was most recently denied an elective angioplasty program, and which continues today – the lack in growth in PCI volume.

YNHH and Greenwich Hospital do not refute but apparently refuse to acknowledge the widely-accepted data showing that PCI volume has been flat to declining in the service area. Rather, the Applicants have based their projected volumes on a series of tenuous assumptions

and misleading information. Some of the more puzzling aspects of Dr. Howes' testimony include:

1. Greenwich Hospital and YNHH's projecting higher volumes now than were projected in 2009 despite the fact that the White Plains angioplasty program has been added to the service area since that time.

2. Greenwich Hospital and YNHH's projecting higher volumes now than were projected in 2009 despite the fact that the number of elective angioplasty cases that Greenwich Hospital has transferred or referred to another facility has dropped each year since that time.

3. Greenwich Hospital and YNHH's claim that TSH and Greenwich Hospital serve different patient populations even though the eight Connecticut towns identified in the Greenwich Hospital Service Area are the same as those identified by Stamford Hospital in its approved 2006 CON to establish a full-service cardiac program.

4. Greenwich Hospital and YNHH are basing their volume projections, in part, on a representation from two interventional cardiologists (Dr. Monsen of NY Presbyterian and Dr. Newman of WestMed Medical Group) who have indicated that, combined, they could bring between 80-105 angioplasty cases to Greenwich Hospital each year (see letters attached to Dr. Howes' testimony).

In support of item 3 above, Dr. Howes refers to Table 2 on page 670 of his testimony as evidence that of the top 20 TSH attending physicians, only one had any admission volume at Greenwich Hospital. Of course, what Dr. Howes fails to mention is that 10 of the physicians listed on Table 2 are Hospitalists who are employed by TSH, do not have offices in the community, and whose job it is to act as attending physicians for unassigned patients whose community physicians do not want to follow the patient into the hospital or who do not have admitting privileges at TSH. Accordingly, these physicians have no opportunity to refer patients outside of TSH. In addition, another physician, Dr. Coady, is a cardiac surgeon. Since Greenwich does not have a cardiac surgery program, he would have no reason to admit patients there.

Item #4 is also emblematic of the serious flaws in the applicant's volume projection methodology. First, it is must be noted that WestMed (then known as The Westchester Medical Group) provided a similar letter in support of Greenwich Hospital's 2009 CON application (see letter attached hereto as Exhibit A). At that time, WestMed represented that it would shift approximately 100 cases to Greenwich Hospital, whereas in 2012 that number fell to 50-75 (at best, a 25% reduction). This would further support the decline in PCI volume from 2009 to present.

Including the volume promised by these physicians in the projections is also misleading, since it merely reflects shifting cases from an existing provider. It does nothing to substantiate the need for the additional PCI program. As stated by Dr. Newman in his letter in support of this application, "*I estimate that we would complete 50-75 angioplasties at Greenwich Hospital that **we currently treat at a hospital outside of Connecticut.***" (emphasis added).

Relying on such promises is tantamount to building a house of cards. These physicians are under no contractual obligation to transfer cases to Greenwich Hospital, and Greenwich Hospital would have no recourse should these physicians decide to direct their patients elsewhere or should there be a change in the structure or ownership of the physician practice. Evidence of changing allegiances of referring doctors is also evidenced by Dr. Monsen's letter of support. Three years ago, Dr. Monsen was affiliated with Westchester Medical Center; today he is a member of NY Presbyterian Hospital. Given the current economic climate and the significant increase in the merger and acquisition of physician practice groups, any promises of future referrals are illusory at best, and should not be given serious consideration when determining a Certificate of Need application.

Rebuttal of Frank Corvino's Testimony

Mr. Corvino states on page 682 of his testimony that "*I want to emphasize that this proposal is all about patient care and patient access.*" As evidenced on page 15 of the CON Application, this statement is inaccurate. In fact, Greenwich and YNHH put forth three reasons to support its contention of public need. Admittedly, two of those reasons were: (1) to improve local access to elective angioplasty care at Greenwich Hospital; and (2) to improve the quality of care of elective angioplasty services provided to Greenwich Hospital service area patients. However, it is the third reason that is the most telling of the true nature of the CON Application and why Greenwich Hospital is seeking an elective angioplasty program. Simply put, it's about money.

Therefore, I respectfully submit that, based on the 2011 ACCF/AHA/SCAI Guideline, which flatly states that financial considerations are inappropriate in determining public need in this context, OHCA deny this CON Application.

EXHIBIT A

000120



The Westchester Medical Group

SIMEON A. SCHWARTZ, M.D.
PRESIDENT

November 14, 2008

Commissioner Cristine Vogel
Office of Health Care Access
MS # 13 HCA
410 Capital Avenue
Hartford, CT 06134-0308

Dear Commissioner:

On behalf of the Westchester Medical Group, I am writing this letter to support the application for Elective PCI at Greenwich Hospital. Over the past several years a growing number of physicians from our practice are on staff at Greenwich Hospital and many of our patients seek their hospital based services there.

An elective PCI service at Greenwich Hospital will provide our cardiac patients with choice and local access to high quality interventional cardiology services. The ability to provide elective angioplasty will also improve continuity of care for patients at Greenwich Hospital.

The Westchester Medical Group projects that on an annual basis there would be 200 cardiac catheterization cases and 100 elective angioplasty cases performed on our patients at Greenwich Hospital.

We urge you to approve this proposal.

Thank you.

Sincerely,

MD

Simeon Schwartz, MD
President

THE WESTCHESTER MEDICAL GROUP, P.C. • 210 WESTCHESTER AVENUE, WHITE PLAINS, NEW YORK 10604
TEL. (914) 682-6404 • FAX (914) 457-1440 • sschwartz@westchestermed.com

WESTCHESTER MEDICAL CENTER NEW YORK MEDICAL COLLEGE
DEPARTMENT OF MEDICINE
DIVISION OF CARDIOLOGY

November 6, 2008

Commissioner Cristine Vogel
Office of Health Care Access
MS # 13 HCA
410 Capital Avenue
Hartford, CT 06134-0308

Dear Commissioner:

I am writing this letter to express my support for the proposed elective angioplasty program at Greenwich Hospital. An elective PCI service at Greenwich Hospital would provide patients in the region with choice and greater access to interventional cardiology services. In addition, this program will improve continuity of care to cardiac patients at Greenwich Hospital.

Our practice, which is located predominantly in the immediately adjacent geographic region of Westchester County is made up of 40 physicians in a single specialty cardiovascular practice. It is one of the largest single specialty groups in the region, if not the East Coast. We presently perform approximately 1500 coronary interventions per year. Many of our patients live very close to Greenwich Hospital. I am sure that a number of them would prefer Greenwich Hospital over the Westchester County Medical Center in Valhalla, New York for their coronary interventions if an elective program were in existence. Presently, the Westchester Medical Center is the only local facility that can perform both emergency and elective PCI. Adding an elective PCI program to Greenwich Hospital would improve access and choice for a significant group of our patients.

We urge you to approve this proposal.

Yours very truly,

Craig Hjemdahl-Monsen, M.D.
Director, Interventional Cardiology
Associate Chief, Division of Cardiology
Westchester Medical Center
CHM:db

Westchester Medical Center
Cardiology Division, Valhalla, NY 10595 (914) 493-8811
19 Bradhurst Avenue, Hawthorne, NY 10532 (914) 593-7800
FAX (914) 593-7857

BEFORE THE OFFICE OF HEALTH CARE ACCESS DIVISION OF THE DEPARTMENT OF PUBLIC HEALTH	:	Docket No. 12-31748-CON
IN RE APPLICATION OF YALE-NEW HAVEN HOSPITAL AND GREENWICH HOSPITAL TO ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM AT GREENWICH HOSPITAL	:	July 17, 2012

Rebuttal Testimony of Dr. William A. Gray

I would like to address some of the statements made by Dr. Howes in his pre-filed and rebuttal testimonies and by Dr. Cabin in his pre-filed testimony.

First, I would like to address statements made by Dr. Howes. On page 668 of his pre-filed testimony, he states that the 2011 ACCF/AHA/SCAI Guideline along with the CPORT-E study results "essentially end the debate over the safety of elective angioplasty programs without onsite cardiac surgery as long as programs adhere to the SCAI program requirements." This statement is a clear mischaracterization of the Guideline and the study results.

In addition, Dr. Howes, on page 761 of his rebuttal testimony, goes on to cite language from page 5 of the 2012 ACCF/SCAI Expert Consensus Document Update stating that

> It is generally believed that elective and primary PCI are permissible in sites without cardiovascular surgery, if there is strict adherence to national guidelines. In particular, there must be a documented working relationship with a larger facility with cardiovascular surgical services and an emergency transportation system operative.

What Dr. Howes fails to mention in providing the above two excerpts is that the 2012 ACCF/SCAI Expert Consensus document also states that performance of elective PCIs without on-site surgical back-up "remains controversial," especially when other active PCI programs are located in the same geographic area. 2012 ACCF/SCAI Expert Consensus Document Update, p.

197 (page reference is to Exhibit 4 of my Pre-filed Testimony). He also fails to mention that the same 2012 ACCF/SCAI Expert Consensus document states that

> there is a declining volume of PCI despite the improvement in outcomes from stent technology and consistent with a better appreciation of which procedures provide optimal benefit to patients. These types of studies suggest maturation of the technology so that further expansion may be limited despite concerns regarding a need for more procedures in the aging population. To this end, some have called for a moratorium on allowing any further expansion of PCI services, especially to low-volume facilities without cardiovascular surgical backup.

2012 ACCF/SCAI Expert Consensus Document Update, p. 197. Finally, he also omits from his testimony the notion that the 2011 ACCF/AHA/SCAI Guideline states that it is only reasonable to consider elective angioplasty programs without on-site cardiac surgery if such programs will "clearly fill a void in the healthcare needs of the community." *See* ACCF/AHA/SCAI Guideline, p. 164 (page reference is to Attachment VI of Applicants' CON Application)).

Given these statements, it is misleading for Dr. Howes to state that the 2011 Guideline and CPORT-E study "essentially end the debate" on this point. The debate may be ended with regard to those programs that will fill a void in the healthcare needs of the community and will improve access to a higher level of care than would otherwise be available, but none of the 2011 Guideline, the 2012 Expert Consensus document or the CPORT-E study in any way endorses duplicative elective angioplasty programs located close to established, high-quality providers with existing capacity. As TSH has said time and again, another elective PCI program in lower Fairfield County will not improve access to cardiovascular care – it will merely shift the volume in the service area from existing programs to a new program, and, in doing so, jeopardize the quality of care rendered by each program. Furthermore, it does not matter that a proposed program intends to strictly adhere to national guidelines if there is not a need for the proposed

program in the first place (*i.e.* if the program will not fill a void in the healthcare needs of the community).

I would also like to state that I did not indicate that I believed Applicants' CON application included the position that elective angioplasty without onsite cardiac surgery is preferred over sites with cardiac surgery. *See* Dr. Howes Rebuttal Testimony, p. 762. I do not believe any cardiac physician would take such a position. I merely indicated that it is only reasonable to consider an elective angioplasty program without onsite cardiac surgery back-up if it will "clearly fill a void in the healthcare needs of the community" and will "improve access to a higher level of cardiovascular care than would otherwise be available." *See* 2011 ACCF/AHA/SCAI Guideline, p. 164; 2012 ACCF/SCAI Expert Consensus Document Update, p. 197; Pre-filed Testimony of Dr. William A. Gray, pp. 5, 7. Here, as we have previously established, there is no such void and, with high-quality programs in the service area already providing the service, it can hardly be stated that the proposed program will improve access to a higher level of care than is already available.

Finally, with regard to page 762 of Dr. Howes' rebuttal testimony, NYP/C's support for White Plains Hospital's program filled a void in the healthcare needs of the community by providing Westchester County with a second, local elective angioplasty program. The Teaneck, New Jersey program and service areas also involved unique factors which are not replicated here.

I would also like to briefly address statements made by Dr. Cabin in his pre-filed testimony. Like Dr. Howes, Dr. Cabin emphasizes Applicants' intent to strictly adhere to the SCAI facility and personnel requirements incorporated into the 2011 ACCF/AHA/SCAI Guideline. *See* Pre-filed Testimony of Dr. Cabin, p. 636. However, like his colleague, Dr. Cabin

also fails to address the fact that a proposed program should only be approved if it will fill a void in the healthcare needs of the community, regardless of whether it can meet the SCAI requirements or not, as I discuss above. Furthermore, Dr. Cabin neglects to mention the risks inherent in angioplasty procedures which are discussed right in the 2011 ACCF/AHA/SCAI Guideline – for example, procedural and periprocedural MI, PCI-related stroke and vascular complications such as access site hematoma and coronary perforation, as well as the need for coronary artery bypass graft (CABG) surgery in some cases. *See* 2011 ACCF/AHA/SCAI Guideline, p. 159. The previous 2005 ACC/AHA/SCAI Guideline Update stated directly that a "small but real fraction of patients undergoing elective PCI will experience a life-threatening complication that could be managed with the immediate onsite availability of cardiac surgical support but cannot be managed effectively by urgent transfer." 2005 ACC/AHA/SCAI Guideline Update, p. 78 (page reference is to Exhibit 2 of my Pre-filed Testimony). These risks have not been eliminated, and they cannot be ignored.

YALE NEW HAVEN HEALTH

RECEIVED
JUL 17 2012
OFFICE OF HEALTH CARE ACCESS

July 16, 2012

Joanne V. Yandow
Hearing Officer
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P. O. Box 340308
Hartford, CT 06134

Re: ***Certificate of Need Application (CON); Docket Number 12-31748***
Proposal to Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital

Dear Hearing Officer Yandow:

Please find enclosed an original and six (6) copies of our rebuttal testimony and procedural motions for tomorrow's public hearing on July 17, 2012.

We will bring signed copies of the rebuttal testimony to the hearing.

Thank you in advance for your time and effort on this critically important CON application.

Sincerely,

Gayle L. Capozzalo
Executive Vice President, Strategy and System Development

Enclosures

Copy to: Stephen M. Cowherd, Jeffers Cowherd P.C.

Yale-New Haven Hospital
Greenwich Hospital

Proposal to Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital

Docket Number: 12-31748-CON

Rebuttal Testimony

July 16, 2012

Certificate of Need Application Docket Number: 12-31748
Greenwich Hospital and Yale New Haven Hospital Elective Angioplasty Program
Rebuttal Testimony

Marna Borgstrom

I would like to begin by addressing some of the statements made by Dr. Sharon Kiely which are either incorrect or misleading.

- It is ironic that Dr. Kiely would raise the need for collaboration among Stamford, Greenwich and Yale-New Haven Hospitals in her testimony given Stamford Hospital's refusal to pursue such collaboration. Yale-New Haven Heart and Vascular Center (YNHHVC) began to discuss collaboration opportunities with Stamford Hospital in March 2012. There were a total of six telephone calls (3/9/12, 4/25/12, 5/4/12, 5/25/12, 6/21/12, and 7/3/12) and multiple email exchanges between Ms. Gayle Capozzalo, our Executive Vice President for Strategy and System Development, and Mr. David Smith, Stamford Hospital's Senior Vice President of Strategy and Chief Strategy and Network Development Officer. In addition, there was a face-to-face meeting held on May 22, 2012 with several representatives including cardiac surgeons and cardiologists from all three hospitals. Stamford Hospital representatives clearly communicated that they were unhappy with the level of support from New York Presbyterian (NYP) and were very interested in developing a relationship with YNHHVC. It was agreed by all three hospitals that there were many opportunities for collaboration, and in fact, an outline of principles was developed as well as a draft letter of intent (LOI) for the arrangement (See Attachment I). We were told by Mr. Smith, that the terms as outlined in the LOI were acceptable to Stamford Hospital. These terms included as an initial focus initiating an elective PCI program at Greenwich Hospital (Attachment I, Principles, Section 3). Our follow-up calls to Mr. Smith regarding the arrangement and the elective angioplasty program at Greenwich Hospital were abruptly discontinued on July 3, 2012, when Mr. Smith informed us that they will be opposing our CON application because he said there was not time to meet with NYP to discuss the concept of transferring an affiliation to

YNHHVC. Ms. Capozzalo will be in attendance at the hearing and can address her discussions with Stamford Hospital under oath.

YNHHVC and Greenwich Hospital fully intended to collaborate with Stamford Hospital in the area of cardiac care and had sought to help strengthen Stamford's open heart surgery program, which is suffering from low volume. The presence of Yale faculty based in southwestern Connecticut communities along with the YNHHVC's clinical program support and quality improvement systems would have significantly improved Stamford Hospital's cardiac surgery program's credibility, which is at significant risk, evidenced by the fact that they performed only 80 open heart cases last year and are on track to perform approximately 50 this fiscal year based on 6 months volumes from CHIME (see Table below).

Connecticut Inpatient Volume for Open Heart Surgery by Hospital for FY 2010 - FY 2012 (6 Months)				
Hospital	**FY 2010**	**FY 2011**	**FY 2012***	
Bridgeport	152	127	140	
Danbury	181	182	150	
Dempsey	67	71	72	
Hartford	793	801	702	
HSR	343	313	300	
St. Francis	867	781	734	
St. Mary's	118	100	114	
St. Vincent's	239	223	200	
Stamford	54	80	54	
Waterbury	109	102	104	
YNHH	869	800	820	
TOTAL	**3,792**	**3,580**	**3,390**	
Source: CHIME				
*FY 2012 annualized based on 6 months actual				

It is clear that YNHHVC acted in good faith to create a cost effective care model for cardiology services in the Stamford and Greenwich area, but it is Stamford Hospital that does not want to collaborate.

- I would also like to point out that Stamford Hospital's extremely low cardiac surgery volume does not come close to meeting professional society recommendations or OHCA's own standards as outlined in the Agreed Settlement for Stamford Hospital (DN: 04-30374-CON) (see Attachment II). Condition #8 states:

  > "If TSH does not perform 125 OHS procedures within twelve months of the initiation of the OHS program, TSH shall submit monthly reports of OHS arrayed by physician to OHCA until such time as these volumes are met by TSH. **If these volumes are not met for a period of <u>two consecutive 12-month periods</u>, TSH's OHS program <u>shall be terminated</u>..."**

  We are not aware that this condition has been modified by OHCA based on a review of OHCA's website and modifications pursued by Stamford Hospital.

  According to OHCA's own data (see Attachment III) through 2010, Stamford Hospital has never come close to reaching 125 open heart surgeries in a year. In fact, it appears that its highest volume was 80 in FY 2011. As previously shown above, based on 6 months of CHIME data for 2012, they are on track to perform about 54 surgeries this year, less than half of the guidelines requirement. These low volumes have been of concern to YNHHVC physicians and we suspect have contributed to fewer referrals to their surgery program. Low surgical volume can also affect the physicians' decisions to transfer patients to Stamford for elective angioplasty, given the uncertain quality of the surgical backup available at that site. Such low surgical volumes present a significant quality concern as identified by the American College of Surgeons which published that an annual volume of 100-125 is **<u>necessary</u>** from a quality standpoint and this requirement has also been noted by OHCA in its draft Cardiac Services section of the new State Health Plan (see Attachment IV).

- Dr. Kiely states that OHCA should not approve Greenwich Hospital's proposed elective angioplasty program because elective angioplasty volumes are flat in Connecticut and the proposed service area. Stamford Hospital did not previously view flat or declining volumes as problematic when it pursued its full service cardiac program CON. At that time, their own cardiac catheterization volumes had been in decline as noted in OHCA's

Agreed Settlement's Findings of Fact #11 (previously referenced as Attachment II); statewide inpatient cardiac catheterization and angioplasty volumes had declined steadily between 2003 and 2005, as shown in Dr. Kiely's own testimony and open heart surgery volumes had also been declining between 2002 and 2005 as shown in the OHCA table and graph below.

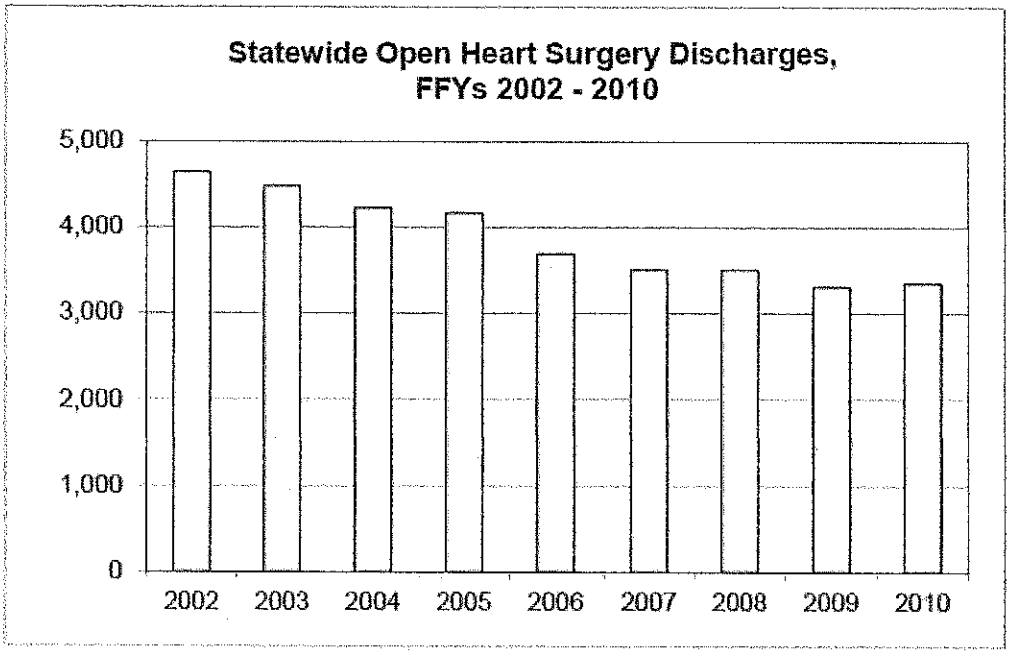
Table 3A: Open heart surgery discharges by provider, FFYs 2002-2010

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	FFY 06-10 (5-yr)% Change	FFY 08-10 (3-yr)% Change	FFY 09-10 (1-yr) % Change
Bridgeport	345	313	268	263	175	194	106	96	136	-22%	28%	42%
CT Children's								6	4	n/a	n/a	na
Danbury	0	0	0	114	177	121	162	148	174	-2%	7%	-9%
Dempsey	115	134	121	174	97	70	84	56	58	-40%	-31%	-33%
Hartford	901	844	756	726	742	685	671	652	695	-6%	4%	-3%
St. Francis	1,239	1,299	1,311	1,188	998	990	912	845	820	-18%	-10%	-7%
St. Mary's	0	0	0	19	72	100	85	114	112	56%	32%	34%
St. Raphael	761	687	617	510	353	342	321	299	318	-10%	-1%	-7%
St. Vincent's	310	296	293	291	259	232	257	219	195	-25%	-24%	-15%
Stamford	0	0	0	0	0	0	75	73	46	n/a	-39%	-3%
Waterbury	0	0	0	20	117	110	134	110	98	-16%	-27%	-18%
Yale	973	905	860	861	704	664	698	691	697	-1%	0%	-1%
Total	**4,644**	**4,478**	**4,226**	**4,166**	**3,694**	**3,508**	**3,505**	**3,309**	**3,353**	**-9%**	**-4%**	**-6%**

Source: CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database.

ICD-9-CM Procedure Codes: 35.10-35.28 and 36.10-36.19

Please note: unduplicated counts utilizing all procedure codes



All of these related and declining volumes did not seem relevant to Stamford Hospital or OHCA as a full service cardiac program was proposed and approved. Stamford Hospital expended more than $8 million dollars in capital expenses to develop their angioplasty and surgery program in a declining volume market (modified from the $5.4 million they estimated at the time of their original CON filing). They based their need on such factors as improved accessibility, continuity of care and improved quality. These are the same reasons why Greenwich Hospital seeks to offer elective angioplasty and can do so without any capital expense.

- Dr. Kiely's testimony includes conflicting statistics and information about New York programs. First, I would like to highlight the following statement from OHCA's 2010 Declaratory Ruling, Docket Number: 09-31433-DCR, which specifically states that:

  "...OHCA only has the authority to act on behalf of the state within the parameters of its enabling statutes and its jurisdiction is limited to health care facilities located within the state. Thus, OHCA has no jurisdiction over health care facilities located in other states just as those states have no authority to regulate facilities located within Connecticut."

Given the language from the above mentioned Declaratory Ruling, as well as the OHCA enabling statutes, it is clear that the agency has no jurisdiction over New York hospitals and their positions regarding this CON application are not relevant. This is likely why White Plains Hospital has submitted its arguments through Stamford Hospital rather than petitioning for status itself.

Even if one considers the information presented about and from White Plains Hospital, there are inconsistent and incorrect statements provided that call into question its credibility. Dr. Kiely states that White Plains Hospital performed 165 total PCIs in FY 2011 in her written testimony and attached a patient origin volume report with the same statistic. Ms. Fox states in her letter that in FY 2011, 290 PCIs were performed at White Plains Hospital. Additionally, Ms. Fox states in her letter that "two hospitals that serve Westchester County residents – Sound Shore Medical Center in New Rochelle and St. John's Riverside in Yonkers -...have been unsuccessful in attempts to gain regulatory approval from the New York Department of Health to provide elective angioplasty services." This statement is inaccurate and misleading. As shown in Attachment V, the email correspondences between Ms. Nancy Rosenthal, Senior Vice President – Health Systems Development at Greenwich Hospital and Anna Colello, Esq., Director of Regulatory Compliance and Cardiac Services Program at the New York State Department of Health, St. John's Riverside withdrew its application in April of this year and the Sound Shore application remains open.

It is also worth noting that within the email correspondences just referenced, New York State currently has 14 hospitals operating elective angioplasty programs without onsite cardiac surgery and one additional program was recently approved but has not yet opened.

- Dr. Kiely claims that flaws exist in our methodology for estimating cardiac catheterization and angioplasty volume. As OHCA is aware, developing projected volume for any proposed service involves multiple considerations and OHCA does not prescribe to a specific methodology for projecting need. Our projections include the

historical volume of emergency angioplasty, transferred (from Greenwich Hospital) elective angioplasty cases, cases referred to YNHH initially, as well as a conservative estimates provided by Greenwich Hospital cardiologists during a telephone survey conducted by Greenwich Hospital's Director of Planning, Ms. Nancy Hamson. Ms. Hamson personally spoke with the medical cardiologists on the staff of Greenwich Hospital, who are not active at Stamford Hospital and obtained their volume estimates. Ms. Hamson will be in attendance at the hearing and can address her methodology under oath. These physicians currently bypass Greenwich Hospital for cardiac catheterization referrals when they suspect an angioplasty procedure may be required, to save their patients from having to undergo two invasive procedures. They do not refer cases to Stamford Hospital. In addition, we have two interventional cardiologists who subsequent to the submission of the CON application have come forward and put in writing their intention to bring 80 – 105 angioplasty cases per year to Greenwich Hospital. These two physicians do not perform invasive cardiac procedures at Stamford Hospital. Their volumes were not even considered when the projections were developed and therefore demonstrate the conservative nature of our projections.

- Dr. Kiely states that since Greenwich Hospital's emergency angioplasty volume has not increased, there is no need for an elective angioplasty program. As I am sure Dr. Kiely is aware, the criteria for emergency angioplasty are very narrow and apply to only a small percentage of patients. The emergency angioplasty patient population is separate and distinct from the elective angioplasty patient population. Dr. Kiely's own testimony including data from White Plains Hospital shows that in FY 2011, the hospital performed 40 emergency angioplasty cases but 250 elective cases. Their emergency volume is quite similar to Greenwich Hospital's.

- I would also like to comment on Dr. Kiely's reference to previous testimony given by YNHH representatives at CON hearings for Danbury Hospital, Waterbury/St. Mary's Hospitals, Norwalk Hospital and Stamford Hospital. At the time of those hearings, which date back almost 10 years, it was clear to us that cardiac surgery volumes had been and were going to continue to decline. That certainly has proven to be true and

we continue to believe as we did then, that there was no need for additional open heart surgery programs. In the case of angioplasty, OHCA approved several emergency angioplasty programs without onsite cardiac surgery and these programs along with many others in the United States, as evidenced by the research we included in our application, have been shown to be safe for patients. In fact, our view regarding angioplasty has evolved as discussed in previously submitted testimony based on evidence described in medical literature, changes to clinical practice guidelines, and the opinions of our excellent cardiovascular physicians.

- Finally, Dr. Kiely's testimony references and attaches Lawrence & Memorial Hospital's recently submitted CON for elective angioplasty. This CON application is completely irrelevant to our application for the following reasons:
    - The CON is incomplete and should not be recognized by OHCA in this proceeding; and
    - The CON is for a program located approximately 90 miles away and serves a completely different service area.

We have separately moved to strike all references of this submission from Stamford's testimony.

The foregoing is my sworn testimony.

Marna Borgstrom
Chief Executive Officer
Yale-New Haven Hospital

ATTACHMENT I

Capozzalo, Gayle

From: Capozzalo, Gayle
Sent: Wednesday, June 20, 2012 7:43 AM
To: Smith, David
Cc: Leary, Tucker; Lombardi, Marc; Aseltyne, Bill
Subject: Cardiology
Attachments: Principle document 06.20.2012.doc; 2012 06 19-LOI-Stamford GH Interventional Cardiology-A-LRSD(ML).docx

David. Hope all is well. I am sorry that this took so long to get revised. Attached please find a new principle document that has been edited based on our discussions. I will call you this afternoon to discuss next steps. Gayle

Gayle Capozzalo
Executive Vice President
Strategy & System Development
Yale New Haven Health System
789 Howard Avenue
New Haven, CT 06519
203-688-2605

DRAFT –June 19, 2012
Confidential: Attorney Client Privilege

Principles
for
Yale-New Haven Heart and Vascular Services at Stamford Hospital and Greenwich Hospital

I. **Mission**

- Create a cost effective care model utilizing the most appropriate location to provide convenient patient access to safe, high quality care
- Develop a sustainable clinical business model with appropriate professional and technical resources allocated to each program or modality
- Maintain the highest standard of care and superior outcomes through comprehensive staff training and QA/PI programs
- Offer technological advances as these become economically and programmatically feasible to the greater Stamford and Greenwich communities through qualified physicians.
- Monitor operational performance to maintain regulatory compliance (CMS/DPH/TJC) and improve patient satisfaction
- Support other elements of the non-profit missions of Stamford Hospital, Greenwich Hospital, Yale School of Medicine and Yale-New Haven Hospital, respectively

II. **Participants**

- Stamford Hospital, as the principal provider and Connecticut Department of Health license holder for technical services rendered in Stamford, Connecticut, will also be responsible for the Conditions of Participation for CMS certification, where applicable.
- The Stamford Hospital Medical Staff, in particular, the employed CT surgeons, Cardiac Interventionalists and primary care cardiologists will participate in various cardiovascular service offerings.
- Greenwich Hospital, which may share coverage of the PAMI/PCI programs with Stamford Hospital and whose cardiologists may refer appropriate CT surgery cases to Stamford Hospital
- The Greenwich Medical Staff, in particular, the employed and independent Cardiac Interventionalists and the primary care cardiologists will participate in various cardiovascular services offerings
- The Yale-New Haven Heart and Vascular Center (YNHHVC), a virtual organization of Yale-New Haven Hospital (YNHH) and Yale University, that integrates the professional and technical service of select Yale University School of Medicine

(YSM) and YNHH Departments to provide care and clinical management services for the proposed programs.

III. **Scope of Strategic Partnership**

The following array of cardiovascular services may be offered to the greater Stamford and Greenwich communities. The initial focus will be on initiating an elective PCI program at Greenwich and strengthening Stamford CT Surgery building on the existing team and program, followed by the development of a heart failure program at Stamford and Greenwich. Clinical protocols and consultation systems will be developed for each service or program to address basic or tertiary services and low or high risk patients for each procedure.

PAMI at Stamford	PAMI at Greenwich	Elective PCI at Stamford	Elective PCI at Greenwich	Elective PCI at YNHH
Yale coverage potential	Yale Coverage	Yale coverage potential	Low risk	High risk and valves

Heart Failure/Cardiology at Stamford and Greenwich	Heart Failure/Cardiology at YNHH	CT Surgical Procedures at Stamford	CT Surgical Procedures at YNHH	Peripheral Vascular Procedures at Stamford	Peripheral Vascular Procedures at YNHH
Class A+B+C	Class C evaluations +D Transplant and VAD evaluations	CABG and valves	Minimally invasive, Transplant and, VAD	Basic	Advanced

- As a general principle, low and moderate risk interventional procedures will be performed at Greenwich under generally recognized criteria, unless patient insurance or personal preference directs another site of care.

- The presence of Yale faculty, based in the Southwestern CT communities coupled with Yale-New Haven Heart and Vascular clinical program support and PI/QA systems should enhance the program's credibility in the community of referring physicians and discerning patients.

- The CT Surgical Director at Stamford Hospital will discuss high risk cases with the YNHHVC CT Surgical Director and determine whether or not patients requiring cardiac surgery should be transferred to Yale-New Haven Hospital. The Y-Access transfer line may be employed for this purpose. Other coverage arrangements may be pursued in the future.

IV. **Physician Credentialing and Privileges**

All participating physicians performing these procedures must be members of the Stamford or Greenwich medical staff in good standing with delineated privileges for the proposed procedures. Minimum procedural volume requirements will be met by including procedures performed at all hospitals.

The hospitals will not limit participating physician eligibility for medical staff privileges based upon geographic considerations as long as comprehensive coverage is incorporated in the proposed service model.

V. **CON and Regulatory Approvals**

To the extent necessary, the Stamford Hospital CON will be amended to reflect this CT Surgery support.

VI. **Physician Employment, Revenue and Expense Allocations**

The entity that funds the cost of physician services will also provide a provider number for professional billing and receive the revenue credit. Physicians will assign their billing right to this entity. Each participating physician should have one employer to reduce tax liabilities and optimize personal benefit contributions. Participating physicians must abide by all principles and policies incorporated into this arrangement.

In certain subspecialties the most attractive candidates may prefer to be part of an academic medical center with access to new clinical trials, fellows and multidisciplinary specialists. The YNHHVC would recruit, if mutually agreeable, those physicians and deploy them at Stamford and Greenwich. YSM has created a clinician track without academic faculty ladder research expectations, which is appropriate for geographic full time physicians and for split and covering physicians.

Stamford and Greenwich would agree to exclusively obtain covering interventional and supporting surgical services from YNHHVC provided that CT Surgery and interventional coverage is maintained by YNHHVC. However, Stamford Hospital has sufficient coverage with two CT surgeons at this time.

Physician compensation should be at fair market value based on work RVUs, including stipends for night and weekend coverage, patient satisfaction and quality measures. Physicians should not have a financial incentive to perform a procedure at Greenwich, Stamford or YNHH so that care decisions may be made solely in the best interest of the patient.

VII. **Medical Directors**

Greenwich Hospital or Stamford Hospital and the YNH Heart and Vascular Center will jointly approve Surgical and Medical Directors. The Directors will have clinical management responsibilities for the program and a jointly approved position descriptions.

The Surgical and Medical Directors will have dual reporting relationships to the Chief of Surgery or Medicine/Chief of Staff at each hospital and to the Medical Director of the YNHHVC, Henry Cabin, M.D., and Surgical Director of the YNHVC, David Yuh, M.D.

VIII. **Branding/Marketing/Communications**

Stamford and Greenwich physicians who maintain voluntary or full-time faculty Yale appointment may reflect such in their practice profiles and on the Stamford and Greenwich website for physician search.

Recognizing that there will not be a discrete practice site of the Yale-New Haven Heart and Vascular Center with respect to the inpatient programs, Greenwich Hospital will represent

these services as the Yale-New Haven Heart and Vascular Center within the Hospital on its website, service line stationary and in community publications. Media advertising will require YNHH approval. Given the more limited direct clinical service provided by YNHHVC at Stamford Hospital this relationship will be initially described as a Stamford program affiliated with Yale-New Haven Heart and Vascular Center Any use of the brand will require YNHH approval. The parties will mutually decide if the branding relationship should be changed in the future.

A joint press release will be issued after formal agreement and any physician appointments. CME events will be organized for primary care physicians and other members of the Stamford and Greenwich medical staff. Participating physicians will support other Stamford and Greenwich community educational activities.

IX. Hospital and Program Staff Relationships

YNHHVC will assign an administrative officer to Stamford Hospital and Greenwich Hospital with matrix management responsibility for general management staff training, QA/PI programs and other YNHHVC duties under this agreement. Stamford and Greenwich will also designate an administrator responsible for local program development and operations. However, all on-site hospital staff responsible for the proposed services will be Stamford or Greenwich employees.

New clinical hospital staff will receive in-service training in the OR or Cath Lab YNHH. All employees will participate in periodic conference conducted by the Medical Directors and other YNHHVC specialists.

- All technical and nursing staff from the Stamford and Greenwich Hospital's OR and cardiac catheterization laboratories will participate in a mandatory education program consisting of didactic, one on one observational and hands on training. Training will include:
  - CT operating room equipment and procedures
  - Pump team training
  - Angioplasty equipment (guide catheters, guide wires and angioplasty catheters including balloons and stents)
  - Commonly used drugs
  - Assessment and monitoring of anticoagulation
  - Use of intra-aortic balloon pump equipment
  - Patient transfer
  - Items related to patient care before, during and after the procedure
- Hospital staff will also rotate through the YNHH OR and cardiac catheterization laboratory and shadow experiences in the CTICU, CCU and general floor units
- YNHHVC policies, protocols and procedures will be adopted by Stamford and Greenwich for program development, care management and staff training.

X. QA/PI Programs and Decision Support Tools

- The local cath lab conference will provide the foundation for full integration into the YNHHVC quality and safety improvement activities including monthly morbidity and mortality (M&M) conferences and quality indicator monitoring.

- Participation in YNHVC Surgical M&M and Heart Failure video conference will also be facilitated.

- Stamford and Greenwich will participate in the ACC benchmarking registry and Door to Balloon (D2B) benchmarking.

- Utilization and outcomes will be tracked by YNH Heart and Vascular Center and the Yale-New Haven Hospital Center for Outcomes Research and Evaluation (CORE) and provided to Stamford and Greenwich on a quarterly basis for ongoing quality improvement.

- Stamford and Greenwich may also participate in jointly approved state and national benchmarking projects.

- YNHH has piloted a patient consent tool that specifies risks of bleeding and other complications for use by Stamford and Greenwich nurses and the interventional attendings.

- IT interfaces will be enhanced, where feasible at Stamford. Greenwich Hospital will experience complete IT integration through Epic.

XI. **Fees**

An annual management fee of $250,000 will be paid by Stamford to YNHH for professional, management, training and QA/PI services described herein for which can be amended as additional programs are introduced. The management fee will include the achievement of quality indicators..

A more efficient coverage system may enhance the financial benefits of the programs. A review of service schedules and volume projections will be required to further this analysis.

XII. **Term and Amendments**

Stamford Hospital and Greenwich Hospital will agree to an exclusive arrangement with YNHH during the term of the agreement. A legally appropriate agreement will be developed with an initial five year term, with five year renewals. .

If this relationship becomes financially or clinically unstable or is in conflict with new regulations, the Participants agree to modify the agreement. Any unwind must minimize impact on care in the greater Stamford and Greenwich communities.

Additional services will be added after joint review of programmatic and financial feasibility. Most of the proposed services offering elements should not require a CON.

Draft June 19, 2012

YALE NEW HAVEN HEALTH

June ___, 2012

Stamford Hospital
30 Shelburne Road
Stamford, CT 06904
Attention: [_____]

Re: ***Letter of Intent Regarding Proposed Affiliation with Greenwich Hospital, Yale-New Haven Hospital and Yale University relating to Interventional Cardiology Services***

Dear [_____]:

Yale-New Haven Hospital ("***YNHH***") and Yale University, acting through its School of Medicine ("***Yale***") have long collaborated on various patient-care services, including cardiology services. Together, YNHH and Yale have established and supported the Yale-New Haven Heart and Vascular Center ("***YNHHVC***"), renowned for providing comprehensive cardiac and vascular care, including cardiac catheterization, emergency and elective angioplasty and open-heart surgery.

Greenwich Hospital has been affiliated with Yale-New Haven Hospital and the Yale New Haven Health System since 1996. Through this affiliation, Greenwich Hospital, YNHH and Yale collaborated to obtain regulatory approvals for Greenwich Hospital to provide, in addition to diagnostic cardiac catheterization services, primary angioplasty services for acute myocardial infarction ("***PAMI***") patients presenting with ST-segment elevation and left bundle branch blockage, with professional interventional cardiology services provided by Yale physicians (the "***Greenwich PAMI Program***"). Regulatory approval is currently being sought to expand this program to include elective angioplasty ("***Elective PCI***") services without open-heart surgery back-up.

Stamford Hospital currently provides a range of cardiovascular services, including PAMI, Elective PCI and open-heart surgery. A relationship with a quaternary center such as YNHH for surgical program support and consultation may strengthen Stamford Hospital's position and relationships with Greenwich Hospital cardiologists.

Each of YNHH, Yale, Greenwich Hospital and Stamford Hospital (each, a "***Party***" and, collectively, the "***Parties***") desire to enter into this letter of intent (this "***Letter of Intent***") to confirm their intent to collaborate to establish a cost-effective care model for heart and vascular patients that utilizes the most appropriate location to provide convenient patient access to safe, high quality care (the "***Collaboration***"). The Parties agree that the goal of the Collaboration is to ensure that patients can be cared for in the community when appropriate, but also have access to tertiary and quaternary care when medically required.

It is expressly understood and agreed that this Letter of Intent is only binding with respect to Section 2, Section 3 and Section 4. Any Party may, for whatever reason, terminate this Letter of Intent and further negotiations by written notice to the other Parties. In such event, there shall be no liability among the Parties hereto as a result of the execution of this Letter of Intent, any action taken in reliance on this Letter of Intent, or such termination, except as set forth in Section 2, Section 3 or Section 4.

1. Terms of Collaboration. Based upon the dialogue to date, attached as Exhibit A sets out the proposed principal terms of the Collaboration. During the Exclusivity Period (as defined below), the Parties will exercise good faith and use their reasonable efforts to negotiate and agree upon the terms and usual and customary covenants, conditions, indemnities, representations and warranties of the definitive agreements related to the Collaboration, all of which are to be generally consistent with the provisions of the Term Sheet. The parties acknowledge and agree that execution of any definitive agreements and consummation of the Collaboration may be subject to the approval of relevant government authorities, including the Office of Health Care Access, and agree to support each other's efforts in obtaining any such approvals.

2. Exclusivity. Each Party understands and agrees that it is a significant premise of its participation hereunder and agreement hereto that this Letter of Intent be exclusive as to the subject matter set forth above. Therefore, each Party agrees that for a period of **[six (6) months]** following the date hereof it will not (a) enter into any agreement (b) carry on or continue any discussions of any kind with a third party or (c) enter into negotiations concerning the subject matter of this Letter of Intent, and specifically, any affiliation relating to interventional cardiology or CT Surgery services in Fairfield County. Notwithstanding anything herein to the contrary, nothing in this Letter of Intent shall limit or restrict YNHH and Greenwich Hospital from collaborating to provide any services, including interventional cardiology services at facilities affiliated with the Yale New Haven Health System.

3. Confidentiality. In furtherance of the negotiations contemplated by this Letter of Intent, the Parties may request of each other certain information, some of which may be confidential. As a condition to, and in consideration for, each Party furnishing such information to the other Parties, each Party hereby agrees to treat the information furnished by the other Parties in accordance with the provisions of this Letter of Intent and to take or refrain from taking certain other actions as set forth herein.

For purposes of this Letter of Intent, the term "***Confidential Information***" means all information in whatever form furnished to any Party by or on behalf of any other Party, together with any other information concerning such other Party which has already been furnished to the Party receiving such information; provided that it does not include information which the Party receiving such information can demonstrate (a) is generally available to or known by the public other than as a result of disclosure by such Party or (b) was obtained by the Party receiving such information from a source other than the Party furnishing such information, provided that such source is not bound by a duty of confidentiality to the Party furnishing such information or another person or entity with respect to such information.

Each Party shall use Confidential Information solely to evaluate and consider a possible transaction among the Parties. No Party shall use any such Confidential Information to compete with or adversely affect the business or operations of the Party furnishing such information or its affiliates or those doing business with them, including the other Parties. Each Party shall keep the Confidential Information of each other Party strictly confidential and, except as authorized in this Letter of Intent, will not disclose or distribute the Confidential Information of the any other Party to any person or entity without the prior written consent of the Party furnishing such information. Each Party may disclose Confidential Information of the other Parties to such of its directors, officers, employees and agents (the "***Representatives***") who need to have the Confidential Information to participate in or contribute to the proposed transaction, so long as those Representatives agree to be bound by this Letter of Intent, and then only to the extent necessary to their participation or contribution. Each Party shall be responsible for any breach of this Letter of Intent by its Representatives.

Except as and to the extent mutually agreed in accordance with Section 4 hereof, or as required by law, no Party shall, and each Party shall direct its Representatives not to, directly or indirectly, make any public comment, statement or communication with respect to, or otherwise disclose or permit the disclosure of the existence of, this Letter of Intent or any discussions regarding a possible transaction between the Parties or any of the terms, conditions or other aspects of such transactions.

Upon request by any Party at any time, the other Parties shall promptly return to the Party furnishing such information the original and all copies of all non-oral Confidential Information furnished by such Party. Each Party shall, upon request of any other Party, certify as to its compliance with the preceding sentence.

4. Publicity. As the Parties evaluate the Collaboration, they shall also consult as to the propriety and need, timing, form and substance of any press release or other public disclosure (including without limitation disclosure to government regulatory agencies, government officials and community groups) related to the Collaboration. No such disclosure shall be made without the mutual consent of the Parties.

This Letter of Intent may be executed in counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument. Each Party acknowledges that in the event of the breach of this Letter of Intent by any Party, the non-breaching Parties shall be entitled to all remedies available at law or in equity for such breach.

* * *

If you are in agreement with the foregoing, please execute and return one copy of this Letter of Intent, whereupon each of the Parties shall be legally bound to the extent described herein under Connecticut law.

Sincerely,

YALE-NEW HAVEN HOSPITAL

By:_____
Richard D'Aquila
Chief Operating Officer

By: _____
Tucker Leary
Vice President
Heart & Vascular Center

YNHHS:
By: _____
Gayle Capozzalo
Executive Vice President

YALE UNIVERSITY

By:_____
Janet Lindner
Associate Vice President for
Administration

By:_____
Michael Berman, M.D.
Interim CEO, Yale Medical Group

By: _____
Henry Cabin, M.D.
Medical Director
YNHHVC

By:_____
David Yuh, M.D.
Section Chief, CT Surgery

Accepted and Agreed:

GREENWICH HOSPITAL

By:_____
Frank A. Corvino
President and Chief Executive Officer

STAMFORD HOSPITAL

By: _____
Brian Grissler
President and Chief Executive Officer

ATTACHMENT II

Office of Health Care Access
Certificate of Need Application

Agreed Settlement

Hospital:	The Stamford Hospital and New York Presbyterian Healthcare System, Inc.
Docket Number:	04-30374-CON
Project Title:	Establish Elective Angioplasty and Open Heart Surgery Program at The Stamford Hospital
Statutory Reference:	Sections 19a-638 & 639, Connecticut General Statutes
Filing Date:	August 15, 2005
Hearing Dates:	Public Portion: September 22, 2005 Technical Portion: October 6, 2005 and October 27, 2005
Commissioner & Presiding Officer:	Cristine A. Vogel
Agreed Settlement Date:	January 4, 2006
Default Date:	Not Applicable
OHCA Staff	Steven W. Lazarus Michael Sabados

Project Description: The Stamford Hospital ("TSH" and "Hospital") and New York Presbyterian Healthcare System, Inc. ("Applicants") propose the establishment of an elective angioplasty ("PCI") and open-heart surgery ("OHS") program, to be located at the Hospital, at a capital expenditure of $5,404,425.

Nature of Proceedings: On August 15, 2005, the Office of Health Care Access ("OHCA") received the Applicants' Certificate of Need ("CON") application seeking authorization to establish an elective angioplasty and open-heart surgery program, to be located at the Hospital, at a capital expenditure of $5,404,425. The Stamford Hospital is organized under the laws of Connecticut, and New York Presbyterian Healthcare System, Inc. is a corporation organized under the laws of the State of New York. The Hospital is a health care facility or institution as defined by Section 19a-630 of the Connecticut General Statutes ("C.G.S.").

Public hearings regarding the CON Application were held on September 22, 2005, October 6, 2005 and October 27, 2005. The Hospital was notified of the date, time, and place of the hearings and notices to the public were published prior to the hearings in *The Advocate* (Stamford) by OHCA. The hearings were conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the Connecticut General Statutes) and Sections 19a-638 and 19a-639, C.G.S.

Yale-New Haven Hospital, Bridgeport Hospital, and Greenwich Hospital collectively known as Yale-New Haven Heart Health Institute were granted Intervenor status with rights to cross-examine. St. Vincent's Medical Center was granted Intervenor status with the rights to cross-examine.

The Presiding Officer heard testimony from the general public, legislators, local officials and witnesses for the Hospital and Intervenors. In rendering this decision, the presiding officer has considered the entire record of the proceeding. OHCA's authority to review, approve, modify or deny this proposal is established by Sections 19a-638 and 19a-639, C.G.S. The provisions of these sections, as well as the principles and guidelines set forth in Section 19a-637, C.G.S., were considered by OHCA in its review.

Findings of Fact

Clear Public Need
Impact on The Hospital's Current Utilization Statistics
Proposal's Contribution to Accessibility and Quality of Health Care Delivery in the Region

1. The Stamford Hospital ("TSH" and "Hospital") is a not-for-profit, 305-bed acute care hospital located in Stamford, Connecticut. TSH, as an affiliate member of the New York Presbyterian Healthcare System ("System"). TSH provides a comprehensive array of services including: Medicine, Surgery, Obstetrics/Gynecology, Psychiatry as well as Medical and Surgical critical care units. *(Completeness Responses, Proposed Resolution, August 15, 2005, Exhibit 3 and Certificate of Need Application, August 15, 2005, page 1-3)*

2. The New York Presbyterian Healthcare System, Inc ("NYPHS") coordinates a system of hospitals and other healthcare institutions throughout the tri-state area, including The Stamford Hospital ("TSH") and New-York Presbyterian Hospital ("NYPH"). NYPH operates New York-Presbyterian Hospital/Columbia University Medical Center ("NYP/C") in affiliation with Columbia University College of Physicians and Surgeons ("CU"). *(Certificate of Need Application, August 15, 2005, pages 2-3)*

3. TSH and NYPHS ("Applicants") propose the establishment of an elective percutaneous coronary angioplasty[a] ("PCI") and open-heart surgery[b] ("OHS") program, to be located at the Hospital. *(Certificate of Need Application, August 15, 2005, page 2)*

4. TSH's proposal is for a full-service cardiovascular services program in the lower Fairfield County. TSH is located in the region's largest population center. *(Prefiled Testimony of Brian Grissler, September 19, 2005,)*

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[a]Elective (Scheduled) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure performed in a catheterization laboratory whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a previously diagnosed blockage in the heart. An expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow.

[b] Open-heart surgery is a surgical intervention performed on the opened heart while the bloodstream is diverted through a heart-lung machine. Cardiac Surgery includes Coronary Artery Bypass Graft (CABG), Valvuloplasty, and Valve Replacement. CABG is where a vein from the chest or leg, or a prosthesis, is grafted onto either side of a blockage in the coronary artery. This reroutes blood flow around the blockage to the heart muscle. Valvuloplasty is where a balloon tipped catheter is inserted into plaque-blocked heart valves to widen and separate them through repeated balloon inflation. A Valve Replacement is a replacement of plaque-blocked heart valves with prosthetic or tissue graft.

5. On August 25, 2004, TSH received CON authorization from OHCA to perform primary[c] PCI services. *(Certificate of Need Application, August 15, 2005, page 2)*

6. The proposed program will augment existing cardiovascular services at the Hospital. The Hospital currently offers:

Primary Angioplasty	Electrocardiogram
Interventional electrophysiology (ablations)	Electrophysiology
Diagnostic cardiac catheterization	Holter monitoring
Coronary care unit	Intra-aortic balloon pump
Telemetry inpatient care	Nuclear stress testing
Cardiac imaging	Pulmonary function testing
Cardiac rehabilitation	Stress testing
Cardiac ultrasound	Tilt table testing
Cardiopulmonary testing	Vascular and thoracic surgical services

(Certificate of Need Application, August 15, 2005, pages 8-9)

7. TSH's cardiology primary and secondary service areas consist of the following Connecticut towns:

Table 1: Stamford Hospital's Proposed Service Area for this Proposal for FYs 2002 – 2005 (1st Two Quarters)

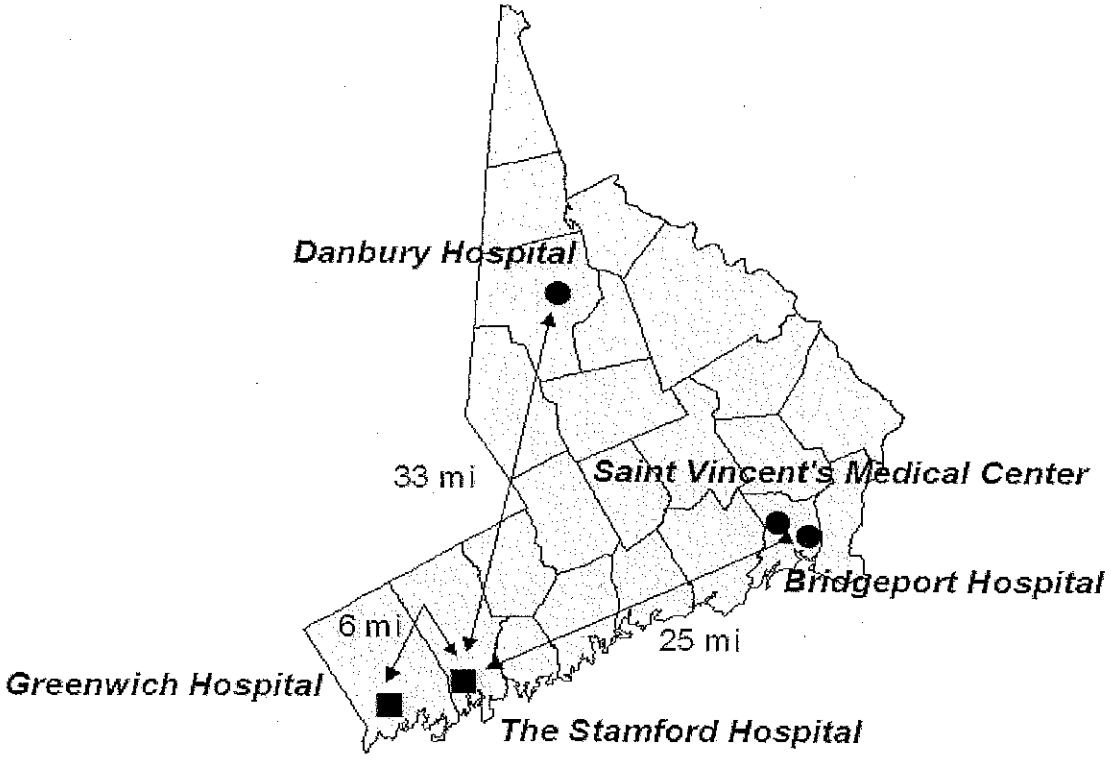
Towns	Primary	Secondary	Total Service Area
	Darien Stamford	Greenwich New Canaan Norwalk Weston Westport Wilton	Darien Greenwich New Canaan Norwalk Stamford Weston Westport Wilton
TSH's Share of Service Area's Inpatient Cardiac Catheterizations	57.4%	4.2%	26.1%
Service Area's share of TSH's Inpatient Cardiac Catheterizations	84.6%	8.7%	93.3%

(Source: Cardiac catheterization volume from *OHCA's Acute Care Hospital Inpatient Discharge Database. Service Area from Certificate of Need Application August 15, 2005, page 22)*

[c] Primary (Emergent) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure performed in a catheterization laboratory whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a previously diagnosed blockage in the heart. An expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow. Non-ST Segment elevation MI (NSTEMI or high-risk) patients consist of 80% of all MIs and are considered for angioplasty on an elective basis within 72 hours. Performance of elective angioplasty without cardiac surgery back up is not recommended by the American College of Cardiology or the American Heart Association.

8. Providers of interventional cardiac services in the Hospital's total service area ("TSA") are as follows

Map 1: Area Providers of Interventional Cardiac Services



Danbury Hospital began performing open heart surgery in January 2005.
Greenwich Hospital began performing Primary PCI in February 2005.
Stamford Hospital began performing Primary PCI in August 2005.

(Connecticut Acute Care Hospital Inpatient Discharge Database and Travel Distances from Yahoo Maps)

9. The Applicants based the need for the proposed Elective PCI and OHS program on the following:
   - Improved accessibility for patients;
   - Improved continuity of care;
   - Historical/Existing cardiac volume;
   - Adopting a standard of care that exists in the other large urban area; and
   - Improved quality of cardiac services.

   (Certificate of Need Application, August 15, 2005, pages 2-55)

10. TSH stated that the establishment of a full-service cardiac program in Stamford will provide timely access and local availability of these services in keeping with trends that have been already established nationally.
    (Prefiled Testimony of Kathleen Silard, Senior Vice President for Operations at TSH, September 19, 2005)

11. TSH's cardiac catheterization volume for FYs 2000 through 2005 are as follows:

Table 2: TSH's Historical Cardiac Catheterization Volume, FYs 2002 – 2005 1st Two Quarters

CT Service Area	2002	2003	2004	2005
Inpatient	354	352	296	147
Outpatient	321	283	332	-
Total	**675**	**635**	**628**	**147**

(Inpatient catheterization figures from OHCA's Acute Care Hospital Inpatient Discharge Database and outpatient volume from August 15, 2005, Responses to OHCA Completeness Letter, pages 1-2)

12. The following is a table of the average annual historical and projected Total PCI volumes (Primary & Elective) in TSH's service area:

Table 3: Average Annual Historical and Projected Total PCI Volumes in TSH's Service Area, FYs 2002 – 2005

	FYs 2002–2005 1st Two Quarters		Year One		Year Two		Year Three	
TSH Service Area	**Average PCIs**	**Adult Use Rate**	**Market Share (%)**	**Projected PCIs**	**Market Share (%)**	**Projected PCIs**	**Market Share (%)**	**Projected PCIs**
Primary	277	2.55	78%	216	83.5%	231	83.4%	231
Secondary	418	2.48	6.8%	28	11.0%	46	20.3%	85
Total Service Area	695	2.51	36.3%	244	40.6%	276	45.7%	316
Connecticut	**8,024**	**2.98**	-	-	-	-	-	-

Note: "Adult" refers to those 15 years and older. Adult use rate per 1,000 population.
Projected PCI volumes were calculated by applying the applicant's projected capture rate to the current PCI volume in the service area. For example, in Year One in the primary service area: 277 (average volume) * .78 (market share) = 216 PCIs.
(OHCA Acute Care Hospital Inpatient Discharge Database; MA, NY, and RI Hospital Discharge Databases; Census 2000 for population figures, and August 15, 2005 CON Application, *pages 45& 23)*

13. The following table is the annual average historical and projected OHS for TSH in the proposed service area for FYs 2002-2005:

Table 4: Historical and Projected, Average Annual OHS Volumes in TSH's Service Area, FYs 2002–2005

	FYs 2000 – 2005 1st Two Quarters		Year One		Year Two		Year Three	
TSH Service Area	**Average OHS**	**Adult Use Rate**	**Market Share (%)**	**Projected OHS**	**Market Share (%)**	**Projected OHS**	**Market Share (%)**	**Projected OHS**
Primary	112	1.03	78.1%	88	83.5%	94	83.5%	94
Secondary	213	1.27	6.7%	14	10.9%	23	20.3%	43
Total Service Area	325	1.17	32.9%	102	38.8%	117	45.7%	137
Connecticut	**4,640**	**1.72**	-	-	-	-	-	-

Note: FY 2005 is First two quarters only.
"Adult" refers to those 15 years and older. Adult use rate per 1,000 population
Projected OHS volumes were calculated by applying the Applicant's projected capture rate to the current PCI volume in the service area. For example, in Year One in the primary service area: 112 (average volume) * .781 (market share) = 88 open-heart surgeries.
(OHCA Acute Care Hospital Inpatient Discharge Database; MA, NY, and RI Hospital Discharge Databases; Census 2000 for population figures; and August 15, 2005, CON Application, pages 46&23).

14. TSH projects the following number of elective PCIs procedures and OHS for its service area.

Table 5: Projected Cardiac Volume for TSH's Service Area

Service	FY 2007	FY 2008	FY 2009
Angioplasties (Elective only)	193	324	417
Open-heart surgeries	86	150	197

Note: TSH based the projected volumes on historical utilization and population data. The use-rates utilized are based on Claritas data. OHCA can not verify any of the above claimed data. *(Responses to the Interrogatories, September 28, 2005, Updated Financial Attachment and CON Application)*

15. The 2001 American College of Cardiology ("ACC") and the American Heart Association ("AHA") Guidelines for Percutaneous Coronary Intervention ("PCI") recommend that PCI be performed by higher volume operators (>75 cases/year) with advanced technical skills (e.g. subspecialty certification) at institutions with fully equipped interventional laboratories and experienced support staff. This setting will most often be in a high-volume center (>400 cases/year) associated with an on-site cardiovascular surgical program. Therefore, PCI is best done by high-volume operators in high-volume institutions. *(JACC, 2001, Vol. 37, No.8, page 2239)*

16. The ACC/AHA Guidelines for CABG Surgery (1999) state the following:
    - Studies suggest that survival after CABG is negatively affected when carried out in institutions that perform fewer than a threshold number of cases annually. Similar conclusions have been drawn regarding individual surgeon volumes.
    - The ACC/AHA are supportive of a posture of close monitoring of institutions or individuals that perform <100 cases annually.

17. TSH states that it will utilize the existing guidelines published by the ACC and AHA as a basis for the development of standards for the proposed services, as specified in **Attachment I.** *(Certificate of Need Application, August 15, 2005, page 11)*

18. The Guidelines for Standards in Cardiac Surgery by the Advisory Council for Cardiothoracic Surgery ("ACCS") and the American College of Surgeons ("ACS") (1996) state the following:
    - An annual volume of at least 100 to 125 open-heart procedures per hospital is necessary from a quality standpoint and there is a greater variation in adjusted mortality rates for teams doing lower volumes of procedures as compared with those doing a high volume.
    - At least 200 procedures per year as previously recommended in the 1975 report of the Inter-Society Commission on Heart Disease Resources are necessary in order for a program to function efficiently.
    - A team approach with a minimum of two qualified cardiac surgeons is recommended to provide adequate and continuous perioperative care as well as assistance in the operating room.

19. Dr. Steven F. Horowitz testified to the following at the public hearing:
    - TSH can sustain a full-service cardiac program due to the increase in the size of the minority population.
    - Numerous studies have confirmed that the cardiovascular risk profile for both Hispanics and African Americans has been worsening in recent years as obesity and diabetes continue to rise exponentially within these populations.
      (Prefiled Testimony of Steven F. Horowitz, M.D. Chief of Cardiology at TSH, September 19, 2005)

20. Kathleen Silard testified to the following at the public hearing:
    - TSH has examined the significant disparity in utilization rates for PCI and OHS that exists for African Americans in TSH service area as well as other regions of the state when compared to the Caucasian population. TSH has seen how some of the major precursors of heart disease, such as diabetes and obesity, can disproportionately effect minority populations as well as the economically disadvantaged.
    - One of the primary goals of TSH's proposed program will be to address and hopefully eradicate some of those disparities by improving access to PCI and OHS to these high-risk groups.
      (Prefiled Testimony of Kathleen Silard, Senior Vice President for Operations at TSH, September 19, 2005)

21. The demographic characteristics by Race for TSH's TSA are as follows:

Table 6: TSH Demographics by Race

Service Area	Caucasian	African American	Native American	Asian	Other	Total
Primary	73.6%	13.2%	0.2%	4.6%	8.4%	100%
Secondary	85.7%	6.6%	0.1%	3.5%	4.1%	100%
Total Service Area	81.0%	9.2%	0.2%	3.9%	5.7	100%
Connecticut	81.6%	9.1%	0.3%	2.4%	6.6%	100%

Source: Census 2000.

22. The demographic characteristics by Hispanic ethnicity for the proposed TSA:

Table 7: Hispanic Ethnicity of TSH Service Areas

Service Area	Hispanic or Latino	Non-Hispanic	Total
Primary	14.7%	85.3%	**100%**
Secondary	8.4%	91.6%	**100%**
Total Service Area	10.8%	89.2%	**100%**
Connecticut	**9.4%**	**90.6%**	**100%**

Source: Census 2000.

23. The AMI discharges for the TSH TSA are as follows:

Table 8: Share of AMI by Race and Hispanic Ethnicity, FYs 2002 – 2005 (First 2 Quarters)

Service Area	Caucasian	African American	Hispanic	Asian	Native American	Other	Total
Primary	84.7%	7.0%	4.2%	0.1%	0.0%	4.0%	**100%**
Secondary	85.1%	7.1%	3.4%	1.0%	0.1%	3.3%	**100%**
Total Service Area	84.9%	7.0%	3.7%	0.6%	0.1%	3.6%	**100%**
Connecticut	**87.1%**	**4.7%**	**4.0%**	**0.3%**	**0.1%**	**3.8%**	**100%**

(Discharges from OHCA Acute Care Hospital Inpatient Discharge Database and MA, NY, and RI Hospital Discharge Databases. "White," "Black," "Asian," "Native American," and "Other" are non-Hispanic categories.)

24. NYPH has one of the largest cardiac surgery and cardiac catheterization[d] programs in New York State with its physicians performing over 3,000 PCIs and close to 2,000 OHS in calendar year 2004. *(Prefiled Testimony of Arthur A. Klein, M.D., September 19, 2005)*

[d] Diagnostic Cardiac Catheterization is a diagnostic procedure in which a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to the heart to measure electrical activity, blood pressure, and locate blockages.

25. Dr. Steven Horowitz, testified on behalf of TSH to the following:
    - Diabetes is a leading cause of hospitalization among Connecticut's African American and Hispanic populations which are 3.8 and 2.2 times more likely to be hospitalized directly due to the disease as compared to the Caucasian Connecticut residents.
    - The percent difference for the African American utilization rates in the TSH's TSA versus those statewide is nearly 26% and 62% for PCI and cardiac surgery respectively. The same numbers skyrocket to 41% and 95% when the focus is placed solely on the City of Stamford.
    - TSH can target the African American and Hispanic population and relieve some of these barriers to access through the comprehensive preventive and medical outreach program.
      (Prefiled Testimony of Steven F. Horowitz, M.D., Chief of Cardiology Department at TSH, September 19, 2005)

26. Dr. Arthur Klein testified to the following at the public hearing:
    - NYPH and NYPHS have developed a number of strong and effective partnerships with affiliated hospitals to elevate the scope of and quality of cardiac care in the tri-state region.
    - NYPHS assists in the operation of nine (9) diagnostic cardiac catheterization programs through out the tri-state area, four elective angioplasty programs and one primary angioplasty program.
    - In this proposal, the cardiac surgery professional services will be provided exclusively by full-time faculty of the Division of Cardiothoracic Surgery, Department of Surgery of Columbia College of Physicians and Surgeons.
    - Oversight of elective angioplasty shall be through a joint committee co-chaired by Drs. Moses and Stone, senior faculty from Columbia University's Division of Cardiology and Stamford Hospital's cardiology leadership.
      (Prefiled Testimony of Arthur A. Klein, M.D., September 19, 2005)

27. Dr. Eric A. Rose testified at the public hearing that Columbia University Department of Surgery's professional expertise in cardiothoracic research, its strategic network of partnerships and its vast clinical experience will help support TSH in their cardiac health services. *(Prefiled Testimony of Eric A. Rose, M.D., Chairman for the Dept. of Surgery at NYP/C, September 19, 2005)*

28. TSH submitted a signed Draft Agreement with NYPHS. NYPHS' role is defined as follows:
    - Arrange consultative assistance to the Hospital in the following areas:
        - Preparation of the CON Application;
        - Clinical training of nursing and technical staff;
        - Development of the Hospital's standards of care, risk stratification criteria and operational policies;
        - Development of clinical guidelines and protocols;
        - Collection and analysis of quality data for clinical outcomes and performance monitoring;
        - Recruiting procedures; and

- Adoption by the Hospital of policies, procedures and protocols, including developing practice guidelines and requirements related to the proposed program.

- Recommend CPC standards and/or the standards of NYPHS-affiliated Connecticut institutions for physician, nursing and technical staff protocols to foster a high-quality credentialing program; and
- Advise the Hospital with respect to quality assurance and utilization management functions related to the proposed program.

(Completeness Responses, August 15, 2005, Draft Agreement between the Applicants, Exhibit 4, page 4)

29. TSH proposes to provide elective PCI utilizing five (5) interventional cardiologists, who are currently providing primary PCI services at TSH. *(Certificate of Need Application, August 15, 2005, page 11)*

30. The PCI volumes for the proposed interventionalists for FYs 2002-2005 1st two quarters are as follows:

Table 9: Volume of Proposed Program Interventionalists (FYs 2002 – FY 2005 1st Two Quarters)

Physician	Hospital Affiliation	Office/Home	Average Annual PTCA Volume
Alcan[1]	St. Vincent's & TSH	Norwalk	347
Jumper[2]	St. Vincent's & TSH	Valhalla, NY	119[3]
Charney	NY Presbyterian, Greenwich, & TSH	New Rochelle	X[4]
Messinger	NY Presbyterian, Greenwich, & TSH	New Rochelle	X[4]
Stone	NY Presbyterian, TSH (pending)	Greenwich	-

[1]Member of Cardiology Associates of Fairfield County
[2]In training
[3]Dr. Jumper performed 57 in FY 2004 and 122 in the first two quarters of FY 2005.
[4] TSH reported volume (FYs 2003 & 2004 – NYP physicians not specifically identified)
Physician C: 156 & 145 and Physician D: 108 & 126
(OHCA Acute Care Hospital Inpatient Discharge Database and CON Application, August 15, 2005, page 11&58 and Completeness Responses, August 15, 2005, page 8)

31. TSH stated that three additional cardiac interventionalists, Drs. Portnay, Lorenz and Corvaja will be added to the proposed program to perform PCIs at TSH. *(CON Application, August 15, 2005, pages 11&58 and Completeness Responses, August 15, 2005, page 8)*

32. TSH proposes to staff the proposed OHS program with two (2) board-certified cardiac surgeons, who will practice full-time at TSH and be credentialed at both TSH and at NYP/C. These two surgeons will be recruited through the formation of a three (3) person committee which will include as its members, Dr. Craig Smith, Dr. Mehmet Oz and Dr. Eric Rose, Chair of the Surgery Department at NYP/C. *(Certificate of Need Application, August 15, 2005, page 11)*

33. The average annual PCI and OHS volumes in TSH's TSA by hospital provider for FYs 2000-2005 (1st two quarters) are as follows:

Table 10: Average Annual PCI and Open-Heart Surgery Volumes by Provider in TSH's TSA by Provider, (FYs 2002 – 2005 1st Two Quarters)

	PCIs			Open-Heart Surgeries		
Hospital	**Procedures**	**Market Share**	**Area Volume as Share of Total Provider Volume (%)**	**Procedures**	**Market Share**	**Area Volume as Share of Total Provider Volume (%)**
Bridgeport	154	22.2%	12.3%	75	23.1%	24.3%
Danbury	0	0.0%	-	0	0.0%	-
Greenwich	1*	0.1%	100%	-	0.0%	-
Hartford	0	0.0%	-	0	0.0%	-
John Dempsey	1	0.1%	0.2%	0	0.0%	-
Saint Francis	0	0.0%	-	1	.3%	.1%
Saint Raphael's	4	0.5%	0.4%	3	.9%	.4%
Saint Vincent's	392	56.4%	34.9%	119	36.6%	39.7%
Yale	78	11.2%	4.8%	57	17.5%	6.4%
Out of State	65	9.3%	-	70	21.6%	-
Totals	**695**	**100%**	**-**	**325**	**100%**	**-**

*Greenwich Hospital began providing primary PCI in February 2005.
(OHCA Acute Care Hospital Inpatient Discharge Database and MA, NY, and RI Hospital Discharge Databases)

34. Danbury Hospital, along with Waterbury Hospital and St. Mary's Hospital (one program, two sites in Waterbury) were authorized by OHCA to offer full-service cardiac programs in 2003. *(Certificate of Need Applications, Final Decision Docket Numbers 03-30167 & 03-30143, both dated July 23, 2005)*

35. St. Vincent's Medical Center ("SVMC") testified to the following:
    a. Angioplasty volume is flat nationally and has begun to decline in Connecticut.
    b. If TSH proposal is approved, St. Vincent's Medical Center would not be able to achieve both institutional and surgeon specific minimum volumes for OHS and would put the quality of St. Vincent's Medical Center at significant risk.
    c. SVMC performed 1,097 PCIs and 283 OHS in FY 2005.
    d. The overall risk adjusted mortality rate at SVMC is 1.3%.
    e. Other than volume, SVMC measures quality through independent third party companies (to whom they report data to).
    (Prefiled Testimony of Jose Missri, M.D. St. Vincent's Medical Center, September 28, 2005 and Public Hearing Testimony, October 6&27, 2005)

36. Bridgeport Hospital ("BH"), as part of Yale-New Haven Health Heart Institute, testified to the following:
    a. BH performed under 1,200 PCIs and under 250 OHS in FY 2005.
    b. BH could not specify their overall risk adjusted mortality rate, BH simply stated that it was under 2.0%.
    c. Other than volume, BH measures quality through independent third party companies (to whom they report data to).

d. If the proposed CON was to be approved, this would not impact the physician coverage at BH.
(Prefiled Testimony of Stuart .Zarich, M.D., Bridgeport Hospital, September 28, 2005 and Public Hearing Testimony, October 6&27, 2005)

37. Yale-New Haven Hospital ("YNHH"), as part of Yale-New Haven Health Heart Institute, testified to the following:
    a. There is a statewide decline in the number of OHS cases,
    b. There is a flattening of PCI volumes,
    c. Proliferation of full-service cardiac program will place additional stress on the state's staffing infrastructure,
    d. Additional cardiac programs will not improve mortality rates,
    e. The residents of Fairfield County have a wide range of options for their full-service cardiac care needs,
    f. There is a direct correlation between physician and institutional case volumes and quality outcomes, and
    g. In FY 2004, YNHH had 64 PCI discharges (4.3% of YNHH"s total PCI) and 52 OHS discharges (6.2% of YNHH's total OHS) from the Stamford service area.
    (Prefiled Testimony of Kyle Kramer, Executive Director of the Yale-New Haven Health Heart Institute, September 28, 2005 and Public Hearing Testimony, October 6&27, 2005)

38. In order to implement the proposed project, TSH will require a series of facility renovations. The renovations will include an expansion of surgical facilities on Level 2 of TSH's North building to allow for the creation of two new, state-of–the-art operating rooms that will be the primary operating suites for the proposed program as well as enlarged perioperative and other surgical support areas.
(Certificate of Need Application, August 15, 2005, page 13)

Financial Feasibility of the Proposal and its Impact on the Hospital's Rates and Financial Condition

Impact of the Proposal on the Interests of Consumers and Payers of Health Care Services

Consideration of Other Section 19a-637, C.G.S. Principles and Guidelines

39. The proposal has a total expenditure cost of $5,404,425 which consists of the following:

Table 11: Total Capital Expenditure

Description	Cost
Medical Equipment	3,109,345
Construction/Renovation	1,590,065
Project Contingency	704,925
Total Capital Expenditure	**$5,404,425**

(Certificate of Need, August 15, 2005, page 63)

40. The proposal will be financed from the TSH's equity through operations. *(Certificate of Need, August 15, 2005, page 64)*

41. TSH will pay NYPHS a fee for expenses related to training and oversight of TSH's proposed program. This arrangement will be finalized if the proposal is approved by OHCA. *(Arthur S. Klein, Chief Operating Officer of NYPHS, Public Hearing Testimony, October 6&27, 2005)*

42. TSH projects incremental to the project losses from operations for the first two years of operation for FYs 2007 and 2008 of ($1,940,000) and ($294,000), respectively. This is due to program start up. However, TSH is projecting incremental gains from operation of $1,082,000 for the third year of operation, FY 2009. *(Responses to the OHCA Completeness Letter, August 15, 2005, Updated Financial Attachment)*

43. TSH is projecting a gain from operations with the CON project of $10,137,000, $12,327,000 and $14,365,000, for FYs 2007, 2008 and 2009. *(Responses to the OHCA Completeness Letter, August 15, 2005, Updated Financial Attachment)*

44. TSH proposes to hire 26, 34 and 38 Full Time Equivalent employees for FYs 2007, 2008 and 2009, respectively. *(Responses to the OHCA Completeness Letter, August 15, 2005, Updated Financial Attachment)*

45. There is no State Health Plan in existence at this time. *(Certificate of Need Application, August 15, 2005, page 14)*

46. TSH has adduced evidence that this proposal is consistent with TSH's long-range plan. *(Certificate of Need Application, August 15, 2005, page 14)*

47. TSH has improved productivity and contained costs by participating in group purchasing, energy conservation, reengineering and through application of technology. *(Certificate of Need Application, August 15, 2005, page 59)*

48. TSH stated that this proposal will help enhance the existing academic affiliation with Columbia University College of Physicians and Surgeons. *(Certificate of Need Application, August 15, 2005, pages 59&60)*

49. TSH stated that the patient physician mix of TSH is unique as the cardiac patient care is fully integrated across all medical disciplines and is managed through a state-of-the-art multi-modality data management system. *(Certificate of Need Application, August 15, 2005, page 60)*

50. TSH's rates are sufficient to cover the proposed capital expenditure and operating costs associated with this proposal. *(Responses to Interrogatories, September 28, 2005, Updated Financial Attachment)*

Rationale

The Office of Health Care Access ("OHCA") approaches community and regional need for proposed services on a case-by-case basis. Certificate of Need ("CON") applications for cardiac services do not lend themselves to general applicability due to the variety and complexity of factors, which may affect any given proposal; e.g., the characteristics of the population to be served, the nature of the existing services, the specific services proposed to be offered, the current utilization of services, and the financial feasibility of the proposed service. In considering this application, OHCA determined that TSH's current cardiac utilization, population served, quality of providers and physicians and geographic accessibility were significant factors in determining need.

The Stamford Hospital ("TSH") and New York Presbyterian Healthcare System, Inc. ("NYPHS") (collectively known as "Applicants"), propose to expand the cardiac services delivered at TSH to include elective angioplasty services and open heart surgery. The Applicants based the need for the elective PCI and open heart surgery programs on improved accessibility for patients, improved continuity of care, historical and existing cardiac volume, adopting a standard of care that exists in the other large urban areas and improved quality of care.

TSH's primary and secondary service area ("TSA") consists of eight (8) towns. There are no providers of elective PCI or OHS in TSH's TSA. The Hospital's service area is comprised of a higher proportion of African American and Hispanic population when compared to the rest of the state overall. The primary service area has experienced higher adult per capita rates of AMI discharges for African American and Hispanic as compared to the state as a whole. In addition, there appears to be a disparity in the utilization rates for PCI and OHS for Hispanics and African Americans in the service area when compared to the Caucasian population. This proposed cardiac program will enhance the access for the African American and Hispanic population in TSH's TSA. OHCA concludes that the Applicants proposal will provide the residents of lower Fairfield County with improved access to the full continuum of cardiac care.

TSH's historical cardiac catheterizations volumes for FYs 2002, 2003, 2004, and 2005 (1st 2 quarters) were 675, 635, 628 and 147, respectively. OHCA determined that TSH could potentially perform a minimum of 244 annual total PCIs (primary & elective) and 102 OHS cases on residents of TSH's TSA in the first full year of operation of the proposal based upon historical catheterization volume and its market share. This volume increases to 276 total PCI procedures and 117 OHS cases for the second year of operation, and 316 total PCI procedures and 137 OHS cases for the third of operation. Based on historical inpatient diagnostic cardiac catheterization volume and market share, the proposed full-service cardiac program at TSH would exceed institutional minimum volumes recommended by the ACC/AHA for PCI (200) and the American College of Surgeons--Advisory Council for Cardiothoracic Surgery for open-heart surgery (100–125 surgeries per year).

The proposal involves offering of elective Percutaneous Coronary Intervention ("PCI") through the use of five (5) interventional cardiologists, who are currently providing primary PCI services at TSH. TSH also proposes to provide OHS utilizing two (2) surgeons will be recruited from outside of Connecticut, through the formation of a three (3) person committee comprised of TSH and Columbia physicians. Therefore this program will not impact coverage at any of the existing cardiac programs in Connecticut. In addition, OHCA concludes that even though the PCI and OHS volumes may decline at the existing providers, the PCI and OHS volumes will not fall below the institutional minimum volumes recommended by ACC/AHA for PCI and American College of Surgeons-Advisory Council for Cardiothoracic Surgery for OHS.

TSH's proposal will increase the availability of quality PCI and OHS services for residents of TSH's TSA. The proposed elective PCI and OHS program will be developed in collaboration with NYPHS. NYPHS will provide or arrange for TSH consulting in the areas of clinical training for staff, development of TSH's standards of care, development of clinical guidelines, collection and analysis of data and recruiting procedures. NYPHS expects the initial training to continue over an eighteen month period. NYPHS will also advise TSH with respect to quality assurances and utilization management and provide assistance to TSH concerning the adoption of policies, procedures and protocols, including developing practice guidelines and program requirements. This proposal will improve the quality of care and continuity of TSH's cardiac services.

Finally, the CON proposal is financially feasible. The proposal has a total capital expenditure of $5,404,425, which consists $3,109,345 for medical equipment, $1,590,065 for construction/renovations and $704,925 for contingency costs. TSH proposes to fund the proposed total capital expenditure through TSH's equity, specifically through operations. TSH will pay NYPHS a fee for expenses related to training and oversight of TSH's proposed program; however, the details have not yet been finalized. TSH projects incremental losses from project operations for the first two years of operation of ($1,940,000), and ($294,000), respectively. However, TSH is projecting an incremental gain from operation of $1,082,000 by the third year of operation. Further, TSH is projecting gains from total Hospital operations with the CON project of $10,137,000, $12,327,000 and $14,365,000 for the first three years of operations. The projected utilization and financials of this proposal appear to be reasonable, financially feasible and cost-effective and will not adversely impact the interests of consumers and payers of such services.

TSH's proposed elective angioplasty and open heart surgery program is differentiated from other cardiac-related proposals in the following ways. TSH currently operates a high volume diagnostic cardiac catheterization program and recently initiated a primary angioplasty program. The Hospital's service area is comprised of a higher proportion of African American and Hispanic population than the rest of the state. The implementation of the proposed program should address some of the disparities in utilization of cardiac services by this population. Additionally, the proposed program is not expected to impact the physician coverage at any of the existing cardiac programs in Connecticut because the interventionalists are already on staff at TSH and the cardiac surgeons will be

recruited from out of state. TSH's strong collaborative relationship with the NYPHS will enhance the accessibility of high quality, community-based medical services offered by TSH. TSH will utilize the resources of NYPHS to further enhance provision of quality care including access to the expertise, information, and consultative support of a nationally recognized academic healthcare center renowned for the diagnosis and treatment of cardiac disease. Finally, implementation of TSH's proposal will bring appropriate access to high quality cardiac services to the residents of the proposal's TSA. In summary, the proposal will result in enhanced cardiac services in the Stamford region.

Order

NOW, THEREFORE, the Office of Health Care Access ("OHCA") and The Stamford Hospital ("TSH") and New York Presbyterian Healthcare System, Inc. ("NYPHS") (together referred to as "Applicants") hereby stipulate and agree to the terms of settlement with respect to the Applicants' request to establish elective angioplasty and open heart surgery program to be located at Stamford Hospital at a total capital expenditure of $5,404,425, as follows:

1. The Applicants' request for a CON to establish an elective angioplasty and open-heart surgery program to be located at TSH, a total capital expenditure of $5,404,425, is hereby approved.

2. TSH shall only commence operation of the OHS program at The Stamford Hospital initially. Once the number of OHS procedures exceeds 125, the Hospital may commence operation of the elective angioplasty program. Prior to commencement of the angioplasty services, TSH is required to provide OHCA evidence that it has performed the required 125 OHS.

3. TSH will have at least two cardiac surgeons as part of this proposal, who are in the process of being recruited and shall be identified prior to the beginning of the OHS program. The surgeons must be fully credentialed and have the following qualifications:
   - Board-Certified in cardiac surgery
   - Maintains a Connecticut license and admitting privileges at the Hospital
   - Has performed OHS procedures at a cardiac surgical center that meets or exceeds the annual ACCS/ACS minimum institutional volume standard for cardiac surgery for the past 2 years
   - TSH shall provide the Curriculum Vitae ("CV") of the cardiac surgeons prior to commencement of the OHS program. TSH shall demonstrate that the cardiac surgeons satisfy all requirements specified above. The OHS program shall not commence operation until OHCA acknowledges receipt of the CV and that it complies with this Order.

4. TSH shall provide the CVs of each of the cardiac operating room nurses, Board-certified cardiac anesthesiologists, intensivists and perfusionists for the authorized OHS program prior to commencement of the OHS program. Fifty percent (50%) of each of the core OR staff mentioned above must be trained in OHS prior to commencement of the OHS program. The OHS program shall not commence operation until OHCA acknowledges receipt of the CVs and that they comply with this Order.

5. TSH shall not exceed the approved total capital expenditure of $5,404,425. In the event TSH learns of potential cost increases or expects final project costs will exceed those approved, the Hospital shall file with OHCA a request for approval of

the revised CON project budget. The source of funding for the project will be The Stamford Hospital's operations and owner equity.

6. TSH shall complete and submit to OHCA on a quarterly basis the data elements in the Connecticut Cardiac Data Registry (**Attachment II**). Data should be submitted to OHCA on a computer disk in either an excel workbook or comma-delimited text file in a format specified by OHCA. The most current version of the Connecticut Cardiac Data Registry includes, but may not be limited to, the elements listed in **Attachment II**. Data must be reported to OHCA thirty (30) calendar days following the end of the quarter. Fiscal Year quarters end December 31st, March 31st, June 30th, and September 30th. Upon receipt, OHCA will check the data's conformance to the required specifications and within ten (10) business days notify TSH in writing of its evaluation. If OHCA finds questionable material, TSH will have fifteen (15) business days from notification by OHCA to submit a revised dataset for evaluation. All patient-level data submitted to OHCA to satisfy this requirement will be subject to the laws and regulations of the state of Connecticut and the Office of Health Care Access regarding its collection, use and confidentiality. If TSH does not submit the data elements in the Connecticut Cardiac Data Registry on a quarterly basis, the programs may be terminated. In the event of such a termination, TSH shall file a CON for reinstitution of the programs.

7. TSH shall submit on an annual basis to OHCA the following reports which must be reported to OHCA thirty (30) calendar days following the end the year, for the first three (3) years of operation:
   a. A report of all elective PCIs and OHS performed each year by ethnicity and race, in a format to be specified.
   b. A report which illustrates that this CON proposal helped relieve the barriers to access through comprehensive preventive and medical out-reach programs for the African American and Hispanic population within TSH's TSA.

8. If TSH does not perform 125 OHS procedures within twelve months of the initiation of the OHS program, TSH shall submit monthly reports of OHS arrayed by physician to OHCA until such time as these volumes are met by TSH. If these volumes are not met for a period of two consecutive 12-month periods, TSH's OHS program shall be terminated. In the event of such a termination, TSH shall file a CON for reinstitution of the OHS program.

9. If TSH does not perform 200 elective PCIs within twelve months of the initiation of the PCI program, TSH shall submit monthly reports of elective PCIs arrayed by physician to OHCA until such time as these volumes are met by TSH.

10. TSH shall participate in the Society of Thoracic Surgeons Database (STS-DB) database and the ACC National Cardiovascular Database Registry (ACC-NCDR) and report all data including the optional follow-up section. TSH shall provide OHCA quarterly data reports from STS-DB and ACC-NCDR. Data must be

reported to OHCA thirty (30) calendar days subsequent to TSH receiving the reports from the STS and ACC. TSH is required to comply with the STS and ACC/AHA criteria and standards. If TSH determines not to participate in the STS-DB or ACC-NCDR, TSH shall notify OHCA immediately, and continue to comply with the STS and ACC/AHA criteria and standards set forth in Attachment III.

11. TSH shall provide OHCA with a copy of a dated and signed Consulting Services Agreement with NYPHS or its Affiliates prior to commencement of operation of the OHS program. This contract shall be renewed annually for a period of three years.

12. OHCA and TSH agree that this Agreed Settlement represents a final agreement between OHCA and TSH with respect to this request. The signing of this Agreed Settlement resolves all objections, claims and disputes, which may have been raised by the Hospital with regard to Docket Number 04-30374.

13. This authorization for the OHS program shall expire on December 31, 2008. Should the TSH's open-heart surgery program not commence operation by that date, TSH must seek further approval from OHCA to complete the project beyond that date.

14. This Agreed Settlement is an order of the Office of Health Care Access with all the rights and obligations attendant thereto, and the Office of Health Care Access may enforce this Agreed Settlement pursuant to the provisions of Sections 19a-642 and 19a-653 of the Connecticut General Statutes at TSH's expense, if TSH fails to comply with its terms.

January 4, 2006

Brian G. Grissler
Duly Authorized Agent for
The Stamford Hospital

December 28, 2005

Arthur A. Klein, M.D.
Duly Authorized Agent for
New York Presbyterian Health System, Inc.

The above Agreed Settlement is hereby accepted and so ordered by the Office of Health Care Access on January 4, 2006.

January 4, 2006

Cristine A. Vogel
Commissioner & Presiding Officer

CAV:sl

ATTACHMENT III

Table 1A: Inpatient cardiac catheterization discharges by provider, FFYs 2002-2010

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	FFY 06-10 (5-yr) % Change	FFY 08-10 (3-yr) % Change	FFY 09-10 (1-yr) % Change
Backus	156	210	200	170	116	53	106	135	115	-1%	8%	-15%
Bridgeport	1,148	1,185	1,274	1,129	902	809	817	632	626	-31%	-23%	-1%
CT Children's								10	5	n/a	n/a	-50%
Danbury	263	299	260	327	748	533	475	452	418	-44%	-12%	-8%
Dempsey	519	564	633	640	487	439	480	419	462	-5%	-4%	10%
Greenwich	100	42	35	106	167	158	163	177	166	-1%	2%	-6%
Hartford	2,546	2,405	2,241	2,128	2,135	2,032	2,008	1,833	1,892	-11%	-6%	3%
Hospital of Central CT	448	465	409	411	436	401	319	344	269	-38%	-16%	-22%
Lawrence & Memorial	420	473	466	393	414	303	337	440	503	21%	49%	14%
Middlesex	28	169	168	150	182	142	161	138	138	-24%	-14%	0%
New Milford	0	0	0	22	37	38	65	37	0	-100%	-100%	-100%
Norwalk	247	203	195	182	128	67	77	104	126	-2%	64%	21%
Rockville	0	79	99	24	4	3	0	0	0	-100%	n/a	n/a
St. Francis	2,742	2,802	2,800	2,656	2,421	2,543	2,431	2,292	2,206	-9%	-9%	-4%
St. Mary's	291	299	260	307	519	469	455	480	469	-10%	3%	-2%
St. Raphael	1,744	1,878	1,833	1,496	1,383	1,200	1,113	1,062	1,098	-21%	-1%	3%
St. Vincent's	1,276	1,259	1,324	1,432	1,554	1,540	1,562	1,375	1,267	-18%	-19%	-8%
Stamford	354	352	296	299	311	297	293	358	321	3%	10%	-10%
Waterbury	451	477	367	412	658	622	611	675	608	-8%	0%	-10%
Yale	2,549	2,587	2,330	2,200	2,021	1,939	1,954	2,135	2,129	5%	9%	0%
Total	**15,282**	**15,748**	**15,190**	**14,484**	**14,623**	**13,588**	**13,427**	**13,098**	**12,818**	**-12%**	**-5%**	**-2%**

***Source**: CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database.*

ICD-9-CM Procedure Codes: 37.21-37.23

Please note: unduplicated counts utilizing all procedure codes

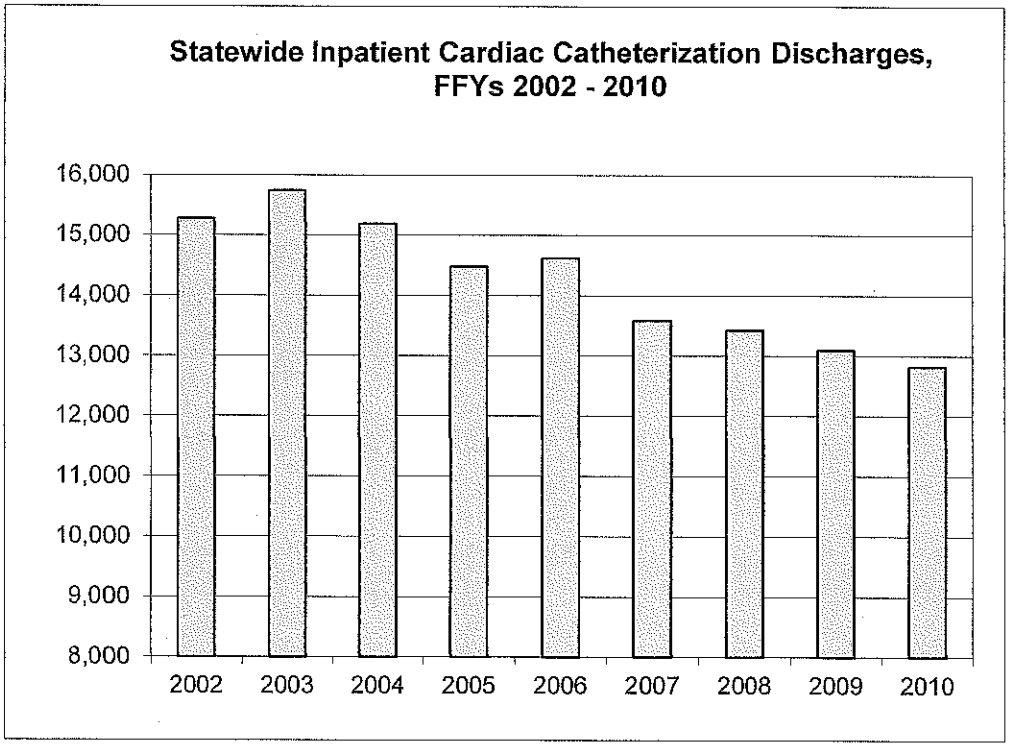


Table 2A: PCI discharges by provider, FFYs 2002-2010

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	FFY 06-10 (5-yr) % Change	FFY 08-10 (3-yr) % Change	FFY 09-10 (1-yr) % Change
Bridgeport	1,191	1,249	1,288	1,052	692	560	580	428	379	-45%	-35%	-11%
CT Children's								2	0	n/a	n/a	n/a
Danbury	0	0	0	0	453	409	330	326	277	-39%	-16%	-15%
Dempsey	452	464	453	519	401	353	376	334	368	-8%	-2%	10%
Greenwich	0	0	0	20	38	32	40	40	32	-16%	-20%	-20%
Hartford	1,312	1,483	1,321	1,282	1,246	1,206	1,093	1,031	1,122	-10%	3%	9%
Hospital of Central CT	0	0	0	26	61	70	60	74	69	13%	15%	-7%
Lawrence & Memorial	0	0	0	0	41	-	29	74	74	80%	155%	0%
New Milford	0	0	0	0	0	6	11	11	0	n/a	-100%	-100%
Norwalk								14	57	n/a	n/a	307%
St. Francis	1,192	1,253	1,349	1,223	1,170	1,188	1,171	1,232	1,030	-12%	-12%	-16%
St. Mary's	0	0	0	59	297	246	251	255	291	-2%	16%	14%
St. Raphael	715	970	924	708	680	632	595	534	523	-23%	-12%	-2%
St. Vincent's	1,063	1,035	1,085	1,150	1,181	1,101	1,124	958	925	-22%	-18%	-3%
Stamford	0	0	0	9	39	34	45	159	151	287%	236%	-5%
Waterbury	0	0	0	61	347	373	325	361	361	4%	11%	0%
Yale	1,635	1,715	1,460	1,297	1,218	1,131	1,186	1,352	1,469	21%	24%	9%
Total	**7,560**	**8,169**	**7,880**	**7,406**	**7,864**	**7,341**	**7,216**	**7,185**	**7,128**	**-9%**	**-1%**	**-1%**

***Source**: CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database*

ICD-9-CM Procedure Codes: .66, 36.01, 36.02, 36.05, 36.06 and 36.07

Please note: unduplicated counts utilizing all procedure codes

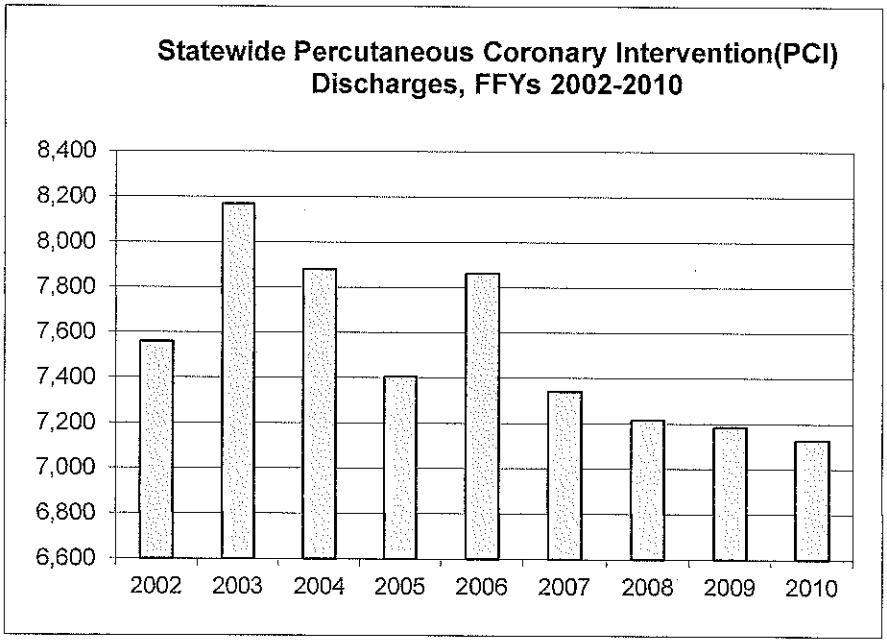


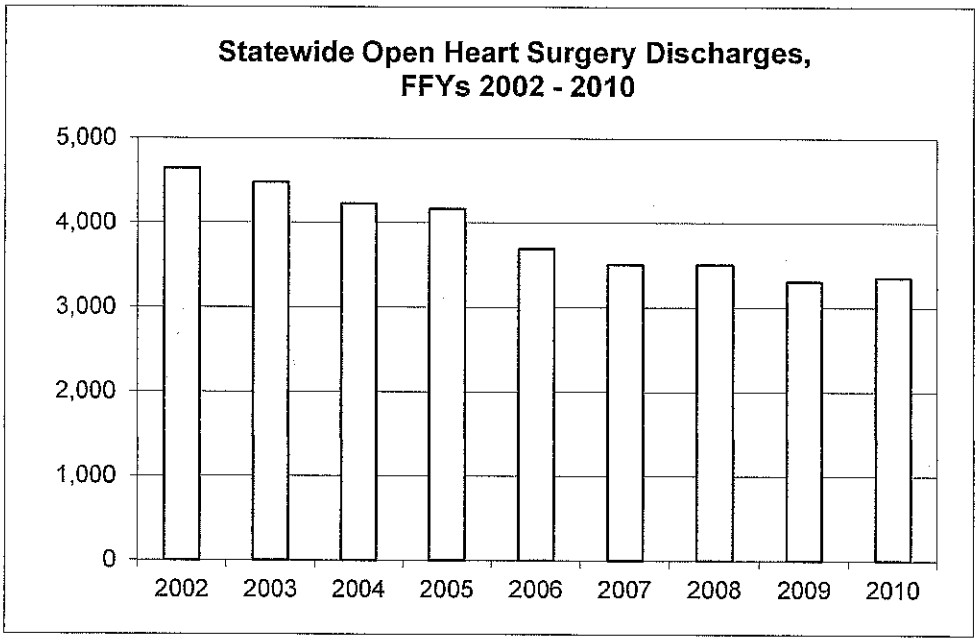
Table 3A: Open heart surgery discharges by provider, FFYs 2002-2010

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	FFY 06-10 (5-yr)% Change	FFY 08-10 (3-yr)% Change	FFY 09-10 (1-yr) % Change
Bridgeport	345	313	268	263	175	194	106	96	136	-22%	28%	42%
CT Children's								6	4	n/a	n/a	na
Danbury	0	0	0	114	177	121	162	148	174	-2%	7%	-9%
Dempsey	115	134	121	174	97	70	84	56	58	-40%	-31%	-33%
Hartford	901	844	756	726	742	685	671	652	695	-6%	4%	-3%
St. Francis	1,239	1,299	1,311	1,188	998	990	912	845	820	-18%	-10%	-7%
St. Mary's	0	0	0	19	72	100	85	114	112	56%	32%	34%
St. Raphael	761	687	617	510	353	342	321	299	318	-10%	-1%	-7%
St. Vincent's	310	296	293	291	259	232	257	219	195	-25%	-24%	-15%
Stamford	0	0	0	0	0	0	75	73	46	n/a	-39%	-3%
Waterbury	0	0	0	20	117	110	134	110	98	-16%	-27%	-18%
Yale	973	905	860	861	704	664	698	691	697	-1%	0%	-1%
Total	**4,644**	**4,478**	**4,226**	**4,166**	**3,694**	**3,508**	**3,505**	**3,309**	**3,353**	**-9%**	**-4%**	**-6%**

***Source** : CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database.*

ICD-9-CM Procedure Codes: 35.10-35.28 and 36.10-36.19

Please note: unduplicated counts utilizing all procedure codes



ATTACHMENT IV

GUIDELINES FOR STANDARDS IN CARDIAC SURGERY

The following statement is an updated version of guidelines that were first published by the American College of Surgeons in 1991. The revised statement was developed by the Advisory Council for Cardiothoracic Surgery and approved by the College's Board of Regents in October 1996.

Preamble

This report provides guidelines to be used by hospital executives and appropriate medical staff only. It places no value judgment on existing successful programs or on the treatment of individual patients.

While current standards of practice form the basis of this report, it is recognized that large programs in cardiac surgery grow from smaller ones. Hospitals and their staffs should exercise their own discretion in approving programs based on local need and the responsibility for achieving a good standard of practice.

While attention is directed primarily to open-heart surgery, the proposed standards should apply to closed-heart operations as well as to operations on the great vessels within the chest.

In borderline situations, in which the number of open-heart operations does not meet the established guidelines, the American College of Surgeons recommends the use of peer review.

Professional team

Specification of the qualifications for cardiac surgeons in an established practice is beyond the scope of these guidelines. Surgeons practicing cardiac surgery should be certified or awaiting certification by the American Board of Thoracic Surgery or its Canadian equivalent within five years after completion of an approved residency program in cardiac surgery. It is recommended that hospital committees for staff accreditation exercise their judgments for privileges based on the nature of the cardiothoracic residency or postresidency experiences of the applicant.

A team approach with a minimum of two qualified cardiac surgeons is recommended to provide adequate and continuous perioperative care as well as assistance in the OR. It is recognized that, depending on the particular setting and situation, the assistant on a particular case may vary in experience and qualification.

Hospital operative volume–Adult cardiac surgery

The 1975 report of the Inter-Society Commission on Heart Disease Resources recommended that cardiac surgical programs in a *hospital* should perform at least 200 procedures annually. This recommendation was based on the premise of a hospital dedicating 1 operating room to cardiac surgery and functioning at 80 percent capacity (4 cases per week x 52 weeks = 200 per year). While there are no presently available data linking an *individual surgeon's* patient volume and hospital mortality rate, there are data to suggest that an annual volume of at least 100 to 125 open heart procedures (including coronary artery bypass procedures, valve replacements, and other operations requiring the use of cardiopulmonary bypass) per *hospital* is necessary from a quality standpoint and that there is a greater variation in adjusted mortality rates for teams doing lower volumes of procedures as compared with those doing a high volume. While 100 to 125 cases per year per *hospital* appears sufficient from a quality standpoint, it is likely that considerably more, and at least 200 procedures per year as previously recommended, are necessary in order for a program to function efficiently.

Congenital heart surgery

Surgery for congenital heart disease, especially in infants, requires a setting that readily meets the complex and special needs

of this group of patients. These requirements include a cardiac surgeon experienced in the operative and perioperative management of such patients. There should be a pediatric cardiologist, an anesthesia team, perfusionists, intensive care nurses, and appropriate intensive care facilities for the treatment of infants and children. At a hospital where congenital heart operations are performed, a total of 100 congenital heart operations (both open and closed, not including neonatal ductus ligations) should be done. The occasional management of an infant or child with congenital heart disease by an otherwise busy and well-functioning adult cardiac surgical team is strongly discouraged.

Hospital facilities and personnel

It is urged that hospital committees for staff accreditation use peer review to determine that adequate standards of practice are maintained in terms of case frequency and results. A registry for the recording of cardiac surgical results is mandatory.

The complex operating room environment required by cardiac surgery in terms of equipment and instruments requires constant improvement in technique and proper indoctrination of personnel. Such educational programs should be under the direction of a clearly designated individual with particular interest and skill in cardiac surgery. Operating room nurses and technicians specializing in cardiac surgery are important. It should be mandatory that operating room nurses and technicians be assigned to cardiac surgery sufficiently often to develop and maintain the skills required for proficient performance in this area.

Anesthesia for cardiac surgical patients encompasses a variety of special problems. To ensure technical competence, frequent changing of the anesthesiologists assigned to cardiac surgery should be avoided.

The operation of a heart-lung machine should be performed by a specially trained nurse or technician under the supervision of the operating surgeon. A perfusionist certified by the American Board of Cardiovascular Perfusion is recommended. Perfusionists who are not certified should have at least two years of experience under supervision in an active clinical program in open-heart surgery and have a thorough background in operating room sterile techniques, perfusion physiology, the use of monitoring equipment, and a general understanding of commonly performed cardiac surgical procedures. The primary responsibility for determining the capability of the perfusionist remains with the cardiac surgeon.

Cardiac surgeons must be primarily responsible for the postoperative care of their patients, including that provided in the intensive care unit. Portions of that care may be shared with others, such as nurses and other physicians. However, only the cardiac surgeon is fully cognizant of all aspects of a given patient's condition and retains the responsibility for the continuity of care, which includes the preoperative status, the operative management, and the postoperative care.

Intensive care nursing of cardiac surgical patients is recognized as a true specialty involving skills in dealing with cardiac and respiratory emergencies. Assignment to cardiac surgical patients should be sufficiently often to maintain competence in this area of nursing. The surgeon should participate in the supervision of cardiac intensive care unit nurses.

The operating room, intensive care unit, and other facilities must conform to standards mandated by the Joint Commission on Accreditation of Health Care Organizations.

The nature of cardiac surgery makes it mandatory that diagnostic facilities be available to the surgical team. A proper cardiac catheterization laboratory must be available for hemodynamic and cine' angiographic studies. This laboratory should be under the direction of a qualified specialist and be accessible for preoperative elective studies, postoperative elective studies, and emergency procedures on a 24-hour basis.

Standard laboratory studies should be available on a 24-hour basis, including blood-gas analysis.

A blood bank facility with full resources under the direction of qualified specialists in this field is mandatory.

An intensive care facility must be available for all patients following cardiac surgery, and in some instances, for patients who are severely ill, preoperatively. This should be a limited-access area that is off limits to nonparticipating personnel and should have facilities for the adequate isolation of septic patients.

Patient follow-up

Proper patient follow-up is an integral part of surgical treatment. An effective follow-up system for patients having open-heart surgery is the responsibility of the surgical team. The team should be able to demonstrate that it has an adequate follow-up system and that patients are seen as often as necessary during the immediate postdischarge period and, subsequently, are followed up at appropriate intervals.

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Guidelines

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sponsor hospitals and OEMS the ability to begin to collect EMS data, creating the potential in the near future to begin to analyze the data and create best practices to elevate the quality of care and delivery of Emergency Medical Services to the residents and visitors of Connecticut.

In late 2008/early 2009 the AHA formed a "STEMI stakeholders group" comprised of three sub-committees (pre-hospital, timely transfers and education) intended to develop and promulgate best practice related to ST segment myocardial infarction (STEMI). The group had a varied composition including physicians (EMS/ED, cardiology, and interventional cardiology), nurses, pre-hospital providers and health care administrators/regulators. This group drafted a document outlining recommendations to improve care in relation to pre-hospital triage of STEMI patients, timely transfers of patients between facilities and issues of education for pre-hospital providers. A "STEMI Protocol" was also drafted that was intended to offer state-wide guidance for best practice regarding patients experiencing chest pain and subsequently diagnosed with a STEMI by pre-hospital EKG (including bypass for more timely cardiac catheterization).

The "STEMI Protocol" was reviewed by the CT EMS Medical Advisory Committee (CEMSMAC) beginning in 2010. In 2011, after a significant amount of thoughtful work by the CEMSMAC, a revised version of the document entitled "CT EMS STEMI Guideline" was completed and submitted to the Commissioner of Public Health for review; it was approved in January 2012.

OHCA would encourage the adherence of the "CT EMS STEMI Guideline." The foremost goal is for authorized EMS personnel to obtain a 12-lead electrocardiogram in the field for all patients suspected of myocardial infarction, thereby increasing the likelihood for percutaneous coronary intervention (PCI) within 90 minutes of first medical contact. Please see link below for the complete "CT EMS STEMI Guideline" document:

http://www.ct.gov/dph/lib/dph/ems/pdf/stemi_patients.pdf

CARDIAC SERVICES

Heart disease is the leading cause of death for both men and women in the United States.[53] In 2010, coronary heart disease alone was projected to cost the United States approximately $108.9 billion in health care services, medications, and lost productivity.[54] In Connecticut, cardiovascular disease (CVD) is also a significant public health concern and contributor of resident deaths. In fact, about one third of Connecticut resident deaths are due to CVD; coronary heart disease (48%), cerebrovascular disease (15%) also known as stroke and heart failure (8%) account form the majority of CVD deaths.[55]

Existing Connecticut statute requires CON authorization for the establishment of cardiac services, including inpatient and outpatient cardiac catheterization, interventional cardiology and cardiovascular surgery. According to OHCA's Policies and Procedures, "interventional cardiology" is defined as non-

surgical procedures performed in the cardiac catheterization laboratory for the treatment of coronary artery and peripheral vascular disease. Procedures include, but are not limited to, angioplasty, valvuloplasty, cardiac ablation, coronary thrombectomy, and congenital heart defect correction. Only those procedures authorized pursuant to CON may be performed by a health care facility or provider. Multiple cardiac services may be authorized under one CON decision. A facility that is authorized to provide open heart surgery is also authorized to provide the full range of cardiac procedures mentioned above.

CARDIAC CATHETERIZATION

Cardiac catheterization is defined as a medical procedure requiring the passage of a catheter into one or more cardiac chambers of the left and right heart, with or without coronary arteriograms, for the purpose of diagnosing congenital or acquired cardiovascular disease, or for determining measurement of blood pressure flow.

ANGIOPLASTY/PERCUTANEOUS CORONARY INTERVENTION

Primary (emergent) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a previously diagnosed blockage in the heart. An expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow

Elective (scheduled) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure performed in a catheterization lab whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a previously diagnosed blockage in the heart. An expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow.

PCI and Elective PCI are often combined with the permanent placement of a small wire mesh tube called a stent to help prop the artery open and decrease the chance of it narrowing again. Some stents are coated with medication to help keep the artery open (drug-eluting stents), while others are not (bare-metal stents).

OPEN HEART SURGERY

Open heart surgery refers to a therapeutic operative procedure performed on the heart and/or its coronary arteries in order to correct anomalous conditions (for example, coronary artery bypass surgery, heart valve replacement), often using a heart-lung by-pass machine to perform the functions of circulation during surgery.

Authorization for Connecticut hospitals to perform elective catheter-based interventions for coronary artery disease has been limited in the past to hospitals with the ability to perform cardiac surgery onsite. However, increasing operator experience, improvements in surgical technique and major advances in technology and pharmacology have contributed to a progressive trend to allow PCI without on-site surgical backup. New evidence gives support to the positive effects that these medical advances have contributed to the significant reduction in emergency surgery following PCI[56]. Elective PCI without on-site surgical backup was, until recently, recommended as class III (not recommended, potentially harmful). However, an important change occurred in 2011, when the ACCF-AHA-SCAI PCI guidelines were modified to a class IIb (Level of evidence B) recommendation. CPORT-E trial findings conclude that patients have no greater risk of death or complications when they have Elective PCI at a hospital without cardiac surgery backup. However, similar to the 2007 SCAI Expert Consensus document, the revised guidelines also recommend stringent criteria for such programs. Connecticut hospitals seeking authorization to initiate an Elective PCI program without on-site cardiac surgery capabilities will be required to meet the SCAI conditions required in guidelines as well as demonstrate clear public need for the program.

DESCRIPTION OF DATA SOURCES

The primary source to be used for Acute Care utilization will be the CT Office of Health Care Access Acute Care Hospital Inpatient Discharge Database.

MAP OF CURRENT SERVICE LOCATIONS

Table 3.10: Adult Cardiac Services in Connecticut[57]

Hospital	Cardiac Cath	Primary PCI	Elective PCI	Open Heart
William. W. Backus	X			
Bridgeport Hospital	X	X	X	X
Danbury Hospital	X	X	X	X
John Dempsey Hospital	X	X	X	X
Greenwich Hospital	X	X		
Hartford Hospital	X	X	X	X
Lawrence & Memorial Hospital	X	X		
Middlesex Hospital	X			
Hospital of Central CT	X	X		
Norwalk Hospital	X	X		
Rockville General[1]	X			
St. Francis Hospital	X	X	X	X
HCGW (Saint Mary/Waterbury)	X	X	X	X

Hospital of Saint Raphael	X	X	X	X
St. Vincent's Medical Center	X	X	X	X
Stamford Hospital	X	X	X	X
Yale-New Haven Hospital	X	X	X	X

[1]Although allowed to provide the service, the hospital has not provided the cardiac services.
Source: CT DPH-OHCA Acute Care Hospital Service Line Survey, 2012

STANDARDS/GUIDELINES

Connecticut General Statutes Section 19a-638 specifies that at CON is required for: the establishment of cardiac services, including inpatient and outpatient cardiac catheterization, interventional cardiology and cardiovascular surgery.

The Office of Health Care Access has historically utilized Professional Societies and Organizations held to be the experts for establishing standards and guidelines for cardiac care and will continue to make appropriate use of their recommendations in the future review and determination of CON applications. Examples of expert sources to be used in determining standards and guidelines include: the American College of Cardiology, the American Heart Association and the Advisory Council for Cardiothoracic Surgery.

PERCUTANEOUS CORONARY INTERVENTION (PCI)

Primary PCI

1. Based on ACC and AHA, Primary PCI for STEMI should be performed by experienced operators who perform more than 75 elective PCIs per year and, ideally, at least 11 PCI procedures for STEMI per year. Ideally, these procedures should be performed in institutions that perform more than 400 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year.
2. A report by the American College of Cardiology/American Heart Association Task Force on practice guidelines, referring to Class II b, suggests that Primary PCI for patients with STEMI might be considered in hospitals without on-site cardiac surgery provided that appropriate planning for program development has been accomplished and includes: appropriately experienced physician operators (more than 75 total PCIs and, ideally, at least 11 primary PCIs per year for STEMI); an experienced catheterization team on a 24 hours per day; a 7 day per week call schedule; a well-equipped catheterization lab with digital imaging equipment; a full array of interventional equipment; intra-aortic balloon pump capability; and a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital with appropriate hemodynamic support capability for transfer. Primary PCI should be limited to patients with STEMI or MI with new or presumably new LBBB on ECG and should be performed in a timely fashion (goal of balloon inflation within 90 minutes of presentation) by persons skilled in the procedure (at least 75 PCIs per year) and at hospitals that perform a minimum of 36 Primary PCI procedures per year. (Level of Evidence: B - Limited populations evaluated. Data derived from a single randomized trial or nonrandomized studies).

Elective PCI

1. Elective/urgent PCI should be performed by operators with an acceptable annual volume (>75 procedures) at high volume centers (> 400 procedures) with on-site cardiac surgery (Level of Evidence: C)
2. Elective/urgent PCI should be performed by operators and institutions whose current risk-adjusted outcome statistics are comparable to those reported in contemporary national data registries, (Level of Evidence: C)
3. It is reasonable that low volume operators (< 75 PCI procedures per year) perform elective/urgent PCI at high volume centers (> 400 PCI procedures per year) with on-site cardiac surgery. Ideally, operators with an annual procedure volume of fewer than 75 procedures per year should only work at institutions with an activity level of more than 600 procedures per year. Operators who perform fewer than 75 procedures per year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume of at least 150 procedures per year. (Level of Evidence C)
4. It is not recommended that elective/urgent PCI be performed by low volume operators (< 75 PCI procedures per year) at low volume centers (200 to 400 procedures per year) with or without on-site cardiac surgery. An institution with a volume of fewer than 200 procedures per year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer this service. (Level of Evidence: C)
5. The 2005 PCI Guideline does not establish an explicit minimum hospital volume threshold for elective PCI; there are multiple references in the context of operator and institutional competency to "centers" performing 200 – 400 elective PCI procedures per year.
6. The 2011 PCI Guideline states that operator and hospital volume recommendations have been carried over from the ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention.

   a. PCI in Hospitals without On-Site Surgical Back-up is in the Class IIb category.

      Class II b: Elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection (Level of Evidence: B)

      Any hospital considering elective PCI without on-site-cardiac surgery must meet the criteria set forth in the 2011 ACCF/ANA/SCAI PCI Guideline, Section 4.8., PCI in Hospitals Without On-Site Surgical Backup: Recommendations (see link below):

      http://content.onlinejacc.org/cgi/reprint/58/24/e44.pdf

      Any hospital not meeting the 2011 ACCF/ANA/SCAI PCI Guideline criteria will be considered to be in Class III.

Class III–Harm: Primary and elective PCI should not be performed in hospitals without on-site cardiac surgery capabilities without a proven plan for rapid transport to a surgery operating room in a nearby hospital or without appropriate hemodynamic support capability for transfer. (Level of Evidence: C)

Quality and Performance Considerations for PCI Programs

Based on the 2011 American College of Cardiology Foundation/American Heart Association/Society for Cardiovascular Angiography and Interventions Guidelines for Percutaneous Coronary Intervention:

1. Every PCI program should operate a quality improvement program that routinely:
   a) reviews quality and outcomes of the entire program;
   b) reviews results of individual operators;
   c) includes risk adjustment;
   d) provides peer review of difficult or complicated cases; and
   e) performs random case reviews (Level of Evidence: C)
2. Every PCI program should participate in a regional or national PCI registry for the purpose of benchmarking its outcomes against national norms. (Level of Evidence: C)

PCI quality and performance considerations are defined by attributes related to structure, processes, and risk adjusted outcomes. Structural elements include, for example, staffing, equipment, supplies, operator and institutional volumes, and the availability of electronic medical records. Processes include strategies for the appropriate patient, protocols for pre- and post-procedural care, appropriate procedural execution and management of complications, and participation in databases and registries for benchmarking program and individual operator performance. The end result of these structures and processes of care are risk-adjusted outcomes, and when available, are more reliable measures of quality than the institutional and individual operator volumes.[58]

CARDIAC SURGERY/OPEN HEART SURGERY[59]

1. Guidelines for Standards in Cardiac Surgery developed by the Advisory Council for Cardiothoracic Surgery and approved by the American College of Surgeons' Board of Regents in October 1996 – Bulletin of the American College of Surgeons, Vol. 82, No. 2, February 1997
   a. An annual volume of at least 100 to 125 open heart procedures per hospital is necessary from a quality standpoint and there is a greater variation in adjusted mortality rates for teams doing lower volumes as compared with those doing a high volume.
   b. At least 200 procedures per year are necessary in order for a program to function efficiently
   c. A team approach with a minimum of 2 qualified cardiac surgeons is recommended to provide adequate and continuous perioperative care as well as assistance in the OR.
2. The following conditions must be met to initiate a new OHS program:

a. The annual caseload of other programs w/in the proposed PSA shall not drop below 350 procedures.
b. Epidemiological evidence of conditions for which OHS is appropriate w/in the PSA or demonstrates a significant unmet need in the PSA for these procedures.
c. Existing program(s) in the service area are performing at least 350 open heart surgeries annually.
d. Evidence demonstrating the performance of a minimum of 200 open heart surgeries annually within the first three years of the start of the new Open Heart Surgery program.

CARDIAC UTILIZATION

Based on hospital discharge data, inpatient cardiac care is declining both in patient volume and overall patient days (see Table 4.7 and Chart 4.3). From FY 2008 to FY 2011, Cardiac Care-Medical discharges dropped 6%, while the corresponding patient days declined by 3%. During the same time period, Cardiac Care-Surgical care declined even more significantly, with both discharges (11%) and patient days (8%) falling.

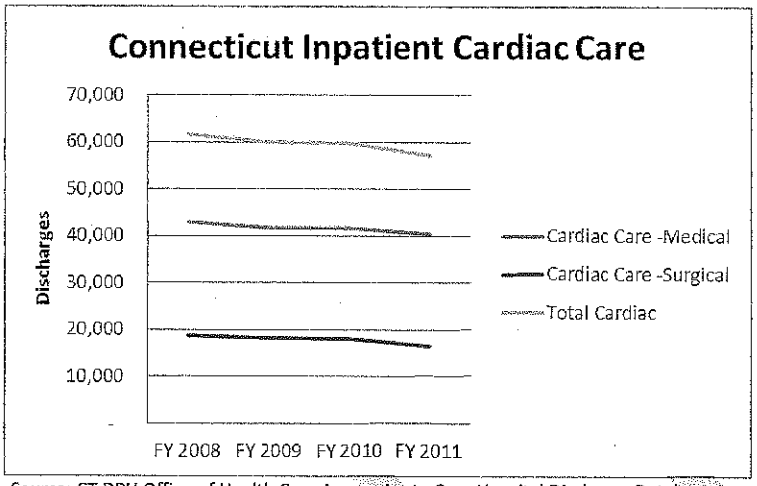
Table 3.11: Statewide Cardiac Inpatient Data

Discharges	FY 2008	FY 2009	FY 2010	FY 2011	chg 08-11	chg 10-11
Cardiac Care -Medical	43,072	41,747	41,795	40,542	-6%	-3%
Cardiac Care -Surgical	18,681	18,299	18,104	16,710	-11%	-8%
Total Cardiac	**61,753**	**60,046**	**59,899**	**57,252**	**-7%**	**-4%**

Patient Days	FY 2008	FY 2009	FY 2010	FY 2011	chg 08-11	chg 10-11
Cardiac Care -Medical	159,087	156,890	155,239	153,817	-3%	-1%
Cardiac Care -Surgical	95,344	93,054	90,455	87,361	-8%	-3%
Total Cardiac	**254,431**	**249,944**	**245,694**	**241,178**	**-5%**	**-2%**

Source: CT DPH Office of Health Care Access Acute Care Hospital Discharge Database

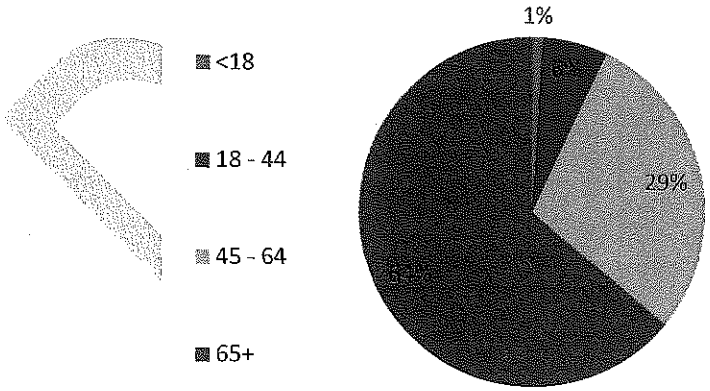
Chart 3.4: Connecticut Inpatient Cardiac Care



Source: CT DPH Office of Health Care Access Acute Care Hospital Discharge Database

Cardiac discharges are highly prevalent among the elderly. As seen in Chart 4.3, sixty-four percent of inpatient cardiac discharges in FY 2011 were for patients age 65 and older.

Chart 3.5: Cardiac Discharges by Age (FY 2011)



Source: CT DPH Office of Health Care Access Acute Care Hospital Discharge Database

DISCUSSION OF UNMET NEED AND GAPS IN SERVICES, CAPACITY ISSUES, ETC.

The tables below provide an initial step toward the identification of potential areas of unmet need for cardiac care in the state. The tables below provide information that compares the number of residents from a given region that received treatment for cardiac medical services or surgery in a given year (patient demand). This patient demand is compared to the overall volume of cardiac patients served by hospitals in the same region. If hospital volumes are lower than patient demand in the region, it may indicate the need for additional capacity and warrants additional study to examine patient migration patterns to confirm or refute this assertion.

Table 3.12: Bed Need for Inpatient Cardiac Services

Hospitals	DEMHS Region	Service		Discharges				Patient Days			
				2007	2008	2009	2010	2007	2008	2009	2010
Bridgeport, Norwalk, Greenwich, Stamford, St Vincent's	1	Medical	Demand	7,589	7,249	7,242	7,060	29,191	28,470	27,882	27,702
			Served	8,642	8,345	8,412	8,230	32,392	32,060	31,436	31,124
			Surplus (-) or Deficit (+)	(1,053)	(1,096)	(1,170)	(1,170)	(3,201)	(3,590)	(3,554)	(3,422)
		Surgical	Demand	3,418	3,340	3,031	2,926	17,810	16,340	15,777	14,429
			Served	3,850	3,728	3,263	3,205	19,693	17,724	16,198	15,181
			Surplus (-) or Deficit (+)	(432)	(388)	(232)	(279)	(1,883)	(1,384)	(421)	(752)

Hospitals	DEMHS Region	Service		Discharges				Patient Days			
				2007	2008	2009	2010	2007	2008	2009	2010
Yale, Griffin, Milford, St Raphael, MidState	2	Medical	Demand	10,202	10,250	9,967	10,664	36,304	37,646	36,740	38,338
			Served	10,000	9,936	9,745	10,539	35,660	37,066	36,198	38,379
			Surplus (-) or Deficit (+)	202	314	222	125	644	580	542	(41)
		Surgical	Demand	4,243	4,119	4,088	4,176	21,406	21,045	20,583	20,451
			Served	5,117	5,118	5,323	5,441	25,969	26,043	26,558	25,675
			Surplus (-) or Deficit (+)	(874)	(999)	(1,235)	(1,265)	(4,563)	(4,998)	(5,975)	(5,224)

Hospitals	DEMHS Region	Service		Discharges				Patient Days			
				2007	2008	2009	2010	2007	2008	2009	2010
Dempsey, Saint Francis, Bristol, HOCCT, Manchester, Hartford, CTCMC, Middlesex, Rockville, Johnson	3	Medical	Demand	12,700	12,162	11,646	10,991	45,621	47,067	46,730	44,209
			Served	14,235	13,846	13,164	12,561	51,503	53,644	53,461	50,397
			Surplus (-) or Deficit (+)	(1,535)	(1,684)	(1,518)	(1,570)	(5,882)	(6,577)	(6,731)	(6,188)
		Surgical	Demand	5,902	5,599	5,600	5,357	33,547	29,771	30,034	28,463
			Served	7,704	7,280	7,172	6,951	43,656	39,799	39,143	38,204
			Surplus (-) or Deficit (+)	(1,802)	(1,681)	(1,572)	(1,594)	(10,109)	(10,028)	(9,109)	(9,721)

Hospitals	DEMHS Region	Service		Discharges				Patient Days			
				2007	2008	2009	2010	2007	2008	2009	2010
Backus, L&M, Day Kimball, Windham	4	Medical	Demand	5,252	5,773	5,422	5,451	17,269	19,042	18,659	17,806
			Served	4,772	5,187	4,904	4,926	14,865	16,203	15,676	15,085
			Surplus (-) or Deficit (+)	480	586	518	525	2,404	2,839	2,983	2,721
		Surgical	Demand	1,948	2,051	1,980	2,120	10,652	10,340	9,556	10,658
			Served	382	426	396	414	2,227	1,982	1,923	2,052
			Surplus (-) or Deficit (+)	1,566	1,625	1,584	1,706	8,425	8,358	7,633	8,606

Hospitals	DEMHS Region	Service		Discharges 2007	Discharges 2008	Discharges 2009	Discharges 2010	Patient Days 2007	Patient Days 2008	Patient Days 2009	Patient Days 2010
Danbury, New Milford, Hungerford, Sharon, St Mary's, Waterbury	5	Medical	Demand	6,454	6,026	5,884	5,864	22,071	21,794	21,988	21,740
			Served	6,183	5,758	5,522	5,539	20,718	20,114	20,119	20,254
			Surplus (-) or Deficit (+)	271	268	362	325	1,353	1,680	1,869	1,486
		Surgical	Demand	3,001	2,864	2,901	2,811	14,999	14,367	13,705	12,906
			Served	2,164	2,129	2,145	2,093	10,302	9,796	9,232	9,343
			Surplus (-) or Deficit (+)	837	735	756	718	4,697	4,571	4,473	3,563

Hospitals		Service		Discharges 2007	Discharges 2008	Discharges 2009	Discharges 2010	Patient Days 2007	Patient Days 2008	Patient Days 2009	Patient Days 2010
Distributed among several hospitals	Out of State, Unk Address	Medical	Demand	1,635	1,612	1,586	1,765	4,682	5,068	4,891	5,444
			Served								
			Surplus (-) or Deficit (+)								
		Surgical	Demand	705	708	699	714	3,433	3,481	3,399	3,528
			Served								
			Surplus (-) or Deficit (+)								

RECOMMENDATIONS

1. Examine volume as indicator of quality, as well as other indicators, by examining institutional and operator performance.
2. Continue to review and update Connecticut's cardiac guidelines to reflect updated information and recommendations provided by Professional Societies and Organizations with expert knowledge of cardiac care.

CANCER TREATMENT

Oncology is the branch of medicine concerned with the study and treatment of cancer, including screening, diagnosis, therapy, follow-up and palliative care. It includes various sub specialties such as radiation oncology (medical use of high-energy radiation to kill malignant cells), surgical oncology, and pediatric oncology. Chemotherapy, most generally the treatment of disease by chemicals, can be used for a range of diseases but most frequently refers to antineoplastic drugs to treat cancer.

In Connecticut, there is no unique licensure category for cancer treatment. The Commission on Cancer (CoC), a consortium of professional organizations dedicated to improving cancer patients' lives, administers an accreditation program that encourages hospitals, treatment centers, and other facilities to improve the quality of patient care by focusing on prevention, early diagnosis, pretreatment evaluation, staging, optimal treatment, rehabilitation, surveillance for recurrent disease, support services, and end-of-life care. A broad range of available medical services combined with a multidisciplinary team approach has resulted in 80 percent of all newly diagnosed cancer patients in the US being treated in CoC-accredited cancer programs.[60] According to the CT Cancer Partnership, 67% of acute care hospitals in Connecticut are ACoS accredited.[61].

ATTACHMENT V

From: Nancy Rosenthal
To: "Jennifer Groves"; Karen Banoff; Marc Kosak; Nancy Hamson; Ahn, Jean; Capozzalo, Gayle
Subject: Fwd: PCI without surgery on site
Date: Friday, July 13, 2012 12:34:06 PM

Sent from my iPhone

Begin forwarded message:

From: Nancy Rosenthal <argrjrnr@optonline.net>
Date: July 13, 2012 12:33:06 PM EDT
To: Nancy Rosenthal <Nancy.Rosenthal@greenwichhospital.org>
Subject: Fwd: PCI without surgery on site

Sent from my iPhone

Begin forwarded message:

From: "Anna D. Colello" <adc05@health.state.ny.us>
Date: July 13, 2012 12:11:20 PM EDT
To: JONATHAN ROSENTHAL <argrjrnr@optonline.net>
Subject: RE: PCI without surgery on site

I do not know

Anna

<graycol.gif> JONATHAN ROSENTHAL ---07/13/2012 11:55:06 AM---
Because I heard they were unsuccessful in getting regulatory approval. Why did St. John's withdraw its application.

JONATHAN ROSENTHAL <argrjrnr@optonline.net> <ecblank.gif> <ecblank.gif>
To
07/13/2012 11:55 AM adc05@health.state.ny.us
<ecblank.gif> <ecblank.gif>
cc
<ecblank.gif> <ecblank.gif>
Subject
RE: PCI without surgery on site

<ecblank.gif> <ecblank.gif>

Because I heard they were unsuccessful in getting regulatory

approval. Why did St. John's withdraw its application.

On Fri, Jul 13, 2012 at 11:51 AM, Anna D. Colello wrote:

They have not been denied privileges. Why did you think so?

St John's Riverside withdrew its application in April 2012.
Sound Shore requested more time and their application remains open.

Anna Colello, Esq.
Director, Regulatory Compliance/OHSM
Cardiac Services Program
One University Place, Suite 218
Rensselaer, New York 12144
Phone: 518-402-4091
Fax: 518-402-6992

Inactive hide details for JONATHAN ROSENTHAL --- 07/13/2012 11:42:56 AM---Anna, Could you tell me when and why St. Johns Riversi JONATHAN ROSENTHAL --- 07/13/2012 11:42:56 AM---Anna, Could you tell me when and why St. Johns Riverside and Sound Shore Hospitals were denied angioplasty privileges?

JONATHAN ROSENTHAL <arqrjmr@optonline.net>
07/13/2012 11:42 AM

To

adc05@health.state.ny.us

cc

Subject

RE: PCI without surgery on site

Anna,

Could you tell me when and why St. Johns Riverside and Sound Shore Hospitals were denied angioplasty privileges?

Nancy

On Fri, Jul 13, 2012 at 11:37 AM, Anna D. Colello wrote:

This is in response to your query regarding the number of hospitals which perform elective angioplasty (PCI - percutaneous coronary intervention) without surgery on site. Section 405.29 of the Department of Health regulations specify that hospitals wishing to perform PCI must perform both primary (emergency) and elective. These regulations were promulgated in November 2009. Prior to that time there was a waiver process which

allowed first primary and later elective procedures to be approved for centers without surgery on site. One center (Bronx Lebanon Hospital) was approved for primary under the waiver system which has not yet requested approval for elective. No new center would be permitted to do just primary because of the regulations.

The centers which perform PCI without surgery on site are:
Unity Health System (Wilson Hospital)
South Nassau Communities Hospital
Faxton-St Luke's Healthcare (St Luke's Division)
Orange Regional Medical Center
St Luke's Cornwall Hospital
St Catherine of Siena Medical Center
Glens Falls Hospital
White Plains Hospital
Brookdale Hospital Medical Center
Long Island College Hospital
Lutheran Medical Center
City Hospital at Elmhurst
Jamaica Hospital Medical Center
St Barnabas
Good Samaritan Hospital on Long Island received approval as a surgery center but has not opened its surgery center so remains PCi w/o surgery at this time
Brookhaven Hospital was very recently approved to do PCI (but do not believe it has opened for PCI) It previously was diagnostic only.

Southside Hospital was approved as a surgery center in 2011

Anna Colello, Esq.
Director, Regulatory Compliance/OHSM
Cardiac Services Program
One University Place, Suite 218
Rensselaer, New York 12144
Phone: 518-402-4091
Fax: 518-402-6992

****

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****

Dr. Christopher Howes

I would like to make some comments regarding certain aspects of Dr. William Gray's testimony including some content from the 2011 ACCF/AHA/SCAI Guidelines for Angioplasty and the 2012 ACCF/SCAI Expert Consensus Document Update.

- Dr. Gray highlighted certain content from the above referenced documents, but neglected to mention other content which clearly is consistent with the proposed program at Greenwich Hospital.

  The 2012 ACCF/SCAI Expert Consensus Document Update states on page 5 of the publication that:

  > "It is generally believed that elective and primary PCI are permissible in sites without cardiovascular surgery, if there is strict adherence to national guidelines. In particular, there must be a documented working relationship with a larger facility with cardiovascular surgical services and an emergency transportation system operative."

  As our CON application clearly says, the proposed elective angioplasty program would be a satellite of the YNHHVC, which is a full service cardiac facility. There is already an emergency transportation system in operation that includes both land and air. Consistent with the 2011 ACCF/AHA/SCAI Guidelines for Angioplasty, our ambulance provider has committed to respond to requests within 20 minutes (see Attachment I). The 2012 ACCF/SCAI Expert Consensus Document Update also stresses (page 5) that a QA/QI system be operative and active, operate 24/7 if emergency angioplasty is provided and participate in a national registry such as the ACC's National Cardiovascular Data Registry. The current emergency angioplasty program at Greenwich Hospital meets all of these recommendations and the proposed elective angioplasty program will as well.

The change in the 2011 ACCF/AHA/SCAI guidelines for elective angioplasty without onsite cardiac surgery from a Class III to a Class IIb is significant. Dr. Gray states this change is only "incremental", but my opinion is to move from a Class III which indicates harm to a Class IIb which states such a program might be considered as long as there is appropriate program development and rigorous criteria for proper patient selection is beyond "incremental". OHCA has recognized this significant change and incorporated in their Cardiac Services section of the new State Health Plan (draft form) the following statement:

> "...an important change occurred in 2011, when the ACCF-AHA-SCAI PCI guidelines were modified to a class IIb (Level of evidence B) recommendation".

- Dr. Gray discusses the results of the CPORT-E study recently published in the New England Journal of Medicine and suggests that our CON application included the position that elective angioplasty without onsite cardiac surgery is preferred over sites with onsite surgery. Our application never included any such suggestion. But the CPORT-E study, along with others noted in Dr. Cabin's prefiled testimony, and the shift from a Class III to a Class IIb assignment by the ACCF/AHA/SCAI Angioplasty Guidelines all support the reasonableness of offering elective angioplasty without onsite cardiac surgery as long as number of criteria are met which we have already addressed in our CON application. Dr. Gray's skepticism and criticism of angioplasty without onsite cardiac surgery is puzzling given his institution's (NYP) support of White Plains Hospital's program as well as support of a similar program by another NYP affiliate, Holy Name Hospital in Teaneck, New Jersey.

- Dr. Gray also highlights the statement in the 2011 ACCF/AHA/SCAI Guidelines which discusses competition with another angioplasty program in the same geographic area, particularly an established program with surgical back-up and that such competition MAY not be in the best interests of the community. The data we included in our prefiled testimony clearly shows that Greenwich and Stamford Hospitals are overwhelmingly serving residents of different communities. I would go so far as to say that we do not compete in the area of cardiology, despite our close geography. Our medical staff in

cardiovascular services does not overlap to any measurable degree and referral patterns to the interventional cardiologists are different. We have offered emergency angioplasty for approximately 8 years and despite the entrance of Stamford Hospital's program, we have maintained our emergency and elective transfer volume because patients want their care from Greenwich Hospital and the YNHHVC. In this case, a program at Greenwich Hospital IS in the best interest of the community because the Greenwich Hospital community has demonstrated that is where they want their care.

- Dr. Gray states that if the program at Greenwich Hospital is approved there is a risk that Stamford and Greenwich Hospital's angioplasty programs may perform less than 200 PCIs per year. For the reasons I have outlined above, we do not believe our program will impact Stamford's program due to the lack of patient and physician crossover. It is worthy to note that since the opening of White Plains Hospital's program, Stamford Hospital has not seen any decline in their angioplasty volume. According to Stamford Hospital's Petition, Stamford Hospital "...is on track to perform 277 PCIs in FY 2012" which represents a 25% increase from its 2011 volume as noted on Dr. Kiely's testimony page 32 (PCR data). Clearly, the presence of the White Plains Hospital program, which is located only 15 miles from Stamford Hospital and performed as many as 290 PCIs last year, has not had any impact on Stamford Hospital's angioplasty volumes.

- I must comment on Dr. Gray's suggestion that approval of the proposed program at Greenwich Hospital would in some way encourage physicians to feel "...pressure to refer patients for procedures to keep institutional volumes up. Occurrences like these will only drive up healthcare costs for payers and patients." Dr. Gray is suggesting that physicians may send a patient for an unnecessary procedure just to increase institutional volumes. This may be the practice at New York Presbyterian, but I can assure you that this is NOT the practice of YNHHVC physicians nor would it ever be condoned or permitted.

- Finally, I would like to put on the record that the State of New York regulations cited in Dr. Gray's testimony have no relevance in this CON application. Those regulations apply only to New York hospitals. Although they are irrelevant to this proceeding, it is interesting to note in New York State, hospitals seeking to perform angioplasty without onsite cardiac surgery must perform BOTH primary and elective (refer to Attachment V of Marna Borgstrom's rebuttal testimony). I suspect New York State incorporated this requirement because they recognize the benefits to patients by ensuring access to both types of angioplasty and the positive impact on institutional volumes.

The foregoing is my sworn testimony.

Christopher Howes, MD
Assistant Professor at the Yale University School of Medicine
Medical Director, Greenwich Hospital Primary Angioplasty Program

Nelson Ambulance Pride in Service | Access Ambulance Service | Connecticut Handivan, Inc.

208 Quinnipiac Ave North Haven, CT 06473

July12,2012

To whom it may concern,

Nelson /Access Ambulance and Connecticut Handivan has the privilege of serving Greenwich hospital for patient transportation at ALS and BLS level care as well as wheelchair transportation.

We also staff a critical care Ambulance at Greenwich hospital to facilitate transport for any Advanced Life Support patients. The Paramedic units are equipped with ventilators and Greenwich hospital compatible IV pumps.

It will be our commitment to have an ALS ambulance on scene for pick up within the twenty (20) minute time frame of the call for all Catheterization Lab patient needed transfers to other hospitals.

We appreciate the opportunity to service Greenwich Hospital for all patient transportation, we look forward to servicing the patient's needs as a new innovative procedural department opens.

Denise Markavich
Director of Operations EMT-P AHA-I
Nelson/ Access Ambulance
Connecticut Handi-Van

PROCEDURAL MOTIONS

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS DIVISION

IN RE: ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM AT GREENWICH HOSPITAL	DOCKET NO. 12-31748-CON
	JULY 16, 2012

GREENWICH HOSPITAL AND YALE-NEW HAVEN HOSPITAL'S OBJECTION TO THE STAMFORD HOSPITAL'S PETITION FOR INTERVENOR STATUS & MOTION TO STRIKE TESTIMONY

Greenwich Hospital ("Greenwich") and Yale-New Haven Hospital ("YNHH") (collectively "Applicants"), Applicants in the above-referenced matter, hereby object to the Petition for Intervenor Status With Full Procedural Rights filed by The Stamford Hospital ("TSH"), on July 12, 2012 ("Petition"). Specifically, Applicants object to TSH's request that it be allowed to submit "rebuttal testimony" in connection with the public hearing scheduled for July 17, 2012. "Rebuttal testimony" is a privilege that OHCA typically reserves for applicants, who are customarily given the last word on the record in their own applications. In addition, Applicants move to strike all references in the testimony and exhibits to the elective angioplasty CON application filed by Lawrence & Memorial Hospital ("L&M Application"). The L&M Application has not yet been deemed complete by OHCA and, as such, it is not considered an official CON request. Moreover, because OHCA evaluates and

decides each CON application on its own merits, the arguments advanced by L&M in an unrelated CON request are irrelevant to this proceeding.

TSH Is Not Entitled To Submit Rebuttal Testimony

In its Petition, TSH "seeks permission to offer rebuttal testimony" and claims that it will demonstrate the deficiencies in Applicants' proposal through "evidence ... presented in rebuttal." Petition, pp. 8 & 9. As TSH and its counsel are aware, intervenors in a contested case are not usually given the right to submit written rebuttal evidence prior to the public hearing. As an intervenor (should OHCA grant TSH this status), TSH was required to pre-file any and all testimony that it intends to present at the hearing by June 12, 2012 at noon. TSH has had access to a copy of Applicants' initial CON submission since it was filed on February 14, 2012, and has had ample time to consider and prepare its opposition. Applicants, on the other hand, will have had access to TSH's 388-page opposition document for a mere 5 days before the hearing and did not have benefit of reviewing this document prior to submitting their own testimony (which was also due at noon on June 12th). It is for this reason that Applicants are allowed an opportunity to submit a written rebuttal. Also, it is Applicants' burden of proving their case in chief for this CON request, and it is fair that they be given the last word in written submissions.

Moreover, if OHCA grants TSH full procedural rights, TSH will have an opportunity to rebut any information contained in Applicants' pre-hearing submissions through cross-examination of Applicants' witnesses. In addition, as TSH and its counsel surely know, "rebuttal" points are often raised without objection during oral hearing presentations and in response to questions posed by OHCA and the parties. For these reasons, Applicants request that TSH be denied the right to submit

or introduce, at or before the hearing, any additional written testimony or evidence beyond what was included in their June 12th filing.

All References to the L&M Elective Angioplasty CON Application Should be Stricken from the Record

TSH has included in its Petition, as well as in the testimonies of Drs. Sharon Kiely and William Gray, numerous references to the CON application submitted by L&M to establish an elective angioplasty program in New London. Reference is made in the text of the Petition at pages 6-7. Dr. Kiely mentions the L&M project in her testimony (pp. 10-11, 12) and, incredibly, attaches the 56-page CON application in that matter as an exhibit (pp. 53-109). Dr. Gray also mentions the L&M proposal in his testimony at pages 7 and 10 (page 10 makes reference to the CON application for elective angioplasty being filed by The Hospital of Central Connecticut as well).

As a threshold matter, OHCA should not consider the L&M Application because it has not yet been deemed complete. OHCA is still in the process of its completeness review and until L&M responds to any questions from the agency, the CON application remains incomplete and does not constitute an official CON request.

TSH's argument for including the L&M Application is simple – that L&M presents a better case for the addition of elective angioplasty without onsite surgery than Greenwich. However, none of what TSH proposes to say about the L&M Application is relevant to the matter before OHCA. Other than the relationships that both programs have with the Yale New Haven Heart and Vascular Center ("YNHHVC"), the proposals are entirely different. As TSH aptly points out, the programs operate at opposite ends of the state serving distinct patient populations. Allowing this type of

testimony into the record opens the door for future applicants to claim relevance of similar proposals at hospitals and facilities that are nowhere near their own.

OHCA has been clear in its policy that each CON request is evaluated on its own merits and that applications do not lend themselves to general applicability. The fact that TSH has included the L&M Application in its opposition submission is inappropriate. It is a not-so-veiled attempt by TSH to convince OHCA that it should approve only one YNHHVC satellite elective angioplasty program without onsite surgery – the one that is 90 miles away from Stamford. TSH has an obvious self-interest in defeating Applicants' proposal, which is clearly needed and which will undoubtedly improve the quality and accessibility of angioplasty services for area residents. TSH should not be allowed to distract from the real issues before this agency by testifying and cross-examining Applicants' witnesses on a CON that has no relevance to the pending application. For these reasons, Applicants request that all references to the L&M Application be stricken from the record.

WHEREFORE, for the foregoing reasons Applicants request that their Objection to TSH's Petition for Intervenor Status be sustained and their Motion to Strike be granted.

Respectfully Submitted,

GREENWICH HOSPITAL
YALE-NEW HAVEN HOSPITAL

By: _____

JENNIFER L. GROVES, ESQ.
Updike, Kelly & Spellacy, P.C.
265 Church Street
One Century Tower
New Haven, CT 06510
Tel: (203) 786-8300
Fax (203) 772-2037

CERTIFICATION

I hereby certify that a copy of the foregoing has been sent via facsimile and first class mail, postage prepaid, this 16th of July, 2012 to the following:

Stephen M. Cowherd
Jeffers Cowherd
5 Walls Drive
Fairfield, CT 06824

Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS DIVISION

IN RE: ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM AT GREENWICH HOSPITAL	DOCKET NO. 12-31748-CON
	JULY 16, 2012

GREENWICH HOSPITAL AND YALE-NEW HAVEN HOSPITAL'S OBJECTION TO THE ADMINISTRATIVE NOTICE OF DOCKET NO. 08-31210-CON

Greenwich Hospital ("Greenwich") and Yale-New Haven Hospital ("YNHH") (collectively "Applicants"), Applicants in the above-referenced matter, hereby object to OHCA's decision (see Exhibit A attached) to take administrative notice of the entire record of Applicants' previous CON request for permission to establish an elective angioplasty program in Greenwich (Docket No. 08-31210-CON) (the "2008 Docket"). Applicants object to the inclusions of the 2008 Docket in the record of this matter on the grounds that (i) it is the written policy of OHCA to evaluate every CON proposal on a case-by-case basis and decide each application on its own merits; and (ii) the current application is fundamentally different than the 2008 Docket and the inclusion of outdated and irrelevant information from that docket will only serve to confuse the issues before OHCA in this proceeding.

While OHCA has the authority to take administrative notice of judicially cognizable facts, including prior orders and decisions, it has long been the policy of the agency not to take notice of prior dockets in their entirety for purposes of a hearing on a CON request. Participants in a hearing will often ask the agency to take notice of prior dockets involving their opponents so that they can cross-examine for inconsistencies. Applicants sometimes also ask OHCA to take

administrative notice of the dockets of similar proposals for purposes of comparison. OHCA's response has typically been to deny the requests for administrative notice on the grounds that each CON is unique (while giving latitude to cross-examine witnesses on select parts of relevant dockets that are included in pre-hearing submissions) – meaning prior dockets, whether they involve the same parties or the same or similar services, are irrelevant to the analysis of a CON proposal. The preamble to virtually every CON decision since 2005 includes a caveat stating that CONs do not lend themselves to general applicability and that every case is reviewed and judged on its merits.

Applicants are concerned that by taking administrative notice of the 2008 Docket, and by possibly allowing The Stamford Hospital to cross-examine Applicants' witnesses on prior submissions, the issues before OHCA will become confused and the current application will not be decided on its own merits. Much of the information contained within the 2008 Docket has changed and is no longer relevant to Applicants' elective angioplasty proposal. This includes, but is not limited to, changes in the structure of the proposed affiliation arrangement; changes to the ACCF/AHA/SCAI Guidelines recommendations for elective angioplasty without onsite surgical backup; revised need methodology; and changes in the treatment of border hospitals by OHCA for state health planning purposes. In addition, the CON laws themselves have changed since the 2008 Docket was decided and the statutory decision criteria that governed that application are not applicable to this CON request.

For these reasons, Applicants respectfully request that OHCA reconsider its decision to take administrative notice of the 2008 Docket. In the alternative, if the 2008 Docket remains a part of the record in this matter, Applicants request that any cross-examination be limited to information relevant to the 2012 elective angioplasty proposal. Applicants further request that

any information from that docket be given appropriately limited weight and consideration. This will afford Applicants' the fairest possible resolution of the current CON request.

WHEREFORE, Applicants respectfully request that their Objection to the Administrative Notice of Docket No. 08-31210-CON be granted.

Respectfully Submitted,

GREENWICH HOSPITAL
YALE-NEW HAVEN HOSPITAL

By: _____

JENNIFER L. GROVES, ESQ.
Updike, Kelly & Spellacy, P.C.
265 Church Street
One Century Tower
New Haven, CT 06510
Tel: (203) 786-8300
Fax (203) 772-2037

CERTIFICATION

I hereby certify that a copy of the foregoing has been sent via facsimile and first class mail, postage prepaid, this 16th of July, 2012 to the following:

Stephen M. Cowherd
Jeffers Cowherd
5 Walls Drive
Fairfield, CT 06824

Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.

EXHIBIT A

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
Office of Health Care Access

March 15, 2012

VIA FAX & EMAIL ONLY

Ms. Jean Ahn
System Director
Yale-New Haven Hospital
Planning & Business Development Office
20 York Street (Howe 3)
New Haven, CT 06504

RE: Certificate of Need Application; Docket Number: 12-31748-CON
Yale-New Haven Hospital and Greenwich Hospital
Proposal to Establish and Operate an Elective Angioplasty
Program without Onsite Surgical Backup at Greenwich Hospital

Dear Ms. Ahn:

On February 14, 2012, the Office of Health Care Access ("OHCA") received your initial Certificate of Need ("CON") application filing on behalf of Yale-New Haven Hospital ("YNHH") and Greenwich Hospital ("Hospital") (collectively the "Applicants") for the establishment and operation of an elective angioplasty program without onsite surgical backup at the Hospital.

Note: Please be advised, administrative notice is being taken of the entire record of the prior CON application in this matter, as identified under Docket Number: 08-31210-CON. A copy of the Final Table of the Record from the aforementioned record has been attached as Exhibit I, identifying all the individual exhibits included in the record.

OHCA has reviewed the CON application and requests the following additional information pursuant to General Statutes §19a-639a(c):

Clear Public Need - pages 15 through 29

1. With respect to the state map presented on page 18 of the CON application, please provide a map legend and notes of a legible size as the application's presentation is difficult to discern.

2. With respect to the table entitled "Number of Patients Discharged Directly from GH to Another Institution for Elective Angioplasty" on page 19 of the CON application, please address the following:

    a. Identify the distance in miles and travel time between Greenwich Hospital and each of the other six hospitals to which Greenwich Hospital transfered patients requiring elective angioplasty over the last four and a quarter fiscal year period.

    b. Describe the existing physician referral patterns that have resulted in 232 patients needing elective angioplasty, not being able to access this service and being transferred to other Connecticut hospitals; 235 to Yale-New Haven Hospital and 2 to Stamford Hospital over four and a quarter fiscal year period.

3. The Applicants point out that: "... transferring patients to another facility creates an unnecessary stressful and uncomfortable situation for patients and family." Further "transferring to another facility is an increased stress for the patients and their families with regard to transportation. For some, in Greenwich Hospital's greater service area, transportation outside the service area is problematic." This being the case, why is Yale-New Haven Hospital the institution of choice when transferring a patient requiring elective angioplasty, as Stamford Hospital presents a much closer Connecticut alternative hospital site?

4. With respect to the table entitled Population Projections- Greenwich Hospital Service Area on page 27 of the CON application, please provide two tables in the same format, the first depicting the population projections for the state of Connecticut and the second depicting the population projections for the state of New York.

5. Please address the following questions regarding existing providers of elective angioplasty closest to the Hospital and its service area:

    a. Please identify all providers that currently offer Elective Angioplasty.
    b. Identify the existing providers that currently offer elective angioplasty with on-site surgical backup.
    c. What impact will this proposal have on these exiting providers financially and on their elective PCI utilization?

6. Provide a copy of the Hospital's protocols related to the proposed elective angioplasty without cardiac surgery backup. Additionally, explain any protocols that will be specific to this program.

2011 ACCF/AHA/SCAI Guidelines for Percutaneous Coronary Intervention-pages 140-230

7. In regard to the Attachment VI: 2011 ACCF/AHA/SCAI Guidelines for Percutaneous Coronary Intervention, please address the following questions:

a. How does the Hospital meet each of the criteria listed in Class IIa, IIb, III and tables 5 & 6?

b. How does the Hospital plan to meet the guidelines regarding the rapid transport to a cardiac surgery operating room in a nearby hospital and without hemodynamic support to transfer?

c. How do ACCF/AHA/SCAI guidelines define "nearby" hospital/operating room?

d. How does the Hospital's transport agreement with YNHH (where majority of the patients have been transferred in the past) relate to or meet the guidelines?

e. The Hospital's median time to immediate PCI for STEMI patients is 67.0 minutes. As reported in the ACC-NCDR report (Attachment XI of the CON application) all hospitals in the 90th percentile have a median time to immediate PCI for STEMI patients of 50.4 minutes. How does Hospital's median time relate to the ACCF/AHA/SCAI guidelines published in November 2011?

8. The Applicants state on page 15, that the Hospital "must address the cost-effectiveness of angioplasty services." Please address how this goal of the Applicants is consistent with the statement in Class III, which states that desires for personal or institutional financial gain…are not appropriate consideration(s) for initiation of a PCI program without on-site cardiac surgery.

9. The guidelines state that "[c]ompetition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interests of the community." Please address your proposal in relation to this statement while taking into consideration the existing providers of elective angioplasty in the Hospital's service area (and geographic) (in CT and NY).

10. Considering that the Hospital does not have access to a helicopter, explain how it expects to meet the protocols related to emergency transportation to a cardiac facility with a cardiac surgery program. In particular, discuss the Hospital's transfer agreement with its affiliate YNNH in this matter.

In responding to the questions contained in this letter, please repeat each question before providing your response. **Paginate and date** your response (i.e., each page in its entirety). Information filed after the initial CON application submission (i.e. completeness response letter, prefile testimony, late file submissions and the like) must be numbered sequentially from the Applicant's document preceding it. Please reference "Docket Number: 12-31748-CON." Submit one (1) original and five (5) hard copies of your response. In addition, please submit a scanned copy of your response including all attachments on CD in an Adobe format (.pdf) and in an MS Word format.

If you have any questions concerning this letter, please feel free to contact me or Steven W. Lazarus at (860) 418-7001.

Sincerely,

Jack A. Huber

Jack A. Huber
Health Care Analyst

Exhibit I

FINAL

TABLE OF THE RECORD

APPLICANTS: **Greenwich Hospital and Yale-New Haven Hospital**

DOCKET NUMBER: **08-31210-CON**

PUBLIC HEARING: **February 24, 2009 at 9:00 a.m.**

PLACE: **410 Capitol Avenue, Third Floor Hearing Room Hartford, Connecticut**

EXHIBIT	DESCRIPTION
A	Letter from Greenwich Hospital and Yale-New Haven Hospital ("Applicants") dated July 25, 2008, enclosing Letter of Intent forms to establish and operate an elective angioplasty program at Greenwich Hospital, received by the Office of Health Care Access ("OHCA") on July 25, 2008.
B	OHCA's request for legal notification in the *Greenwich Times* and the *New Haven Register* and notification to Applicants of receipt of the Letter of Intent in the matter of the CON application under Docket Number 08 - 31210, dated July 30, 2008.
C	OHCA's letter to the Applicants dated S4eptember 12, 2008, enclosing the Certificate of Need ("CON") application forms under Docket Number 08-31210.
D	Various emails between the Applicants and OHCA beginning September 12, 2008 through November 5, 2008 in the matter of the CON application under Docket Number 08-31210.
E	Email between the Applicants and OHCA dated November 6, 2008 in the matter of the CON application under Docket Number 08-31210.
F	Letter from the Applicants dated November 21, 2008, enclosing the CON application under Docket Number 08-31210, received by OHCA on November 21, 2008.
G	OHCA's letter to the Applicants dated December 8, 2008, requesting additional information and/or clarification in the matter of the CON application under Docket Number 08-31210.

H	Applicants' responses to OHCA's letter of December 8, 2008 dated January 23, 2009, in the matter of the CON application under Docket Number 08-31210, received by OHCA on January 23, 2009.
I	OHCA's request for legal notification in the *Greenwich Times* and the *New Haven Register* and OHCA's Notice to the Applicants of the public hearing scheduled for February 24, 2009, in the matter of the CON application under Docket Number 08-31210, dated February 6, 2009.
J	OHCA's letter to the Applicants dated February 11, 2009, requesting prefile testimony and interrogatories in the matter of the CON application under Docket Number 08-31210.
K	OHCA's email to the Applicants dated February 18, 2009 confirming the hearing scheduled for February 24, 2009 in the matter of the CON application under DN 08-31210.
L	Letter from the Applicants enclosing Prefile Testimony and responses to interrogatories dated February 19, 2009 in the matter of the CON application under Docket Number 08-31210, received by OHCA on February 19, 2009.
M	Petition of The Stamford Hospital dated February 19, 2009, requesting party status or intervenor status with full procedural rights as well as prefile testimonies and a notice of appearance of Jeffers and Ireland in the matter of the CON application under Docket Number 08-31210, received by OHCA on February 19, 2009.
N	Email from The Stamford Hospital to OHCA dated February 20, 2009 attaching their request for status, prefile testimony and exhibits in the matter of the CON application under Docket Number: 08-31210, received by OHCA on February 20, 2009.
O	Email from OHCA to the Applicants dated February 20, 2009 forwarding the email OHCA received from The Stamford Hospital in the matter of the CON application under Docket Number 08-31210.
P	Facsimile letter from Wiggin and Dana LLP to OHCA dated February 20, 2009 noticing their appearance on behalf of the Applicants in the matter of the CON application under Docket Number 08-31210, received by OHCA on February 20, 2009.
Q	Facsimile letter from the Applicants to OHCA dated February 23, 2009 requesting a continuance or rescheduling of the hearing in the matter of the CON application under Docket Number 08-31210, receive by OHCA on February 23, 2009.
R	Facsimile letter from Jeffers & Ireland to OHCA dated February 22, 2009 opposing the request by the Applicants to continue or reschedule the hearing in the matter of the CON application under Docket Number 08-31210, received by OHCA on February 23, 2009.

S	Facsimile letter from the Applicants to OHCA dated February 23, 2009 objecting to the request by The Stamford Hospital for party status in the matter of the CON application under Docket Number 08-31210, received by OHCA on February 23, 2009.
T	Facsimile letter from the Applicants to OHCA dated February 23, 2009 responding to The Stamford Hospital's objection to the Applicants request for continuance or rescheduling of the hearing in the matter of the CON application under Docket Number 08-31210, received by OHCA on February 23, 2009.
U	Letter from OHCA to the Applicants dated February 23, 2009 denying their request for continuance or rescheduling of the hearing in the matter of the CON application under Docket Number 08-31210.
V	Email from Jeffers & Ireland to OHCA dated February 23, 2009 responding to Applicants letter for request of continuance in the matter of the CON application under Docket Number 08-31210, received by OHCA on February 23, 2009.
W	OHCA's Ruling on the Petition of The Stamford Hospital to be granted intervenor status in the matter of the CON application under Docket Number 08-31210, dated February 23, 2009.

Where Applicable faxes will be used as originals.

Administrative Notice is taken of the following items:

1. Greenwich Hospital, Docket Number 07-027AR, FY 2007 Annual Reporting.
2. Yale-New Haven Hospital Docket Number 07-016AR, FY 2007 Annual Reporting
3. OHCA's Administrative Folder containing Agenda, Table of the Record etc. in the matter of the CON application under Docket Number:08-31210

Late Files requested by OHCA at the Hearing on February 24, 2009:

1. Information regarding New York's elective angioplasty.

Late File from the Applicant dated March 9, 2009, received by OHCA on March 10, 2009 in the matter of the CON application under Docket Number: 08-31210.

E-mail from OHCA to the Intervenor dated March 13, 2009 confirming due date Of March 17, 2009 for responses to the Applicants late file.

Intervenors responses dated March16, 2009 received by OHCA on March 17, 2009 in the matter of the CON application under Docket Number: 08-31210.

Email from the Applicant to OHCA confirming their response date to the Intervenors response of March 20, 2009 in the matter of the CON application under Docket Number: 08-31210.

Applicants response to the intervenors responses dated March 20, 2009 in the matter of the CON application under Docket Number 08-31210, received by OHCA on March 20, 2009 (email, faxed and hardcopy received on the same day).

Letter from the Intervenor dated March 23, 2009 responding to Applicants letter dated march 20, 2009 in the matter of the CON application under Docket Number: 08-31210, received by OHCA (fax on March 23, 2009 and hardcopy on March 24, 2009)

Letter from White Plains Hospital dated March 16, 2009 in the matter of the CON application under Docket Number: 08-31210, received by OHCA on March 23, 2009

OHCA's letter dated March 26, 2009 to all parties closing the public hearing in the matter of the CON application under Docket Number: 08-31210.

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS DIVISION

IN RE: ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM AT GREENWICH HOSPITAL	DOCKET NO. 12-31748-CON
	JULY 16, 2012

GREENWICH HOSPITAL AND YALE-NEW HAVEN HOSPITAL'S MOTION TO DISQUALIFY COUNSEL FOR THE STAMFORD HOSPITAL

Greenwich Hospital ("Greenwich") and Yale-New Haven Hospital ("YNHH") (collectively "Applicants"), Applicants in the above-referenced matter, hereby move to disqualify Stephen M. Cowherd and the law firm of Jeffers Cowherd (collectively "Cowherd") from representing The Stamford Hospital ("TSH") at the public hearing on this matter scheduled for July 17, 2012[1], should the Department of Public Health Office of Health Care Access Division ("OHCA") grant TSH status in this proceeding.[2] This Motion to Disqualify is based upon the potential ethical conflict of interest that arises from Cowherd having served as a paid consultant for OHCA in connection with YNHH's CON application for the acquisition of the Hospital of St. Raphael (Docket No. 12-31747-CON) (the "YNHH/HSR Proceeding").

[1] Applicants understand that if OHCA grants this Motion to Disqualify Cowherd, a continuance of the hearing may be required so that TSH can secure alternate counsel.

[2] TSH filed a Petition For Intervenor Status With Full Procedural Rights and prefiled the testimony of several witnesses on July 12, 2012.

Factual Background

This docket concerns a request by Applicants for permission to add elective angioplasty to the suite of cardiac services available at Greenwich Hospital ("Greenwich Elective Angioplasty Program"). Greenwich and YNHH are both members of the Yale New Haven Health System ("YNHHS") and Greenwich serves as a satellite of the Yale New Haven Heart and Vascular Center ("YNHHVC"). Notice of this CON was published in the Greenwich Time on December 1, 2 and 3, 2011, and the CON Application was filed with OHCA on February 14, 2012.

On February 9, 2012, Applicant YNHH and the Hospital of St. Raphael ("HSR") filed their CON Application for the change of ownership of HSR. Soon thereafter, OHCA retained Cowherd to serve as a paid consultant with respect to the YNHH/HSR CON. According to the Jeffers Cowherd website, Attorney Cowherd's practice focuses on healthcare and administrative law, including but not limited to, work before OHCA in connection with CON matters. He represents a variety of providers, including acute care hospitals. Notably, Cowherd has represented TSH for many years. He represented TSH in 2009, when the hospital opposed Applicants' last request for permission to establish an elective angioplasty program at Greenwich (Docket No. 08-31210-CON). This representation occurred prior to Cowherd's retention by OHCA as a consultant in connection with the YNHH/HSR Proceeding.

Cowherd was one of several attorneys that OHCA considered for the YNHH/HSR engagement and he was hired over the objection of YNHH. YNHH objected to Cowherd's involvement based on the fact that he represents TSH, which competes with and has been aggressive in opposing projects proposed by Greenwich and YNHH. At the time Cowherd agreed to consult with OHCA on the YNHH/HSR Proceeding, he was aware of the Greenwich

Elective Angioplasty Program filing (which had been noticed in December of 2011) and he knew or should have known, based on past experience, that his client TSH would oppose the CON request.

Cowherd's involvement in the YNHH/HSR Proceeding afforded him unique and unprecedented access to OHCA staff in connection with their evaluation of a CON and formulation of an Agreed Settlement. He reviewed documents and provided advice to staff, the specifics of which cannot be known by Applicants given that they were not involved in the discussions. Moreover, Cowherd was privy to confidential information, not otherwise available to the public, in the discharge of his duties as advisor to OHCA. It is our understanding that Cowherd reviewed "draft" documents from the agency, which are not discoverable under the Connecticut Freedom of Information Act ("CT FOIA"), and had conversations with senior OHCA staff regarding the substance of the agency's completeness review. Cowherd also reviewed information regarding OHCA's statewide facilities planning process, which has yet to be finalized and which presumably had some relevance to OHCA's review of the YNHH/HSR CON.

Argument

Cowherd should be disqualified as counsel in this matter based on the prohibitions set forth in Rule 1.11(c) of the Connecticut Rules of Professional Conduct (see Exhibit A attached). Rule 1.11(c) provides, in pertinent part, as follows:

> [A] lawyer having information that the lawyer knows is confidential government information about a person acquired when the lawyer was a public officer or employee, may not represent a private client whose interests are adverse to that person in a matter in which the information could be used to the material disadvantage of that person. As used in this Rule, "confidential government information" means information that has been obtained under governmental authority and which ... the government is prohibited by law from disclosing to the public or has a legal privilege not to disclose and which is not otherwise available to the public.

According to its commentary, Rule 1.11 is intended to prevent attorneys who have worked with the government from obtaining an unfair advantage over their clients' adversaries as a result of information learned during the attorneys' service.

Here, Cowherd's relationship with OHCA in connection with the YNHH/HSR CON, while characterized as that of consultant, was akin to that of a staff attorney employed by the agency. In fact, Applicants' understanding is that he was hired because the agency was short-staffed, due in part to the recent departure of its in-house counsel. To the best of Applicants' knowledge, Cowherd was asked to review the CON submissions, assist in formulating completeness questions and advise OHCA regarding the application's conformance with the agency's statutes and statewide facilities planning objectives, much like the former OHCA staff attorney would have done. Cowherd's position with OHCA, however titled, gives his client an unfair advantage over Applicants in this matter.

In addition, it is clear that Cowherd was privy to "confidential government information" during his service, which OHCA has the right to withhold from the public. As previously noted, confidential government information is information that has been obtained under governmental authority and which the government is prohibited by law from disclosing to the public or has a legal privilege not to disclose and which is not otherwise available to the public (see Rule 1.11). Cowherd had access to, and reviewed and provided comment on, initial drafts of the completeness questions issued to YNHH and HSR, which in final form had a far more "legal" tone than questions typically issued by OHCA staff (see Exhibit B attached). It is unclear whether Cowherd had access to initial drafts of the Agreed Settlement as well. These preliminary agency documents are not available to the public, including YNHH and HSR, but rather are protected from disclosure by the CT FOIA exemption found in Section 1-210(b)(1) of

the Connecticut General Statutes. Section 1-210(b)(1) provides that an agency need not disclose to the public any "[p]reliminary drafts or notes provided the public agency has determined that the public interest in withholding such documents clearly outweighs the public interest in disclosure." It has been the policy of OHCA not to disclose to the public drafts of documents, including completeness letters and decisions, which ultimately make their way into the administrative record in final form.

Moreover, Cowherd may have had access to certain documents associated with the YNHH/HSR Proceeding that were not made available to the public by agreement between the agency and the parties. These documents included several independent consulting reports obtained by the hospitals and an un-redacted version of the Asset Purchase Agreement for the transaction. OHCA staff may also have shared with Cowherd their thought processes regarding CON decision-making in general, resolution of the YNHH/HSR application specifically, and YNHHS system and service-line development. None of this information is available to the general public or to applicants and counsel who practice before the agency. This information may also be considered "confidential government information" under Rule 1.11.

Now, less than three weeks after the YNHH/HSR transaction was approved by OHCA via Agreed Settlement, Cowherd seeks to represent TSH, a competitor of Greenwich and YNHH, in opposing their CON request for an elective angioplasty satellite. However, Rule 1.11 expressly prohibits a lawyer in Cowherd's position from "represent[ing] a private client whose interests are adverse to that person in a matter in which the information could be used to the material disadvantage of that person." Here, the "private client" is TSH and "that person" is YNHH, an Applicant in this matter along with its sister hospital Greenwich. The "information" at issue could include specific facts regarding YNHH and YNHHS services (including cardiac

services), as well as general OHCA priorities for system development and CONs, any of which could conceivably be used to oppose the current application. Cowherd has filed a lengthy and detailed opposition to the Greenwich Elective Angioplasty Program on behalf of TSH. Applicants have no assurance that Cowherd has not used and will not use, either intentionally or unintentionally, confidential information that he obtained by virtue of his consulting arrangement with OHCA to the material disadvantage of YNHH and Greenwich in this proceeding. As previously noted, Rule 1.11 seeks to avoid just this type of "unfair advantage" resulting from the use of inside information obtained during an attorney's government service.

Furthermore, Canon 9 of the ABA Model Code of Professional Responsibility states that an attorney shall strive to avoid "not only professional impropriety but also the appearance of impropriety" (see Exhibit C attached). The fact that Cowherd agreed to serve as a consultant to OHCA in the YNHH/HSR Proceeding, knowing full well that his client, TSH, would soon be opposing a YNHH CON request for an elective angioplasty satellite in Greenwich, gives at the very least the appearance of impropriety. Applicants and the public are left wondering whether and to what extent Cowherd has gained inside knowledge about OHCA and YNHHS that he will use for the benefit of TSH and to the material disadvantage of Applicants.

Conclusion

The Hearing Officer has the authority to make such orders as will aid in the just resolution of a contested case. Reg., Conn State Agencies, Section 19a-9-29(g). Cowherd cannot separate the information he learned serving as a consultant to OHCA in a YNHH matter from his representation of TSH in opposition to this Greenwich/YNHH CON request.

Accordingly, the interests of justice require that Stephen M. Cowherd and the law firm of Jeffers Cowherd be disqualified from representing TSH in this proceeding.[3]

WHEREFORE, Applicants respectfully request that their Motion to Disqualify Stephen M. Cowherd and the law firm of Jeffers Cowherd be granted.

Respectfully Submitted,

GREENWICH HOSPITAL
YALE-NEW HAVEN HOSPITAL

By: _____

JENNIFER L. GROVES, ESQ.
Updike, Kelly & Spellacy, P.C.
265 Church Street
One Century Tower
New Haven, CT 06510
Tel: (203) 786-8300
Fax (203) 772-2037

[3] Jeffers Cowherd cannot continue to represent TSH through other attorneys because Attorney Cowherd was not timely screened from any participation in this mater (see Exhibit A).

CERTIFICATION

I hereby certify that a copy of the foregoing has been sent via facsimile and first class mail, postage prepaid, this 16th of July, 2012 to the following:

Stephen M. Cowherd
Jeffers Cowherd
5 Walls Drive
Fairfield, CT 06824

Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.

EXHIBIT A

Principles of Imputed Disqualification. The rule of imputed disqualification stated in subsection (a) gives effect to the principle of loyalty to the client as it applies to lawyers who practice in a law firm. Such situations can be considered from the premise that a firm of lawyers is essentially one lawyer for purposes of the rules governing loyalty to the client, or from the premise that each lawyer is vicariously bound by the obligation of loyalty owed by each lawyer with whom the lawyer is associated. Subsection (a) operates only among the lawyers currently associated in a firm. When a lawyer moves from one firm to another, the situation is governed by Rules 1.9 (b) and 1.10 (b).

The Rule in subsection (a) does not prohibit representation where neither questions of client loyalty nor protection of confidential information are presented. Where one lawyer in a firm could not effectively represent a given client because of strong political beliefs, for example, but that lawyer will do no work on the case and the personal beliefs of the lawyer will not materially limit the representation by others in the firm, the firm should not be disqualified. On the other hand, if an opposing party in a case were owned by a lawyer in the law firm, and others in the firm would be materially limited in pursuing the matter because of loyalty to that lawyer, the personal disqualification of the lawyer would be imputed to all others in the firm.

The Rule in subsection (a) also does not prohibit representation by others in the law firm where the person prohibited from involvement in a matter is a nonlawyer, such as a paralegal or legal secretary. Nor does subsection (a) prohibit representation if the lawyer is prohibited from acting because of events before the person became a lawyer, for example, work that the person did while a law student. Such persons, however, must be screened from any personal participation in the matter to avoid communication to others in the firm of confidential information that both the nonlawyers and the firm have a legal duty to protect. See Rules 1.0 (k) and 5.3.

Rule 1.10 (b) operates to permit a law firm, under certain circumstances, to represent a person with interests directly adverse to those of a client represented by a lawyer who formerly was associated with the firm. The Rule applies regardless of when the formerly associated lawyer represented the client. However, the law firm may not represent a person with interests adverse to those of a present client of the firm, which would violate Rule 1.7. Moreover, the firm may not represent the person where the matter is the same or substantially related to that in which the formerly associated lawyer represented the client and any other lawyer currently in the firm has material information protected by Rules 1.6 and 1.9 (c).

Rule 1.10 (c) removes imputation with the informed consent of the affected client or former client under the conditions stated in Rule 1.7. The conditions stated in Rule 1.7 require the lawyer to determine that the representation is not prohibited by Rule 1.7 (b) and that each affected client or former client has given informed consent to the representation, confirmed in writing. In some cases, the risk may be so severe that the conflict may not be cured by client consent. For a discussion of the effectiveness of client waivers of conflicts that might arise in the future, see Rule 1.7 and its Commentary. For a definition of informed consent, see Rule 1.0 (f).

Where a lawyer has joined a private firm after having represented the government, imputation is governed by Rule 1.11 (b) and (c), not this Rule. Under Rule 1.11 (d), where a lawyer represents the government after having served clients in private practice, nongovernmental employment or in another government agency, former-client conflicts are not imputed to government lawyers associated with the individually disqualified lawyer.

Where a lawyer is prohibited from engaging in certain transactions under Rule 1.8, subsection (k) of that Rule, and not this Rule, determines whether that prohibition also applies to other lawyers associated in a firm with the personally prohibited lawyer.

Rule 1.11. Special Conflicts of Interest for Former and Current Government Officers and Employees

(Amended June 26, 2006, to take effect Jan. 1, 2007.)

(a) Except as law may otherwise expressly permit, a lawyer who has formerly served as a public officer or employee of the government:

(1) is subject to Rule 1.9 (c); and

(2) shall not otherwise represent a client in connection with a matter in which the lawyer participated personally and substantially as a public officer or employee, unless the appropriate government agency gives its informed consent, confirmed in writing, to the representation.

(b) When a lawyer is disqualified from representation under subsection (a), no lawyer in a firm with which that lawyer is associated may knowingly undertake or continue representation in such a matter unless:

(1) The disqualified lawyer is timely screened from any participation in the matter and is apportioned no part of the fee therefrom; and

(2) Written notice is promptly given to the appropriate government agency to enable it to ascertain compliance with the provisions of this Rule.

(c) Except as law may otherwise expressly permit, a lawyer having information that the lawyer knows is confidential government information about a person acquired when the lawyer was a public officer or employee, may not represent a private client whose interests are adverse to that person in a matter in which the information could be used to the material disadvantage of that person. As used in this Rule, the term "confidential government information" means information that has been obtained under governmental authority and which, at the time this Rule is applied, the government is prohibited by law from disclosing to the public or has a legal privilege not to disclose and which is not otherwise available to the public. A firm with which that lawyer is associated may undertake or continue representation in the matter only if the disqualified lawyer is timely screened from any participation in the matter and is apportioned no part of the fee therefrom.

(d) Except as law may otherwise expressly permit, a lawyer currently serving as a public officer or employee:

(1) Is subject to Rules 1.7 and 1.9; and

(2) Shall not:

(i) Participate in a matter in which the lawyer participated personally and substantially while in

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private practice or nongovernmental employment, unless the appropriate government agency gives its informed consent, confirmed in writing; or

(ii) Negotiate for private employment with any person who is involved as a party or as lawyer for a party in a matter in which the lawyer is participating personally and substantially; except that a lawyer serving as a law clerk to a judge, other adjudicative officer or arbitrator may negotiate for private employment as permitted by Rule 1.12 (b) and subject to the conditions stated in Rule 1.12 (b).

(e) As used in this Rule, the term "matter" includes:

(1) Any judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, investigation, charge, accusation, arrest or other particular matter involving a specific party or parties, and

(2) Any other matter covered by the conflict of interest rules of the appropriate government agency.

(P.B. 1978-1997, Rule 1.11.) (Amended June 26, 2006, to take effect Jan. 1, 2007.)

COMMENTARY: A lawyer who has served or is currently serving as a public officer or employee is personally subject to the Rules of Professional Conduct, including the prohibition against concurrent conflicts of interest stated in Rule 1.7. In addition, such a lawyer may be subject to statutes and government regulations regarding conflict of interest. Such statutes and regulations may circumscribe the extent to which the government agency may give consent under this Rule. See Rule 1.0 (f) for the definition of informed consent.

Subsections (a) (1), (a) (2) and (d) (1) restate the obligations of an individual lawyer who has served or is currently serving as an officer or employee of the government toward a former government or private client. Rule 1.10 is not applicable to the conflicts of interest addressed by this Rule. Rather, subsection (b) sets forth a special imputation rule for former government lawyers that provides for screening and notice. Because of the special problems raised by imputation within a government agency, subsection (d) does not impute the conflicts of a lawyer currently serving as an officer or employee of the government to other associated government officers or employees, although ordinarily it will be prudent to screen such lawyers.

Subsections (a) (2) and (d) (2) apply regardless of whether a lawyer is adverse to a former client and are thus designed not only to protect the former client, but also to prevent a lawyer from exploiting public office for the advantage of another client. For example, a lawyer who has pursued a claim on behalf of the government may not pursue the same claim on behalf of a later private client after the lawyer has left government service, except when authorized to do so by the government agency under subsection (a). Similarly, a lawyer who has pursued a claim on behalf of a private client may not pursue the claim on behalf of the government, except when authorized to do so by subsection (d). As with subsections (a) (1) and (d) (1), Rule 1.10 is not applicable to the conflicts of interest addressed by these subsections.

This Rule represents a balancing of interests. On the one hand, where the successive clients are a government agency and another client, public or private, the risk exists that power or discretion vested in that agency might be used for the special benefit of the other client. A lawyer should not be in a position where benefit to the other client might affect performance of the lawyer's professional functions on behalf of the government. Also, unfair advantage could accrue to the other client by reason of access to confidential government information about the client's adversary, obtainable only through the lawyer's government service. On the other hand, the rules governing lawyers presently or formerly employed by a government agency should not be so restrictive as to inhibit transfer of employment to and from the government. The government has a legitimate need to attract qualified lawyers as well as to maintain high ethical standards. Thus, a former government lawyer is disqualified only from particular matters in which the lawyer participated personally and substantially. The provisions for screening and waiver in subsection (b) are necessary to prevent the disqualification rule from imposing too severe a deterrent against entering public service. The limitation of disqualification in subsections (a) (2) and (d) (2) to matters involving a specific party or parties, rather than extending disqualification to all substantive issues on which the lawyer worked, serves a similar function.

When a lawyer has been employed by one government agency and then moves to a second government agency, it may be appropriate to treat that second agency as another client for purposes of this Rule, as when a lawyer is employed by a city and subsequently is employed by a federal agency. However, because the conflict of interest is governed by subsection (d), the latter agency is not required to screen the lawyer as subsection (b) requires a law firm to do. The question of whether two government agencies should be regarded as the same or different clients for conflict of interest purposes is beyond the scope of these Rules. See Commentary to Rule 1.13.

Subsections (b) and (c) contemplate a screening arrangement. See Rule 1.0 (*l*) (requirements for screening procedures). These subsections do not prohibit a lawyer from receiving a salary or partnership share established by prior independent agreement, but that lawyer may not receive compensation directly relating the lawyer's compensation to the fee in the matter in which the lawyer is disqualified.

Notice, including a description of the screened lawyer's prior representation and of the screening procedures employed, generally should be given as soon as practicable after the need for screening becomes apparent.

Subsection (c) operates only when the lawyer in question has knowledge of the information, which means actual knowledge; it does not operate with respect to information that merely could be imputed to the lawyer.

Subsections (a) and (d) do not prohibit a lawyer from jointly representing a private party and a government agency when doing so is permitted by Rule 1.7 and is not otherwise prohibited by law.

For purposes of subsection (e) of this Rule, a "matter" may continue in another form. In determining whether two particular matters are the same, the lawyer should consider the extent to which the matters involve the same basic facts, the same or related parties, and the time elapsed.

Rule 1.12. Former Judge, Arbitrator, Mediator or Other Third-Party Neutral

(Amended June 26, 2006, to take effect Jan. 1, 2007.)

(a) Except as stated in subsection (d), a lawyer shall not represent anyone in connection with a matter in which the lawyer participated personally as a judge or other adjudicative officer or law clerk

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EXHIBIT B

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
Office of Health Care Access

March 8, 2012 VIA FAX ONLY

Ms. Jean Ahn
System Director
Yale-New Haven Hospital
20 York Street (Howe 3)
New Haven, CT 06504

Ms. Terrie Estes
Director of Planning and Business Development
Saint Raphael Healthcare System &
Hospital of Saint Raphael
1450 Chapel Street
New Haven, CT 06511

RE: Certificate of Need Application; Docket Number: 12-31747-CON
Proposal for Yale-New Haven Hospital's Acquisition of the Saint Raphael Healthcare System Inc. and Hospital of Saint Raphael

Dear Ms. Ahn and Ms. Estes,

On February 9, 2012, the Office of Health Care Access ("OHCA") received your initial Certificate of Need ("CON") application for Yale-New Haven Hospital's ("YNHH") acquisition of the Saint Raphael Healthcare System Inc. ("SRHS"), including the Hospital of Saint Raphael ("HSR").

OHCA has reviewed the CON application and requests additional information pursuant to General Statutes § 19a-639a(c):

Project Description and Need: Change of Ownership or Control – pages 20 through 25

1. Please describe the following:

   a. SHRHS' ownership and control of Saint Regis Health Center, Inc. d/b/a Sister Virginie Grimes Center;
   b. HSR's ownership and control of Connecticut CK Leasing, LLC;
   c. DePaul Health Services Corporation, Inc.'s ownership and control of Saint Raphael Dialysis Center Partnership; and
   d. The businesses engaged in by Connecticut CK Leasing, LLC and Saint Raphael Dialysis Center Partnership and any services they provide to inpatients or outpatients of HSR.

2. On page 21, applicants state that HSR provides "a number of community based programs" and outlines some of these programs in a list.

   Please indicate whether each of these programs is expected to continue following the acquisition. In addition, please provide information regarding all other HSR community based programs and indicate whether each of these additional programs will continue following the acquisition. If any program will be terminated as a result of or directly following the acquisition, describe the reason for such termination, how the decision was made and how the need will be met.

3. On page 22, applicants state that "[d]espite many efforts to mitigate financial losses, HSR recognized that without outside assistance and investment, it could not survive long term as a standalone entity."

   Please describe in detail the efforts HSR has taken to mitigate financial losses and provide detailed evidence supporting the conclusion that HSR could not survive as a standalone entity.

4. Applicants indicate, on page 24, that, "absent the proposed acquisition of HSR, YNHH will have to construct a 5th bed tower..." and further indicate that such tower is estimated to cost approximately $400 million and take nearly five years to complete.

   Please describe:

   a. The number and types of beds (by service category) that were estimated to be contained in the tower.
   b. How the cost and timeline estimates for the tower were determined.

5. Also on page 24, applicants state that "YNHH will make significant investments in the HSR campus to improve its facilities and technological capabilities."

   Please address the following:

   a. Describe, in detail, the nature of the facility improvements that will be made.
   b. Describe, in detail, the nature of the technological improvements that will be made.
   c. Describe how decisions will be made regarding these facility and technological improvements.
   d. Provide an estimated completion date for the improvements described in subsections (a) and (b), respectively.

6. Also on page 24, applicants state that "HSR's long term debt will be extinguished and resources will be provided to address the current Church plan pension shortfall."

   Please provide the following:

   a. The amount of long term debt that HSR currently carries and the amount that will be extinguished;
   b. The amount of the current Church plan pension shortfall and the amount that the shortfall will be reduced; and
   c. The source of the funds that will be used to make the payments described in subsections (a) and (b).

7. Please address the following:

   a. How are the current 421 operational beds at HSR allocated between medical/surgical, pediatric, obstetric, rehabilitation and psychiatric services.
   b. Would YNNH's acquisition of HSR result in any change to the current allocation of beds on the HSR campus.
   c. What would be necessary to make all of HSR's 511 licensed beds operational (up from the current 421 operational beds).
   d. Beyond the current 421 operational beds at HSR, how many additional beds could be phased into operation before the end of FY 2015, what would the likely phasing schedule be and what would be necessary to achieve this.
   e. From 10/08 to the month of applicants' completeness response, what has been the average monthly census for HSR based on both total beds and medical/surgical beds (please provide this data in chart and table form similar to that found on pps. 15-17 of YNNH's CON Application to Increase the Hospital's Licensed Bed Count by 70 under Docket No. 12-31745-CON).
   f. Assuming YNHH is licensed at 1,407 general hospital beds post-acquisition of HSR, and based on the projected inpatient utilization of both campuses, when would YNHH expect to exceed an 80% occupancy level based on average monthly census projections (please provide evidence of all assumptions and calculations on which such projection is based, and a chart of YNHH's bed need for each year until the 80% threshold is reached).
   g. Provide the same information as requested in subsection (f) above, but restrict the projection to when 80% occupancy of the combined medical/surgical beds on both campuses would be exceeded.
   h. Assuming YNHH is licensed at 1,477 general hospital beds post-acquisition of HSR, and based on the projected inpatient utilization of both campuses, when would YNHH expect to exceed an 80% occupancy level based on average monthly census projections (please provide evidence of all assumptions and calculations on which such projection is based).
   i. Provide the same information as requested in subsection (h) above, but restrict the projection to when 80% occupancy of the combined medical/surgical beds on both campuses would be exceeded.

8. On pages 24 and 25, applicants indicate that they engaged Deloitte "to identify cost savings which could be achieved through the acquisition" and that these cost savings are expected to exceed a half of a billion dollars over the next five years.

   Please provide:

   a. A copy of the Deloitte report;
   b. The applicants' cost savings plan; and
   c. An explanation of how applicants foresee that the savings will reduce costs of health care services for patients served by YNHH if the CON application is granted.

9. On page 25, applicants state that "[b]oth HSR and YNHH have focused on maintaining access and improving the quality of care despite the ever-present financial challenges of the industry."

   Please explain, in detail, HSR's efforts to maintain access and improve quality of care since 10/08.

10. Please describe, in detail, how the acquisition of HSR by YNHH will affect the following:

    a. Teaching and residency programs currently located at HSR and YNHH;
    b. Research and clinical trials conducted at HSR and YNHH;
    c. Emergency department services currently located at HSR and YNHH;
    d. Charity care and financial assistance programs currently operating at HSR and YNHH; and
    e. The rates currently charged for hospital services at HSR and YNNH.

Determination of Need by HSR – pages 26 through 27

11. Please describe, in detail, the steps that HSR took to address its financial situation. In addition, provide detailed evidence for the conclusion that HSR will be unable to achieve financial stability in the future. Please include information regarding the following cost saving efforts in the discussion:

    a. Aggressive negotiations with managed care organizations;
    b. Productivity enhancements;
    c. Supply chain cost reductions;
    d. Adjustments to fringe benefits; and
    e. Postponement of essential renovations and equipment purchases.

12. On page 26, applicants indicate that in early 2010, the SRHS Board's Ad Hoc Strategy Committee "began to explore and evaluate options to ensure continuation of the mission of Saint Raphael's and the Sisters into the future."

    Please provide evidence of the Committee's exploration and evaluation of options. Include information regarding the other options besides integration with YNHH that were explored.

13. Provide any reports prepared by Navigant Consulting relating to the analysis of health systems that it performed for HSR.

14. Provide a copy of the letter of intent signed by YNHH and HSR in March 2011.

Benefits to HSR – pages 27 through 29

15. On page 27, applicants state that HSR identified YNHH as its optimal partner for a number of reasons outlined in the application. Please address the following:

    a. Describe any clinical staff/clinical positions at HSR that would not be retained after the acquisition.
    b. Explain what Centers of Excellence would be created and located at the HSR campus.
    c. How will the HSR campus be held out/identified to the public post-acquisition by YNHH?

16. On pages 28 and 29, applicants state that "[i]n the first five years, YNHH plans to invest $129.5 million" in the HSR campus for a variety of purposes. Please address the following:

    a. Is the $129.5 million investment separate and distinct from the $160 million being paid by Buyer pursuant to Section 2.3 of the Asset Purchase Agreement set forth at Attachment III to the CON application?
    b. List the deferred capital purchases and projects on the HSR campus the investment will address.
    c. List the investments in clinical service infrastructure that will be made on the HSR campus.
    d. Explain when YNHH would expect the existing information technology systems on the HSR campus to be integrated with YNHH's and when the implementation of the Epic electronic medical record system would be completed on the HSR campus.

17. Describe, in detail, the "new, integrated organization [that] will preserve clinical services and ensure HSR's charitable assets for future generations" referenced on page 29. Please also provide the following information regarding the Charitable Funds defined at Section 5.5 of the Asset Purchase Agreement:

    a. What amount of Charitable Funds, if any, will be transferred to Buyer or Buyer's Affiliate as part of the Purchased Assets and how will they be used for the benefit of the Facilities?
    b. What amount of Charitable Funds that cannot be transferred to Buyer or Buyer's Affiliate as part of the Purchased Assets will be used by Sellers at or for the benefit of the Facilities and how will they be used?
    c. What amount of Charitable Funds shall be used by Sellers to fund activities mutually agreed upon by the parties that benefit the delivery of health care services consistent with the Directives in the greater New Haven area and how will they be used?

Determination of Need by YNHH – pages 29 through 35

18. On page 32 in Graphs I and II, respectively, applicants provided information on YNHH's occupancy based on the midnight census and the contact census for all services and for medical/surgical beds as compared to total beds and 80% occupancy levels. Please provide HSR's occupancy based on its census data from FY 2011 to FY 2012 (year to date) in the same format.

19. YNHH recently submitted a CON application to add 70 beds which will be temporarily located in its East Pavilion. Assuming that CON is granted, please explain what will happen to these 70 beds if the CON application for the acquisition of HSR is not approved and, alternatively, if the CON application for the acquisition of HSR is approved.

20. Please provide a copy of YNHH's long range financial plan showing the need for an additional 74 beds by 2016 even if 70 additional beds are added pursuant to Docket No. 12-31745-CON.

21. Please provide copies of the inpatient volume projections submitted to the Connecticut Attorney General and the Federal Trade Commission.

22. Please provide evidence of YNHH's decision-making process regarding the location of the new bed tower that has been contemplated as part of its long range financial planning efforts.

Benefits to YNHH – pages 35 through 40

23. On page 35, applicants state that "[t]he opportunity to avoid duplicative investments and focus on key strategies, such as primary care development, will enhance access to services for patients in the region."

    Please describe the discussions HSR and YNHH have had surrounding the development of primary care and the avoidance of duplication of services.

24. On page 36, applicants state that "discussions have been held with the State of Connecticut Attorney General and the Federal Trade Commission to initiate governmental approval of the transaction."

    Please describe the status of those discussions and provide a timeline for when decisions from the Attorney General's Office and the Federal Trade Commission might be expected if they have not already been rendered.

25. On page 37, applicants state that they "have worked to identify a number of options to achieve cost savings and work flow efficiencies."

    Please describe these cost savings and work flow efficiencies.

    a. Please provide additional detail regarding which subspecialties will be, or are likely to be consolidated, on one campus (indicating which campus) and include the reasoning behind each decision.
    b. What subspecialties will be, or are likely to be, offered on both campuses? Explain how these service lines were selected.

26. On page 37, applicants state that "Deloitte has estimated cost savings from clinical and business operational integrations of at least $300 million over five years."

    Please provide information that describes these cost savings in detail, including a breakdown of the approximate amount of money saved by each measure.

27. Please describe how the acquisition will improve efficiency, access to health care and quality for the area's growing elderly population.

28. Please provide an unredacted copy of the Asset Purchase Agreement and all exhibits thereto.

Quality Measures – pages 40 through 43

29. To the extent not already provided, please describe the $85 million in facility upgrades that YNHH plans to undertake on the HSR campus and the estimated amounts that will be spent in each year.

30. To the extent not already provided, please describe the type of routine capital expenditures that will amount to $25 million in expenditures over the next five years and the estimated amounts that will be spent in each year.

31. When will the EPIC installation at YNHH be complete? If the acquisition is approved, how long after Closing is it estimated that EPIC installation at HSR would begin?

Proposed Capital Expenditures/Costs and Patient Population Mix – pages 45 through 52

32. Please describe what makes up the $60,248,000 in the "Other Non-Construction (Other Asset Purchases)" line of the proposed capital expenditure chart on page 45.

33. On page 45, applicants state that specific capital costs for HSR's assets equal $147,879,000. Please provide information on how much of the remaining $12,021,000 in capital expense is being allocated to the purchase of DePaul Health Services Corporation, Inc.'s ownership interest in the Saint Raphael Magnetic Resonance Center (SRMRC).

34. Please summarize any analyses or reports from Barclays Capital, other underwriters or YNHH's financial advisors regarding YNHH's credit rating and ability to obtain the $160 million in bond financing necessary to complete the proposed acquisition.

35. On page 49, with respect to the assumptions for patient population mix, please explain why volumes for HSR are assumed to be flat through the projection period.

Financial Attachments I & II – pages 50-52 and Attachments VII and VIII

36. On page 231 (Attachment I for YNHH), please explain, in detail, the underlying assumptions for the increases in bad debt and interest expense connected with the HSR acquisition?

37. On page 234 (Attachment I for HSR), please explain, in detail, the underlying assumptions for inpatient discharges dropping in FY 2012 and remaining flat throughout the projection period without the YNHH affiliation taking place.

38. On page 234 (Attachment I for HSR), please explain, in detail, the underlying assumptions for outpatient visits increasing in FY 2012 and remaining flat throughout the projection period without the YNHH affiliation taking place.

39. On page 238, please explain the basis for the net negative adjustment to hospital inpatient and outpatient revenue due to health care reform.

40. On pages 50-51, please explain in more detail how YNHH intends to establish budget neutral agreements "with new payment terms that will not result in an adverse financial impact to the managed care payers or the self-funded employers they represent" if the affiliation occurs. Please also explain whether YNHH would be able to negotiate similar budget neutral agreements if the affiliation with HSR did not occur and how the affiliation impacts YNHH's ability to negotiate with managed care plans as well as other private health insurers.

MRI CON Questions and Responses – Appendix I

41. On page 246, applicants state that inpatient "scan volume is projected to increase in proportion to an expected increase in the average daily census (ADC) at the Saint Raphael campus following the acquisition by YNHH ... ADC is projected to increase by 40 in FY 2012, 60 in FY 2014 and 85 in FY 2015." Yet, at page 236 of the CON Application, no increase in HSR utilization is assumed. Please explain this apparent discrepancy.

42. Will there be any change in the radiologists who provide professional services interpreting the SRMRC MRI scans as a result of YNNH's acquisition of HSR?

In responding to the questions contained in this letter, please repeat each question before providing your response. Paginate and date your response. Information filed must be numbered sequentially from the applicants' document preceding it. For example, if the application concludes with page 100, your completeness response letter would begin with page 101. Please reference "Docket Number: 12-31747-CON" and submit one (1) original and five (5) hard copies of your response. In addition, please submit a scanned copy of your response, including all attachments, on CD using MS Word format or Adobe Acrobat.

Upon receipt of the responses to this letter and after incorporating the provided information into the initial submission, OHCA staff will perform a detailed review of the entire CON application. If you have any questions concerning this letter, please feel free to contact Steven W. Lazarus at OHCA at (860) 418-7012.

Sincerely,

Steven W. Lazarus
Associate Health Care Analyst

EXHIBIT C

CANON 9
A Lawyer Should Avoid Even the Appearance of Professional Impropriety

ETHICAL CONSIDERATIONS

EC 9-1 Continuation of the American concept that we are to be governed by rules of law requires that the people have faith that justice can be obtained through our legal system.[1] A lawyer should promote public confidence in our system and in the legal profession.[2]

EC 9-2 Public confidence in law and lawyers may be eroded by irresponsible or improper conduct of a lawyer. On occasion, ethical conduct of a lawyer may appear to laymen to be unethical. In order to avoid misunderstandings and hence to maintain confidence, a lawyer should fully and promptly inform his client of material developments in the matters being handled for the client. While a lawyer should guard against otherwise proper conduct that has a tendency to diminish public confidence in the legal system or in the legal profession, his duty to clients or to the public should never be subordinate merely because the full discharge of his obligation may be misunderstood or may tend to subject him or the legal profession to criticism. When explicit ethical guidance does not exist, a lawyer should determine his conduct by acting in a manner that promotes public confidence in the integrity and efficiency of the legal system and the legal profession.[3]

EC 9-3 After a lawyer leaves judicial office or other public employment, he should not accept employment in connection with any matter in which he had substantial responsibility prior to his leaving, since to accept employment would give the appearance of impropriety even if none exists.[4]

EC 9-4 Because the very essence of the legal system is to provide procedures by which matters can be presented in an impartial manner so that they may be decided solely upon the merits, any statement or suggestion by a lawyer that he can or would attempt to circumvent those procedures is detrimental to the legal system and tends to undermine public confidence in it.

EC 9-5 Separation of the funds of a client from those of his lawyer not only serves to protect the client but also avoids even the appearance of impropriety, and therefore commingling of such funds should be avoided.

EC 9-6 Every lawyer owes a solemn duty to uphold the integrity and honor of his profession; to encourage respect for the law and for the courts and the judges thereof; to observe the Code of Professional Responsibility; to act as a member of a learned profession, one dedicated to public service; to cooperate with his brother lawyers in supporting the organized bar through the devoting of his time, efforts, and financial support as his professional standing and ability reasonably permit; to conduct himself so as to reflect credit on the legal profession and to inspire the confidence, respect, and trust of his clients and of the public; and to strive to avoid not only professional impropriety but also the appearance of impropriety.[5]

EC 9-7 A lawyer has an obligation to the public to participate in collective efforts of the bar to reimburse persons who have lost money or property as a result of the misappropriation or defalcation of another lawyer, and contribution to a client's security fund is an acceptable method of meeting this obligation.[6]

DISCIPLINARY RULES

DR 9-101 Avoiding Even the Appearance of Impropriety.[7]

(A) -A lawyer shall not accept private employment in a matter upon the merits of which he has acted in a judicial capacity.[4]

(B) -A lawyer shall not accept private employment in a matter in which he had substantial responsibility while he was a public employee.[5]

(C) -A lawyer shall not state or imply that he is able to influence improperly or upon irrelevant grounds any tribunal, legislative body,[6] or public official.

DR 9-102 Preserving Identity of Funds and Property of a Client.[7]

(A) -All funds of clients paid to a lawyer or law firm, other than advances for costs and expenses, shall be deposited in one or more identifiable bank accounts maintained in the state in which the law office is situated and no funds belonging to the lawyer or law firm shall be deposited therein except as follows:

(1) -Funds reasonably sufficient to pay bank charges may be deposited therein.

(2) -Funds belonging in part to a client and in part presently or potentially to the lawyer or law firm must be deposited therein, but the portion belonging to the lawyer or law firm may be withdrawn when due unless the right of the lawyer or law firm to receive it is disputed by the client, in which event the disputed portion shall not be withdrawn until the dispute is finally resolved.

(B) -A lawyer shall:

(1 -)Promptly notify a client of the receipt of his funds, securities, or other properties.

(2) -Identify and label securities and properties of a client promptly upon receipt and place them in a safe deposit box or other place of safekeeping as soon as practicable.

(3) -Maintain complete records of all funds, securities, and other properties of a client coming into the possession of the lawyer and render appropriate accounts to his client regarding them.

(4) -Promptly pay or deliver to the client as requested by a client the funds, securities, or other properties in the possession of the lawyer which the client is entitled to receive.

NOTES

1. "Integrity is the very breath of justice. Confidence in our law, our courts, and in the administration of justice is our supreme interest. No practice must be permitted to prevail which invites towards the administration of justice a doubt or distrust of its integrity." Erwin M. Jennings Co. v. DiGenova, 107 Conn. 491, 499, 141 A. 866, 868 (1928).

2. "A lawyer should never be reluctant or too proud to answer unjustified criticism of his profession, of himself, or of his brother lawyer. He should guard the reputation of his profession and of his brother as zealously as he guards his own." Rochelle & Payne, *The Struggle for Public Understanding*, 25 TEXAS B.J. 109, 162 (1962).

3. *See* ABA CANONS OF PROFESSIONAL ETHICS, CANON 29 (1908).

4. *See* ABA CANONS OF PROFESSIONAL ETHICS, CANON 36 (1908).

5. "As said in Opinion 49, of the Committee on Professional Ethics and Grievances of the American Bar Association, page 134: 'An attorney should not only avoid impropriety but should avoid the appearance of impropriety.' " State ex rel. Nebraska State Bar Ass'n v. Richards, 165 Neb. 80, 93, 84 N.W.2d 136, 145 (1957).

"It would also be preferable that such contribution [to the campaign of a candidate for judicial office] be made to a campaign committee rather than to the candidate personally. In so doing, possible appearances of impropriety would be reduced to a minimum" *ABA Opinion* 226 (1941).

"The lawyer assumes high duties, and has imposed upon him grave responsibilities. He may be the means of much good or much mischief. Interests of vast magnitude are entrusted to him; confidence is reposed in him; life, liberty, character and property should be protected by him. He should guard, with zealous watchfulness, his own reputation, as well as that of his profession." People ex rel. Cutler v. Ford, 54 Ill. 520, 522 (1870), and also quoted in State Board of Law Examiners v. Sheldon, 43 Wyo. 522, 526, 7 P.2d 226, 227 (1932).

See ABA Opinion 150 (1936).

6. Amended, February 1980, House Informational Report No. 105.

7. *Cf.* MODEL CODE OF PROFESSIONAL RESPONSIBILITY, EC 5-6.

8. *See* ABA CANONS OF PROFESSIONAL ETHICS, CANON 36 (1908).

"It is the duty of the judge to rule on questions of law and evidence in misdemeanor cases and examinations in felony cases. That duty calls for impartial and uninfluenced judgment, regardless of the effect on those immediately involved or others who may, directly or indirectly, be affected. Discharge of that duty might be greatly interfered with if the judge, in another capacity, were permitted to hold himself out to employment by those who are to be, or who may be, brought to trial in felony cases, even though he did not conduct the examination. His private interests as a lawyer in building up his clientele, his duty as such zealously to espouse the cause of his private clients and to defend against charges of crime brought by law enforcement agencies of which he is a part, might prevent, or even destroy, that unbiased judicial judgment which is so essential in the administration of justice.

"In our opinion, acceptance of a judgeship with the duties of conducting misdemeanor trials, and examinations in felony

cases to determine whether those accused should be bound over for trial in a higher court, ethically bars the judge from acting as attorney for the defendants upon such trial, whether they were examined by him or by some other judge. Such a practice would not only diminish public confidence in the administration of justice in both courts, but would produce serious conflict between the private interests of the judge as a lawyer, and of his clients, and his duties as a judge in adjudicating important phases of criminal processes in other cases. The public and private duties would be incompatible. The prestige of judicial office would be diverted to private benefit, and the judicial office would be demeaned thereby," *ABA Opinion* 242 (1942).

"A lawyer, who has previously occupied a judicial position or acted in a judicial capacity, should refrain from accepting employment in any matter involving the same facts as were involved in any specific question which he acted upon in a judicial capacity and, for the same reasons, should also refrain from accepting any employment which might reasonably appear to involve the same facts." *ABA Opinion* 49 (1931).

See ABA Opinion 110 (1934).

9. *See ABA Opinions* 135 (1935) and 134 (1935); *cf.* ABA CANONS OF PROFESSIONAL ETHICS, CANON 36 (1980) and *ABA Opinions* 39 (1931) and 26 (1930). *But see ABA Opinion* 37 (1931).

10. "[A statement by a governmental department or agency with regard to a lawyer resigning from its staff that includes a laudation of his legal ability] carries implications, probably not founded in fact, that the lawyer's acquaintance and previous relations with the personnel of the administrative agencies of the government place him in an advantageous position in practicing before such agencies. So to imply would not only represent what probably is untrue, but would be highly reprehensible." *ABA Opinion* 184 (1938).

11. *See* ABA CANONS OF PROFESSIONAL ETHICS, CANON 11 (1908).

"*Rule 9* . . . . A member of the State Bar shall not commingle the money or other property of a client with his own; and he shall promptly report to the client the receipt by him of all money and other property belonging to such client. Unless the client otherwise directs in writing, he shall promptly deposit his client's funds in a bank or trust company . . . in a bank account separate from his own account and clearly designated as 'Clients' Funds Account' or 'Trust Funds Account' or words of similar import. Unless the client otherwise directs in writing, securities of a client in bearer form shall be kept by the attorney in a safe deposit box at a bank or trust company . . . which safe deposit box shall be clearly designated as 'Clients' Account' or 'Trust Account' or words of similar import, and be separate from the attorney's own safe deposit box." CAL. BUSINESS AND PROFESSIONS CODE §6076 (West 1962).

"[C]ommingling is committed when a client's money is intermingled with that of his attorney and its separate identity lost so that it may be used for the attorney's personal expenses or subjected to claims of his creditors . . . . The rule against commingling was adopted to provide against the probability in some cases, the possibility in many cases, and the danger in all cases that such commingling will result in the loss of clients' money. " Black v State Bar, 57 Cal. 2d 219, 225-26, 368 P.2d 118, 122, 18 Cal. Rptr. 518, 522 (1962).

RECEIVED
JUL 17 2012
OFFICE OF
HEALTH CARE ACCESS

Lazarus, Steven

From: Jason Marsh <JMarsh@jeffers-law.com>
Sent: Tuesday, July 17, 2012 8:42 AM
To: Martone, Kim; Lazarus, Steven
Cc: jgroves@uks.com; jean.ahn@ynhh.org; Stephen Cowherd; Carolyn Linsey
Subject: Certificate of Need Docket No: 12-31748-CON
Attachments: Scanned from a Xerox multifunction device001.pdf

Dear Ms. Martone and Mr. Lazarus:

In response to the rebuttal testimony submitted by the Applicants in the above matter, Stamford Hospital sought to further clarify the PCI volumes at White Plains Hospital. Attached is a letter from Susan Fox, the Executive Vice President of White Plains Hospital, which revises the PCI volume data previously reported in a letter attached to Dr. Kiely's pre-file testimony. We ask that this letter be included in the record of this proceeding.

If you have any questions regarding this matter, please do not hesitate to contact us. Thank you.

Best regards,

Jason

Jason A. Marsh
Jeffers Cowherd P.C.
55 Walls Drive
Fairfield, CT 06824
Tel: (203) 259-7900 ext. 226
Fax: (203) 259-1070

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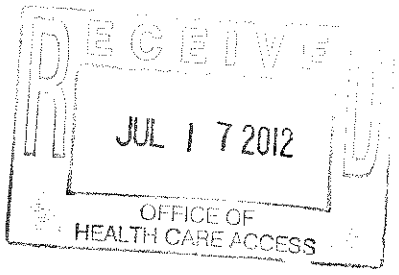
White Plains Hospital

Susan Fox
Executive Vice President
Tel (914) 681-1237
Fax (914) 681-2902
sfox@wphospital.org



July 16, 2012

Sharon Kiely, MD
Senior Vice President of Medical Affairs, Chief Medical Officer
The Stamford Hospital
190 West Broad Street
Stamford, CT 06902

Re: Revision to letter dated July 11, 2012 entitled, "Certificate of Need Application; Docket No. 12-31748-CON Yale New Haven Hospital and Greenwich Hospital Proposal to Establish and Elective Angioplasty Program Without Onsite Surgical Backup at Greenwich Hospital."

Dear Dr. Kiely:

In our previous letter to you dated July 11th 2012, we included incorrect statistical data in regards to our PCI volumes in 2010 and 2011. This data discrepancy was discovered upon closer review of data associated with our cardiac cath program. The third paragraph of our initial letter should be replaced with the following:

> *In fiscal year 2010 (Oct 1 2009 – Sept 30 2010) and with the support of the New York Presbyterian Health System, a total of 93 PCIs were performed at WPH (73 Inpatient, 20 Outpatient). In fiscal year 2011 (Oct 1 2010 – Sept 30 2011) 231 PCIs were performed at WPH (153 Inpatient, 78 Outpatient). In 2012, we have begun to experience a volume shift connected with a change in referral patterns by a large cardiology practice in our area; however, we have maintained our PCI volume with our fiscal year to date (Oct 2011 – May 30) resulting in 191 PCIs being performed (117 inpatient, 74 outptient).*

The above modification to our statistical data has no other impact on our original letter and conclusions. Our opposition to Greenwich Hospital's proposal to establish elective angioplasty remains unchanged.

Sincerely,

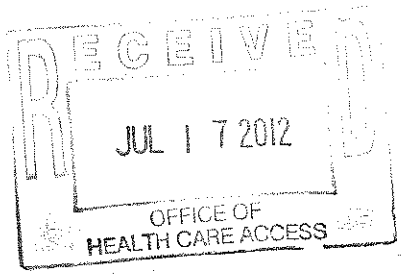
Susan Fox

JEFFERS
COWHERD

JEFFERS COWHERD P.C.
ATTORNEYS AT LAW

55 WALLS DRIVE
FAIRFIELD, CT 06824
203-259-7900
203-259-1070 FAX
WWW.JEFFERS-LAW.COM

STEPHEN M. COWHERD
Email: scowherd@jeffers-law.com



July 12, 2012

VIA HAND DELIVERY

Lisa A. Davis, MBA, BSN, RN
Deputy Commissioner
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: Certificate of Need Application; Docket Number: 12-31748-CON
Yale-New Haven Hospital and Greenwich Hospital to
Establish and Operate an Elective Angioplasty Program at Greenwich Hospital

Dear Deputy Commissioner Davis:

Enclosed please find our firm's Notice of Appearance and an original and five (5) copies of The Stamford Hospital's Petition for Intervenor Status in the above-referenced Certificate of Need Application. Also enclosed are the pre-filed testimonies of Sharon Kiely, M.D., Stamford Hospital's Senior Vice President of Medical Affairs and Chief Medical Officer, and William A. Gray, M.D., Associate Professor of Clinical Medicine at Columbia University and Director, Endovascular Services at the Columbia University Medical Center/New York Presbyterian Hospital.

Please contact the undersigned should you have any questions.

Respectfully submitted,

Stephen M. Cowherd

Enclosures

cc: Kimberly Martone, Director of Operations, OHCA (w/out enc.)
David L. Smith, Senior Vice President, Stamford Hospital (via email)

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

TABLE OF THE RECORD

APPLICANTS: **Yale-New Haven and Greenwich Hospital**

DOCKET NUMBER: **12-31748-CON**

PUBLIC HEARING: **July 17, 2012 at 9:00 a.m.**

PLACE: **410 Capitol Avenue, Third Floor Hearing Room Hartford, Connecticut**

EXHIBIT	DESCRIPTION
A	Letter from Yale-New Haven Hospital and Greenwich Hospital ("Applicants") dated February 10, 2012, enclosing the Certificate of Need ("CON") application under Docket Number 12-31748 to establish and operate an elective angioplasty program without onsite surgical backup at Greenwich Hospital received by the Office of Health Care Access ("OHCA") on February 14, 2012. (583 pages)
B	OHCA's letter to the Applicants dated March 15, 2012 requesting additional information and/or clarification in the matter of the CON application under Docket Number 12-31748. (8 pages)
C	Applicants' responses to OHCA's letter of March 15, 2012, dated May 14, 2012, in the matter of the CON application under Docket Number 12-31748, received by OHCA on May 14, 2012. (45 pages)
D	OHCA's letter to the Applicants dated June 20, 2012 deeming the application complete in the matter of the CON application under Docket Number 12-31748. (1 page)
E	OHCA's request for legal notification in the *Greenwich Times* and OHCA's Notice to the Applicants of the public hearing scheduled for July 17, 2012, in the matter of the CON application under Docket Number 12-31748, dated July 2, 2012. (4 pages)
F	Designation letter, dated July 3, 2012, designating Attorney Joanne V. Yandow as hearing officer in the matter of the CON application under Docket Number 12-31748. (1 page)

G	OHCA's letter to the Applicants dated July 10, 2012, requesting prefile testimony and interrogatories in the matter of the CON application under Docket Number 12-31748. (3 pages)
H	Letter from the Applicants enclosing Prefile Testimony and notice of appearance of Jennifer L. Groves, Esquire on behalf of the Applicants dated July 12, 2012 in the matter of the CON application under Docket Number 12-31748, received by OHCA on July 12, 2012. (69 pages)
I	Petition of Stamford Hospital dated July 12, 2012, requesting intervenor status and included prefile testimony and notice of appearance of Stephen M. Cowherd, Esquire in the matter of the CON application under Docket Number 12-31748, received by OHCA on July 12, 2012. See Exhibit K for additional prefile. (348 pages)
J	OHCA's letter to the Applicants dated July 12, 2012 informing them that the Office is in receipt of Stamford Hospital's petition for intervenor status and any responsive document should be filed by no later than 10:00 a.m. on July 15, 2012. In the matter of the CON application under Docket Number 12-31748. (1 page)
K	Email from Stamford Hospital dated July 13, 2012 enclosing prefile testimony from Dr. Sharon Kiely and Dr. William Gray in the matter of the CON application under Docket Number 12-31748. Received by OHCA on July 13, 2012.(35 pages)
L	Email from Attorney Jennifer Groves dated July 16, 2012, enclosing Applicants' rebuttal testimony and procedural motions related to the July 17, 2012, Public Hearing in the matter of the CON application under Docket Number 12-31748. Received by OHCA on July 16, 2012. (117 pages)
M	Email from Jeffers Cowherd dated July 16, 2012, enclosing revised pages 8 & 10 from Dr. Keily's Pre-file Testimony. Also enclosed are blacklined copies of the same showing the corrections in the matter of the CON application under Docket Number 12-31748. Received by OHCA on July 16, 2012. (11 pages)

N	OHCA's Order on the Petition of Stamford to be granted intervenor status and procedural motions in the matter of the CON application under Docket Number 12-31748, dated July 16, 2012. (5 pages)
O	Email from the Intervenor dated July 17, 2012, enclosing The Stamford Hospital's Objection to and motion to strike a portion of rebuttal testimony of Marna Borgstrom and Christopher Howes, M.D.; Rebuttal Testimony of Dr. William A. Gray; Rebuttal of Sharon Kiely, M.D. to Testimony of Marna Borgstrom, Chirstopher Howes, M.D. and Frank Corvino; Response to Greenwich and Yale-New Haven Hospital's Objection to Intervenor's Rebuttal Testimony and Motion to Strike Testimony in the matter of the CON application under Docket Number: 12-31748. Received by OHCA on July 17, 2012. (71 pages)

Administrative Notice:

1. CON Docket Number: 08-31210-CON
2. CON Docket Number:03-30148-CON
3. Declatory Ruling: 09-31433-DCR

PUBLIC HEARING
APPLICANTS
SIGN UP SHEET

July 17, 2012
9:00 a.m.

Applicant: Docket Number: 12-31748-CON
Yale New Haven Hospital and Greenwich Hospital
Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital

Print Name	Phone	Fax	POSITION HELD
Nancy Rosenthal - Greenwich Hosp	203-561-3908		SVP
Frank Cerrito - Greenwich Hosp	2035633701		CEO
Henry S. Cabin	203 785-4129		Yale Sch. of Medicine, YNHH
Gayle Capozzalo	2036882600		YNHHS -
Tucker Leary	203 688 2610		YNHH - V.P.

Public Hearing
Yale-New Haven Hospital and Greenwich Hospital

Print Name	Phone	Fax	POSITION HELD
Christopher Howes	2038634210		Yale School of Medicine - Physician
JEAN AHN	203 688 - 2609		YNHH
KAREN BANIFF			YNHH
Nancy Hagan	203-863-3505		GH Director
Marie Borgstrom	203 668-2608		YNHHS
Jennifer Jones	203 786-8316		LHKS/GH - YNHH

PUBLIC HEARING
INTERVENOR
SIGN UP SHEET

July 17, 2012
9:00 a.m.

Applicant: Docket Number: 12-31748-CON
Yale New Haven Hospital and Greenwich Hospital
Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital

Print Name	Phone	Fax	POSITION HELD
Carolyn Linsey	203-259-7900	203-259-1070	Counsel, The Stamford Hospital
Stephen Cawley	203-259-7900	203-259-1070	Counsel, The Stamford Hospital
Kathleen Silard	203-276-7525	203 276 5529	KSilard@stamhealth.org
Sharon Kiely MD	203 276-4159	203 276 5529	skiely@stamhealth.org
David L. Smith	203-276-7510	"	SVP, Strategy, Network Dev.

PUBLIC HEARING
INFORMAL PARTICIPANT
SIGN UP SHEET

July 17, 2012
9:00 a.m.

Applicant: Docket Number: 12-31748-CON
Yale New Haven Hospital and Greenwich Hospital
Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital

Print Name	Phone	Fax	POSITION HELD
[illegible]ndbye	545-4398		Cardiology @ Hock
Joyce Potter	276-4029	276-5535	Data Coord.
Michael Coady MD	2764415		Chief, Cardiac Surgery
Beth Chaty	276-2224		Director, Planning
DONNA GLEN	852-3495		Sr. Analyst, Planning

Print Name	Phone	Fax	POSITION HELD
Dr Steven Hausenloy	203 276 7480		Cardiology Chief, Stamford H, Stamford Hospital
Peggy Martino	2032767403		Service Line Director, Heart & Vascular Institute
William Gray MD	347-306-8601		Columbia-NYP physician

OHCA HEARINGS - EXHIBIT AND LATE FILE FORM

Applicants: Yale-New Haven Hospital and Greenwich Hospital

DN: 12-31748-CON

Hearing Date: July 17, 2012

Time: 9:00 a.m.

Proposal: Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital

OHCA Exhibit #	Description
1	Historic Cardiac Volumes from 2002 - 2011 - updated for 2011.
2	
3	
4	
5	

Applicant Late File #	Description	Due Date	Rec'd
1	applicat to provide Health Needs Assesmet-related to cardia		
2			
3			
4			
5			
6			

OHCA EXHIBIT 1

Table 1A: Inpatient cardiac catheterization discharges by provider, FFYs 2002-2011

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	FFY 07-11 (5-yr) % Change	FFY 09-11 (3-yr) % Change	FFY 10-11 (1-yr) % Change
Backus	156	210	200	170	116	53	106	135	115	123	132%	-9%	7%
Bridgeport	1,148	1,185	1,274	1,129	902	809	817	632	626	485	-40%	-23%	-23%
CT Children's								10	5	1	n/a	-90%	-80%
Danbury	263	299	260	327	748	533	475	452	418	398	-25%	-12%	-5%
Dempsey	519	564	633	640	487	439	480	419	462	338	-23%	-19%	-27%
Greenwich	100	42	35	106	167	158	163	177	166	174	10%	-2%	5%
Hartford	2,546	2,405	2,241	2,128	2,135	2,032	2,008	1,833	1,892	1,901	-6%	4%	0%
Hospital of Central CT	448	465	409	411	436	401	319	344	269	352	-12%	2%	31%
Lawrence & Memorial	420	473	466	393	414	303	337	440	503	376	24%	-15%	-25%
Middlesex	28	169	168	150	182	142	161	138	138	126	-11%	-9%	-9%
New Milford	0	0	0	22	37	38	65	37	0	0	-100%	-100%	n/a
Norwalk	247	203	195	182	128	67	77	104	126	149	122%	43%	18%
Rockville	0	79	99	24	4	3	0	0	0	0	-100%	n/a	n/a
St. Francis	2,742	2,802	2,800	2,656	2,421	2,543	2,431	2,292	2,206	2,001	-21%	-13%	-9%
St. Mary's	291	299	260	307	519	469	455	480	469	499	6%	4%	6%
St. Raphael	1,744	1,878	1,833	1,496	1,383	1,200	1,113	1,062	1,098	914	-24%	-14%	-17%
St. Vincent's	1,276	1,259	1,324	1,432	1,554	1,540	1,562	1,375	1,267	998	-35%	-27%	-21%
Stamford	354	352	296	299	311	297	293	358	321	304	2%	-15%	-5%
Waterbury	451	477	367	412	658	622	611	675	608	587	-6%	-13%	-3%
Yale	2,549	2,587	2,330	2,200	2,021	1,939	1,954	2,135	2,129	2,016	4%	-6%	-5%
Total	**15,282**	**15,748**	**15,190**	**14,484**	**14,623**	**13,588**	**13,427**	**13,098**	**12,818**	**11,742**	**-14%**	**-10%**	**-8%**

***Source**: CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database.*

ICD-9-CM Procedure Codes: 37.21-37.23

Please note: unduplicated counts utilizing all procedure codes

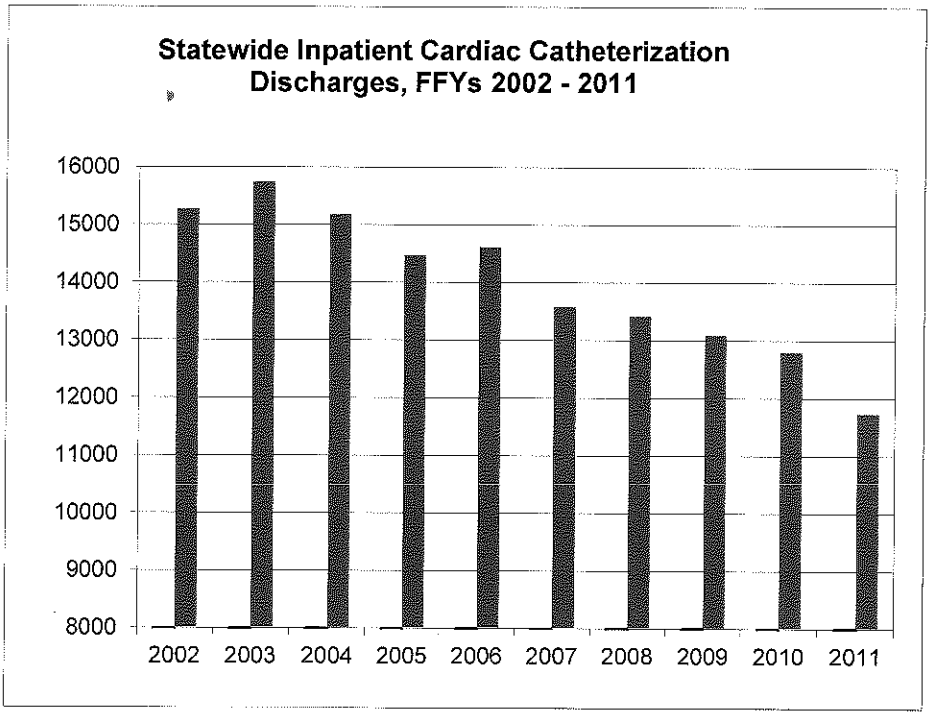


Table 2A: PCI discharges by provider, FFYs 2002-2011

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	FFY 07-11 (5-yr) % Change	FFY 09-11 (3-yr) % Change	FFY 10-11 (1-yr) % Change
Bridgeport	1,191	1,249	1,288	1,052	692	560	580	428	379	298	-47%	-30%	-21%
CT Children's								2	0		n/a	-100%	n/a
Danbury	0	0	0	0	453	409	330	326	277	292	n/a	-10%	5%
Dempsey	452	464	453	519	401	353	376	334	368	253	-32%	-24%	-31%
Greenwich	0	0	0	20	38	32	40	40	32	37	60%	-8%	16%
Hartford	1,312	1,483	1,321	1,282	1,246	1,206	1,093	1,031	1,122	1,195	-6%	16%	7%
Hospital of Central CT	0	0	0	26	61	70	60	74	69	97	169%	31%	41%
Lawrence & Memorial	0	0	0	0	41	-	29	74	74	70	n/a	-5%	-5%
New Milford	0	0	0	0	0	6	11	11	0		n/a	-100%	n/a
Norwalk								14	57	65	n/a	364%	14%
St. Francis	1,192	1,253	1,349	1,223	1,170	1,188	1,171	1,232	1,030	938	-3%	-24%	-9%
St. Mary's	0	0	0	59	297	246	251	255	291	314	317%	23%	8%
St. Raphael	715	970	924	708	680	632	595	534	523	444	-11%	-17%	-15%
St. Vincent's	1,063	1,035	1,085	1,150	1,181	1,101	1,124	958	925	509	-4%	-47%	-45%
Stamford	0	0	0	9	39	34	45	159	151	135	278%	-15%	-11%
Waterbury	0	0	0	61	347	373	325	361	361	379	511%	5%	5%
Yale	1,635	1,715	1,460	1,297	1,218	1,131	1,186	1,352	1,469	1,324	-13%	-2%	-10%
Total	**7,560**	**8,169**	**7,880**	**7,406**	**7,864**	**7,341**	**7,216**	**7,185**	**7,128**	**6,350**	**-1%**	**-12%**	**-11%**

***Source**: CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database.*

ICD-9-CM Procedure Codes: .66, 36.01, 36.02, 36.05, 36.06 and 36.07

Please note: unduplicated counts utilizing all procedure codes

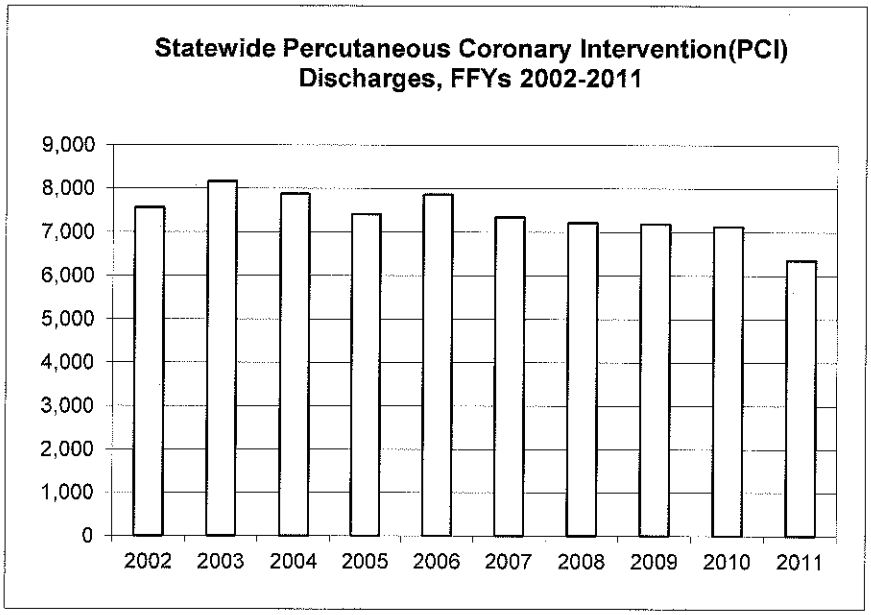


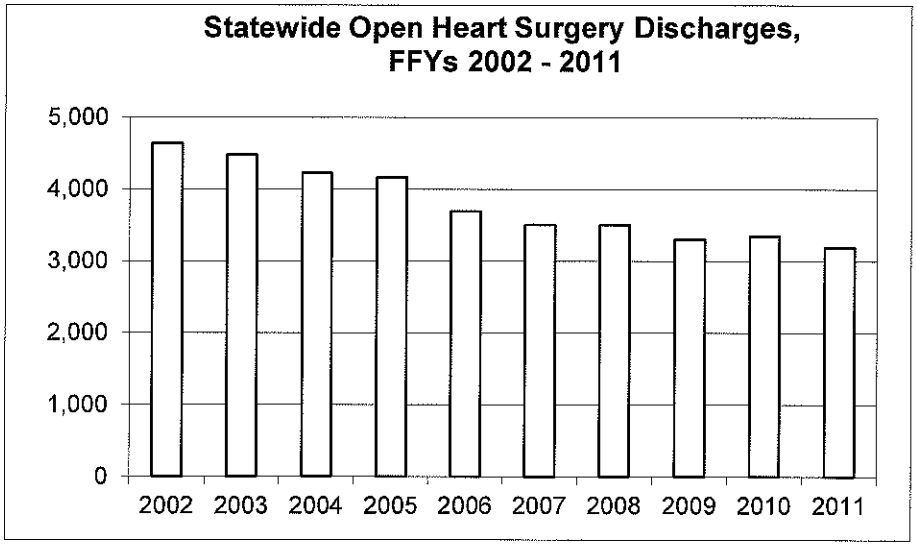
Table 3A: Open heart surgery discharges by provider, FFYs 2002-2011

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	FFY 07-11 (5-yr)% Change	FFY 09-11 (3-yr)% Change	FFY 10-11 (1-yr) % Change
Bridgeport	345	313	268	263	175	194	106	96	136	117	-40%	22%	-14%
CT Children's								6	4	9	n/a	50%	125%
Danbury	0	0	0	114	177	121	162	148	174	170	40%	15%	-2%
Dempsey	115	134	121	174	97	70	84	56	58	66	-6%	18%	14%
Hartford	901	844	756	726	742	685	671	652	695	698	2%	7%	0%
St. Francis	1,239	1,299	1,311	1,188	998	990	912	845	820	735	-26%	-13%	-10%
St. Mary's	0	0	0	19	72	100	85	114	112	94	-6%	-18%	-16%
St. Raphael	761	687	617	510	353	342	321	299	318	294	-14%	-2%	-8%
St. Vincent's	310	296	293	291	259	232	257	219	195	196	-16%	-11%	1%
Stamford	0	0	0	0	0	0	75	73	46	71	n/a	-3%	54%
Waterbury	0	0	0	20	117	110	134	110	98	90	-18%	-18%	-8%
Yale	973	905	860	861	704	664	698	691	697	655	-1%	-5%	-6%
Total	**4,644**	**4,478**	**4,226**	**4,166**	**3,694**	**3,508**	**3,505**	**3,309**	**3,353**	**3,195**	**-9%**	**-3%**	**-5%**

***Source**: CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database.*

ICD-9-CM Procedure Codes: 35.10-35.28 and 36.10-36.19

Please note: unduplicated counts utilizing all procedure codes



Greer, Leslie

From: Olejarz, Barbara
Sent: Tuesday, July 24, 2012 10:18 AM
To: Huber, Jack; Greer, Leslie
Cc: Lazarus, Steven; Martone, Kim
Subject: FW: 7-17-12 YALE & GREENWICH HOSPITALS
Attachments: 0717yale-greenwich (ohca).doc

7/24/12

DN: 12-31748

Jack – attached is Yale's transcript for the FOI you have from Bober & Associates
Leslie – Attached is the transcript from the Yale Hearing for the files, the original will be mailed to us.

Barbara

From: nadinec@postreporting.com [mailto:nadinec@postreporting.com]
Sent: Tuesday, July 24, 2012 10:13 AM
To: Martone, Kim
Cc: Olejarz, Barbara
Subject: 7-17-12 YALE & GREENWICH HOSPITALS

ORIGINAL

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

OFFICE OF HEALTH CARE ACCESS

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DOCKET NO. 12-31748-CON

RE: YALE-NEW HAVEN HOSPITAL
AND GREENWICH HOSPITAL JULY 17, 2012

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HEALTH CARE ACCESS

BEFORE: JOANNE V. YANDOW, HEARING OFFICER

APPEARANCES:

FOR YALE-NEW HAVEN HOSPITAL & GREENWICH HOSPITAL:

JENNIFER L. GROVES, ESQUIRE
One Century Tower
265 Church Street
New Haven, Connecticut 06510

FOR THE INTERVENOR:

JEFFERS COWHERD, P.C.
55 Walls Drive
Fairfield, Connecticut 06824
BY: STEPHEN COWHERD, ESQUIRE

RE: YALE-NEW HAVEN HOSPITAL AND GREENWICH HOSPITAL
JULY 17, 2012

. . .Verbatim Proceedings of a hearing before the State of Connecticut, Department of Public Health, in the matter of Yale-New Haven Hospital and Greenwich Hospital, held at 410 Capitol Avenue, Hartford, Connecticut, on July 17, 2012 at 9:38 a.m. . . .

HEARING OFFICER JOANNE V. YANDOW: Good morning. Before we begin, please make sure all cell phones are turned off. This public hearing is before the Office of Health Care Access, it's Docket No. 12-31748-CON, and is being held on July 17th, 2012 to consider Yale-New Haven and Greenwich Hospitals' application to establish and operate an elective angioplasty program without outside surgical backup at Greenwich Hospital. This public hearing is being held pursuant to General Statutes Section 19a-639a and will be conducted as a contested case in accordance with the provisions of Chapter 54 of the Connecticut General Statutes, the Uniform Administrative Procedures Act.

I am Joanne V. Yandow, I'm the Hearing Officer designated by Commissioner Jewel Mullen of the

Department of Public Health to serve as the Hearing Officer for this matter. Staff members assigned to assist me in this case are Kimberly Martone, Director of Operations; Steve Lazarus, an analyst with OHCA; and Assistant Attorney General, Rosemary McGovern.

Following the hearing I will issue a proposed final decision in accordance with General Statute Section 4-179. In making my decision I will consider and make written findings concerning the principles and guidelines set forth in Section 19a-639 of the Connecticut General Statutes.

The applicants, Yale-New Haven Hospital and Greenwich Hospital, have been designated as parties in this proceeding. The Stamford Hospital has requested intervenor status in this proceeding, and I have approved the request, in part, and have designated the Stamford Hospital as an intervenor with limited rights. And that order was issued yesterday.

Are there any other persons who wish to offer testimony or make a statement in this case other than those individuals representing the applicant or the intervenor? Is there anyone present here who plans on making any public comment? Okay. Let the record show that no one has come forward.

At this time, I would like all of the individuals who are going to testify on behalf of the applicants and intervenor to stand and raise your right hand. Okay. So what I see now, and as each person comes up you will identify yourself. Dr. Sharon Kiely, Dr. William Gray, Marna Borgstrom, Henry Cabin, Christopher Howes, Frank Corvino. Okay. And I see additional people standing just so --

MS. JENNIFER L. GROVES: I don't know if you'd like us to identify them for the record? We've just brought additional --

HEARING OFFICER YANDOW: -- yeah, just so I know --

MS. GROVES: -- to answer questions if need be. And I think, Steve, you've done the same thing? Would people like to identify themselves? Would that help?

HEARING OFFICER YANDOW: -- yeah, I just want to know who's --

MS. KAREN BANOFF: Karen Banoff.

MS. GAYLE CAPOZZALO: Gayle Capozzalo.

MS. NANCY HANSON: Nancy Hanson.

MS. KATHLEEN SILARD: Kathleen Silard.

MR. DAVID SMITH: David Smith.

HEARING OFFICER YANDOW: Okay. If the Court Reporter would please -- and again, when you come up you will again identify yourself, but if the Court Reporter would please swear everyone that's been identified here?

(Witnesses sworn)

MS. ROSE McGOVERN: Good morning. Assistant Attorney General Rose McGovern. I just wanted to clarify what my role is in this proceeding. I'm advising the Hearing Officer on all procedural matters and as far as a decision that's issued by OHCA, it's OHCA's decision, I review for legal sufficiency only.

HEARING OFFICER YANDOW: And again, anyone who filed their prefiled testimony when you come up you will also adopt that testimony under oath. For all those individuals who are testifying, please make sure you printed your name and affiliation on the sign-up sheet that's been made available for this hearing. So if you haven't done that yet, please make sure you do it at a break, if you haven't done that.

At this time I will ask staff to read into the record, those documents already appearing in OHCA's table of the record in this case. All documents have been identified in the table of record for reference

purposes. Mr. Lazarus?

MR. STEVEN W. LAZARUS: Good morning. Steven Lazarus. I would like to enter into the record Exhibits A through O as identified on the table of record, placed on everybody's desk today, and we have an additional item that was e-mailed to OHCA this morning, and that's the e-mail from Jeffers Cowherd, enclosing the second letter from White Plains Hospital. And that will be identified as Exhibit P.

(Whereupon, exhibits A through P were received in full and marked as Record Exhibits.)

HEARING OFFICER YANDOW: Okay. So we have some procedural matters before we start with any testimony. I did issue an order yesterday regarding some of the motions that have been filed. I did not address in that order the motion -- the motion to strike.

So, in addition to Applicant's motion to strike we also have a motion that was filed this morning by the intervenor, Stamford Hospital, the objection to and motion to strike a portion of rebuttal testimony of Marna Borgstrom and Christopher Howes and date. I've reviewed all of the documents. At this point, what will be stricken from the record in Mr. Cowherd's filing, attachment seven to Dr. Kiely's prefiled testimony, is

the L and M, Lawrence and Memorial, CON application, Exhibit 7. That will be stricken from the record. And also with Attorney Cowherd's filings attached to Dr. Gray's prefiled testimony Exhibit 5, the New York regulations, are being stricken.

Regarding rebuttal documents filed by Yale-New Haven, attached to the testimony of Marna Borgstrom, is the draft section of the OHCA plan identified in page numbers 647 -- I'm sorry, 747 through 756 is stricken from the record. Regarding the parts of the prefiled testimony regarding these attachments, we will look at that more closely after, we will keep the record open, and we will identify what parts of the prefiled testimony related to this will be stricken and both the applicant and the intervenor will get notification from OHCA and the opportunity to file a response to that. So that will not be determined today, but after today's hearing and the record will remain open.

So, regarding Mr. Cowherd's motion that was filed this morning, the objection on the motion to strike, I then will rule -- hold on this. I'm not going to rule on it in its entirety as far as what parts of the prefile, because that has not yet been determined on what

part of the testimony. So I'm going to hold on this and rule on that after the hearing. And of course, you will get that decision.

Mr. Cowherd has filed rebuttal testimony of Dr. Sharon Kiely and rebuttal testimony of Dr. William A. Gray. You've had a chance to review this Counsel?

MS. GROVES: I have had a limited opportunity to review. As I mentioned before, I only got this document about quarter after 8:00 this morning, so I had a chance to review it, but I haven't really had a chance to discuss it with my client or process it for purposes of cross-examining witnesses, or you know, presenting responses in our hearing testimony. I think that given the fact that applicants were asked to submit their rebuttal testimony yesterday at 10:00 a.m. Attorney Cowherd had ample time to get us a rebuttal yesterday during business hours, or even last night. Like I mentioned before, I received this when I was driving up. So I feel that we're disadvantaged if this is put into the record and we are not going to have ample opportunity to review before we have to cross-examine in about half an hour.

HEARING OFFICER YANDOW: Okay. So I take it then you're objecting to these rebuttal statements?

MS. GROVES: Yes. We maintain our objection to these being entered into the record.

HEARING OFFICER YANDOW: Okay. I'm going to overrule the objection. You will have the opportunity to cross-examine the witnesses on this. I'll give you what time you need to review and you certainly will have the last word as far as, you know, rebuttal and follow-up. But you will be able to cross-examine.

MS. GROVES: Okay.

HEARING OFFICER YANDOW: As stated in my order yesterday, Mr. Cowherd, as the intervenor, has no right of cross-examination of your witnesses, but you will be able to cross-examine when his witnesses are up.

MS. GROVES: Okay. And would we have any opportunity either at or before the hearing to prepare written responses to these or just give cross-examination?

HEARING OFFICER YANDOW: Let's see -- could you -- I would prefer to do it today. I mean, you haven't looked at it yet?

MS. GROVES: I mean, I've looked at it and it may well be that it's not substantially different than what I've already seen. It may not change what we need to do, but I just want to make sure that everyone here

has had a chance to review it and perhaps if we take a five minute break before cross we can all look and see if we need -- if we think we need to do a written response.

HEARING OFFICER YANDOW: Okay.

MR. STEPHEN COWHERD: Hearing Officer Yandow, Stephen Cowherd on behalf of Stamford Hospital. If that license is granted to submit written responses to the rebuttal testimony, Stamford Hospital would respectfully request the ability to respond to whatever that response is since it is our testimony supplemental going into the record.

HEARING OFFICER YANDOW: Okay. We can address that if that comes up.

MS. GROVES: And we would, I mean, we would object to that.

HEARING OFFICER YANDOW: Okay.

MS. GROVES: Because theirs is a rebuttal. And this can go back and forth for weeks if it needs to, but I think it's fair that applicants get the last word and written permission. I think that's been a policy.

HEARING OFFICER YANDOW: We're not even there yet, so --

MS. GROVES: Yes, right.

HEARING OFFICER YANDOW: -- okay. And

then we have Mr. Cowherd also filed a response to Greenwich and Yale-New Haven Hospitals' objection to intervenors rebuttal testimony and motion to strike testimony. So again, as far as the motion to strike testimony, we're going to review the prefile. A lot of this just came in and we didn't have the time to go through all of the testimony. We've told you what attachments are being stricken and that's giving you notice of any testimony related to those attachments will be stricken. Okay?

All right. And then this document that just was handed to us, any position from applicant?

MS. GROVES: To the extent that this just corrects the letter that was previously in the record, I don't think -- I don't think we have any objection. I think it just corrects a misstatement on PCI volume at White Plains.

HEARING OFFICER YANDOW: So this is entered into the record. I believe --

MS. GROVES: But I --

HEARING OFFICER YANDOW: -- I'm sorry, go ahead. I'm sorry.

MS. GROVES: -- I would ask too, that obviously, that it not replace the letter that was in the

record, because I would like the letter to reflect that the initial letter had the incorrect volumes.

HEARING OFFICER YANDOW: It's all in there.

MS. GROVES: Okay.

HEARING OFFICER YANDOW: Any other motions? I think I've addressed them all. Is there any other motion out there that needs to be addressed?

MR. COWHERD: Not on behalf of Stamford Hospital.

HEARING OFFICER YANDOW: Okay. Just for the record, if we could have both attorneys identify themselves for the record?

MS. GROVES: I'm sorry. I'm Jennifer Groves, from Updike, Kelly and Spellacy. The only question I do have, I know that the Hearing Officer has stricken the draft -- the draft OHCA cardiac standards. I believe from my skimming this that those are referenced in this submission that Attorney Cowherd made this morning. So I'm looking at it to strike from our documents and I would assume it would be stricken from their rebuttal if that stays in as well, right?

HEARING OFFICER YANDOW: All right. Anything related to --

MS. GROVES: Okay.

HEARING OFFICER YANDOW: -- I haven't looked at it that closely. I mean, that will be determined -- you will be noticed as to what's going to be stricken and you can file responses.

MS. GROVES: Okay. Thank you. Other than that I have no --

HEARING OFFICER YANDOW: Any other housekeeping matters?

MR. COWHERD: I'll just let my colleague introduced herself for the record.

MS. CAROLYN R. LINSEY: I'm Carolyn Linsey, representing Stamford Hospital.

HEARING OFFICER YANDOW: Okay.

MS. GROVES: I do -- sorry to interrupt, but I do have one other housekeeping matter and I know that we raised this with Mr. Lazarus in an e-mail last night. Ms. Borgstrom with like if time permits to be able to leave to attend the funeral of --

MS. MARNA BORGSTROM: Sister Ann Vergeon (phonetic) used to run the Hospital of St. Raphael and her funeral is in New Jersey this afternoon.

MS. GROVES: -- and so she would need to leave by 11:00. I'm not sure, given the late hour, I

mean, I assume, we'll be through, but I was wondering if it was possible for OHCA to ask the questions of her before then so she could leave?

HEARING OFFICER YANDOW: Well, let's see where her testimony and we'll do our best and let's see where we go.

MS. GROVES: We appreciate that, thank you.

HEARING OFFICER YANDOW: Do we have an agenda?

MR. LAZARUS: Right here.

HEARING OFFICER YANDOW: Okay. Do we have any OHCA exhibits to be marked into the record?

MR. LAZARUS: Yes. We have one and I'd like to mark it as OHCA Exhibit 1. And these are the historical cardiac volumes for the state of Connecticut. They are in the record as -- submitted by I believe the applicant it might have even been the intervenors, it was taken from our website from 2002-2010. This particular exhibit will include data for 2011 as well. And I'll provide copies to both.

HEARING OFFICER YANDOW: Any objection?

MS. GROVES: The applicant has no objection.

HEARING OFFICER YANDOW: Attorney Cowherd, any objection?

MR. COWHERD: No objection.

HEARING OFFICER YANDOW: It's being marked as OHCA Exhibit 1.

(Whereupon, historical cardiac volumes were received in full and marked as OHCA Exhibit No. 1.)

HEARING OFFICER YANDOW: And I do note that in the table of record exhibits, we do know what OHCA will take administrative notice of. Of course, we will certainly, you know, read those decisions and take out what is relevant. We certainly know how to weigh the evidence and it will be determined, you know, when all of the evidence is in on whether or not notice is taken on any of those past positions. Okay? Any other objections on any Record Exhibits? Okay.

MS. GROVES: No. I'm all choked up. This is overwhelming.

(Laughter)

HEARING OFFICER YANDOW: Are you all set?

MR. LAZARUS: I'm all set. Thank you.

HEARING OFFICER YANDOW: Okay then. If we could just have a brief opening statement from applicant's counsel, just a little brief opening

statement on the proposal, and then you can call your first witness.

MS. GROVES: This is a proposal obviously to add elective angioplasty services at Greenwich Hospital as part of the Yale-New Haven Heart and Vascular Center. I think this is a proposal that's been raised before by this hospital in concert with Yale-New Haven Hospital and as everyone knows, has been denied. But we think there have been significant changes in the recommendations around elective angioplasty without on-site surgery. There are differences in sort of the way need was projected in this application. There are differences that we understand in the way that OHCA is looking at need for border hospitals, things that really made us believe that it was the right time to revisit this application.

And I think that, you know, Greenwich has the infrastructure in place, given its primary angioplasty program to treat these patients and these patients are presenting at Greenwich Hospital, as you'll hear, and we believe that it is the most cost-effective solution to allow these providers to provide this care to these patients as opposed to patient's having to, you know, to undergo unnecessary transfers and second

procedures at other hospitals. So I would introduce to you our witnesses. We're going to start with Marna Borgstrom and then she'll introduce our other witnesses. And we appreciate your time today. Thank you.

HEARING OFFICER YANDOW: Ms. Borgstrom, you've been sworn in --

MS. BORGSTROM: Yes.

MARNA BORGSTROM

Having been called as a witness, having been duly sworn, testified on her oath as follows:

HEARING OFFICER YANDOW: -- and you have two filings. The original prefiled testimony and then rebuttal prefiled testimony. Do you adopt that testimony under oath?

MS. BORGSTROM: Yes, I do.

HEARING OFFICER YANDOW: Okay. And if you want to give a statement, you don't need to read it all in, but if you want to just give sort of a brief summation of what you're prefiled testimony states?

MS. BORGSTROM: Thank you. And I will be even briefer since counsel said a lot of what I have here.

MS. GROVES: I'm sorry.

MS. BORGSTROM: No, that's great. So, Hearing Officer Yandow and members of the OHCA staff, thank you for the opportunity to present to you on this critically important certificate of need application. My name is Marna Borgstrom, and I am the Chief Executive Officer of Yale-New Haven Hospital and the President and Chief Executive Officer of the Yale-New Haven Health System.

I have the distinct privilege of introducing my colleagues who are going to speak to you today in more detail about these developments and they'll summarize our proposal quite nicely. Here with me today, speaking, are Dr. Henry Cabin, Dr. Christopher Howes and Mr. Frank Corvino. The Yale-New Haven Heart and Vascular Center is proposing the development of a satellite elective angioplasty program at Greenwich Hospital. As counsel said, although we proposed this before and it hasn't been approved, there are some new developments surrounding elective angioplasty, without cardiac surgery backup, which has led us to pursue this again.

Yale-New Haven Heart and Vascular Center is one of the leading providers of heart and vascular care. Yale University School of Medicine cardiovascular

physicians have been actively involved in primary angioplasty as Greenwich Hospital since its inception and they will continue to provide clinical oversight, direct patient care, and staff and physician education in the proposed program.

The Heart and Vascular Center has established satellite emergency angioplasty programs at Greenwich and Lawrence and Memorial Hospitals. Our position on the appropriateness and safety of freestanding interventional cardiac programs has evolved as cardiac care and related research have demonstrated the effectiveness of these programs over the last few years. It's clear that smaller volume angioplasty programs can deliver high quality and safe care assuming the proper infrastructure and the proper clinical expertise.

Consistent with our objective to provide accountable cost-effective and high-quality care we want to bring this appropriate care closer to the patient's and eliminate need for repeat procedures and hospitalizations, travel, and unnecessary stress. This especially makes sense in our satellite emergency angioplasty programs where the infrastructure is already in place at Greenwich Hospital.

As I noted, we have tried in good faith to collaborate with Stamford Hospital in today's hearing in this matter, but they have declined to pursue and are opposing the application, even though the proposed program will not negatively impact their program and the market trends were quite similar when their program was approved. We believe the time has come for patients to be offered elective angioplasty at Greenwich Hospital and I encourage you to approve this application.

I'd now like to introduce Dr. Henry Cabin, who will discuss recent medical research and changes in clinical practice guidelines that are very relevant to our proposal. Thanks very much.

HEARING OFFICER YANDOW: Let me just -- Mr. Lazarus, do you want to hold off on the questions we have of -- they said the prefiled --

MR. LAZARUS: Yes --

HEARING OFFICER YANDOW: -- okay.

MR. LAZARUS: -- unless you feel we should ask some questions now?

HEARING OFFICER YANDOW: No.

MR. LAZARUS: I think we'll probably proceed with the agenda --

HEARING OFFICER YANDOW: But I do think we

do -- will we have questions of Ms. Borgstrom, though?

MR. LASARUS: -- we do and if time gets tight we can perhaps call her up sooner.

HEARING OFFICER YANDOW: Okay. So you're not excused at this point.

MS. BORGSTROM: I understand. Thank you.

HEARING OFFICER YANDOW: All right. Okay. Could you identify yourself please?

HENRY CABIN

having been called as a witness, having been duly sworn, testified on his oath as follows:

DR. HENRY CABIN: Sure. My name is Henry Cabin. Good morning Hearing Officer Yandow.

HEARING OFFICER YANDOW: And Mr. Cabin, we do have some prefiled testimony of yours and now that you've been sworn under oath, do you adopt that testimony as your own?

DR. CABIN: Yes, I do.

HEARING OFFICER YANDOW: Okay. You can go ahead.

DR. CABIN: Good morning Hearing Officer Yandow and OHCA staff. My name is Dr. Henry Cabin and

I'm the Clinical Chief of Cardiology and a professor of medicine at the Yale University School of Medicine. I'm also the Medical Director of the Yale-New Haven Heart and Vascular Center and a practicing interventional cardiologist.

I would like to highlight some significant clinical research known as the C-PORT-E Study, which was recently completed and the results of this study, published in 2012 in the New England Journal of Medicine. This large, multi-institutional study found that there were no significant differences between the six-week mortality and in the adverse cardiac events at nine months between the two groups. The results of this study are consistent with other studies and meta-analyses that have been published.

C-PORT-E research, as well as other studies on elective angioplasty without on-site cardiac surgery led to a significant change in our society's 2011's clinical practice guidelines for angioplasty. Specifically, the modification of elective angioplasty without on-site cardiac surgery from a class 3 indication, which is not recommended, no benefit, to a class 2B, where the benefit is either equal or greater than the risk.

I want to emphasize that not all hospitals without on-site cardiac surgery are able to offer safe, high-quality, elective angioplasty services. Yale-New Haven Hospital Heart and Vascular Center's clinical expertise, resources and experience allows us to support the careful expansion of elective angioplasty, without on-site cardiac surgery, as have other tertiary programs throughout the country, such as New York Presbyterian. Our highly skilled Board certified interventional cardiologists collectively perform thousands of procedures a year. Each cardiologist in our group is required to perform a minimum of 75 per year, with most performing significantly more.

Our other clinical staff, both in New Haven and Greenwich, consist of experienced nurses, physician assistants, technicians and other support staff who have received comprehensive training in our interventional laboratory and are very comfortable treating the most acutely ill patients. Nursing and other technical staff in our satellite program at Greenwich Hospital received the same education, training and clinical oversight as the state at Yale-New Haven Hospital.

The current emergency angioplasty program

at Greenwich Hospital operates according to the same policies, procedures and protocols as our program at Yale-New Haven Hospital. And in fact, the same physicians who perform the procedure at Yale-New Haven Hospital are the ones who are performing it at Greenwich Hospital. This will continue to be the case with an elective angioplasty program. This consistency of care is very important for both physicians and patients alike and results in an optimal experience.

The proposed satellite elective angioplasty program at Greenwich Hospital offers the residence of the Greenwich service area the opportunity to receive high-quality interventional cardiac care in their local community by one of the nation's leading cardiac providers. I strongly encourage OHCA to approve this CON application.

I would like to now introduce my colleague, Dr. Christopher Howes, who will discuss the need for the proposed program and provide additional information about the Greenwich Hospital cardiac cath. lab.

HEARING OFFICER YANDOW: Good morning Dr. Howes.

CHRISTOPHER HOWES

having been called as a witness, having been duly sworn, testified on his oath as follows:

HEARING OFFICER YANDOW: We have your prefiled testimony. Now you've been sworn under oath do you adopt the testimony as your own?

DR. CHRISTOPHER HOWES: I do adopt that prefiled testimony.

HEARING OFFICER YANDOW: And you can certainly give a summation now of what your testimony is.

DR. HOWES: Thank you for the opportunity. Good morning Officer Yandow and OHCA staff. My name is Dr. Christopher Howes, and I'm an assistant professor at the Yale School of Medicine and a practicing interventional cardiologist. I'm also the Chief of Cardiology and Medical Director of the primary angioplasty program at Greenwich Hospital.

We've already heard from Dr. Cabin about the recent changes to the 2011 ACCAHIA guidelines regarding angioplasty. Unlike Dr. Gray, from New York Presbyterian, we believe these guideline changes regarding elective angioplasty, without on-site surgery are significant. Along with the results of the recent C-

PORT-E Study our opinion is that the debate is essentially over regarding the safety of elective angioplasty programs without on-site cardiac surgery as long as the programs adhere to strict program requirements as suggested in the SCAI document and that includes close oversight and clinical direction from a full-service provider.

I would like to address the topic of referring physician relationships and why we believe this program will not cause harm to the intervenor. The physicians who refer patients to the Yale-New Haven Heart and Vascular Center physicians do so because of the relationship between these physicians. And these relationships have developed and evolved over many years. Very limited relationships currently exist between these referring physicians and the interventional cardiologists at Stamford Hospital. And in fact, there is minimal crossover between Stamford and Greenwich Hospital cardiovascular physicians and their patients.

The absence of cardiovascular physician crossover between Greenwich and Stamford Hospitals is evident in the patient origin data, which was included in my testimony and shows how the top 80 percent of inpatient cardiovascular patient communities at Greenwich

Hospital are low volume communities at Stamford Hospital and the opposite is true that the high-volume communities for Stamford Hospital are in fact the low-volume communities for Greenwich. It is also significant that although Stamford Hospital was granted a CON approval to open a full service cardiac program, and has been providing elective angioplasty for several years, Greenwich angioplasty -- Greenwich Hospital's angioplasty patient volume, both their PAMI procedures, and those patients that are currently being transferred has remained relatively constant.

This proposal includes providing elective angioplasty services to patients already coming to our hospital and some other patients who are currently receiving these services in New York hospitals. We believe that the patient choice is an important factor to consider, especially in this case where we've already offered this procedure and have all the necessary infrastructure.

In addition to patient choice OHCA must consider the hardships that Greenwich Hospital elective angioplasty patients must endure by having a second hospitalization, second invasive procedure, and having to leave the local area with their family and their

physicians. These factors also add unnecessary wasted cost to the health care system.

We have included letters of support in our CON application from noninvasive cardiologists on the Greenwich Hospital staff who have indicated they are willing to refer cardiac catheterization volume to our hospital if we are able to achieve this CON. In addition, two interventional cardiologists recently provided letter stating they would bring volume between 80 and 105 angioplasty cases to Greenwich Hospital. Their case volume is above and beyond the volumes that were estimated in the original CON and unfortunately, they are unable to appear at today's hearing.

We currently staff our emergency angioplasty program with either on-site or on-call staff 24 hours a day, seven days a week, 52 weeks per year. Our staff are ready and at any given time, we provide the highest quality cardiac care to some of the sickest patients presenting with acute myocardial infarction. We just want to add our opportunity to provide this excellent cardiac care to a broader spectrum of our patients.

Now that we know from recent research and leading experts in the nation that elective angioplasty,

without on-site surgery is safe and appropriate how can we not improve the utilization of our infrastructure and improve the experience for Connecticut residents? I urge you to consider approving this program.

I would like to introduce Frank Corvino, President of Greenwich Hospital. Thank you.

HEARING OFFICER YANDOW: Good morning Mr. Corvino.

MR. FRANK CORVINO: Good morning. How are you?

HEARING OFFICER YANDOW: Fine. Thank you.

FRANK CORVINO

having been called as a witness, having been duly sworn, testify on his oath as follows:

HEARING OFFICER YANDOW: You have some prefiled testimony.

MR. CORVINO: Yes.

HEARING OFFICER YANDOW: And do you adopt that testimony as your own?

MR. CORVINO: Yes, I do. Good morning. And as you know, my name is Frank Corvino and I'm president and CEO at Greenwich Hospital. I'd like to

focus my testimony on the high level and quality and excellence of care at Greenwich Hospital and our commitment to provide the very best cost effective care to our patients who require elective angioplasty services. Our commitment to quality, service excellence, and employee satisfaction and patient satisfaction is well documented. Our efforts to consistently provide high quality and safe patient care have earned top marks from many national organizations, including the Joint Commission, the Connecticut Hospital Association, the Connecticut Quality Improvement Award Partnership, and the Leapfrog Group, just to name a few.

We are committed to this significant investment required to offer elective angioplasty in our community. In this era of health reforms and the need for all healthcare providers and health systems to provide more cost-effective services we believe this program will reduce the overall cost of angioplasty care to the Connecticut health system.

We estimate that the unnecessary costs that now result from the current restriction on elective angioplasty impact payers and patients by a total of approximately $425,000 each year. We arrive at that amount based on an average of 53 cases that are currently

transferred that could be cared for at Greenwich Hospital under an elective angioplasty program, multiplied by $8,000, which includes 7,000 for the average cost of an angioplasty admission at Yale-New Haven Hospital plus $1,000 for emergency transportation. We need to ensure that we are providing care in a cost-effective and efficient manner. It just makes sense to maximize both the use of our existing clinical capabilities, and resources, as well as to maximize the benefit and community need. There really is no downside.

I want to emphasize that this proposal is really all about patient care and patient access. It does not make sense that Greenwich Hospital is able to do the most difficult angioplasty cases and do them with excellent outcomes, I might add, and is not allowed to do the elective cases. Especially in light of the revised guidelines. It really just does not make sense for our patients.

So thank you for your time and attention, and I urge you to approve the CON application.

HEARING OFFICER YANDOW: And I believe that's all of the testimony from the applicant?

MS. GROVES: Yes, that concludes our presentation. Thank you.

HEARING OFFICER YANDOW: Okay. And before -- OHCA will have questions, but we're going to take in evidence from the intervenor before we do that.

MR. COWHERD: Thank you Hearing Officer Yandow. Our first witness will be Sharon Kiely, Chief Medical Officer for Stamford Hospital.

HEARING OFFICER YANDOW: Good morning Dr. Kiely.

SHARON KIELY

having been called as a witness, having been duly sworn, testified on her oath as follows:

DR. SHARON KIELY: Good morning. Thank you. I adopt my prefiled testimony.

HEARING OFFICER YANDOW: Prefiled and also --

DR. KIELY: (Indiscernible, talking over each other) in its entirety.

HEARING OFFICER YANDOW: -- okay. Thank you.

DR. KIELY: Good morning. Again, my name is Dr. Sharon Kiely. I'm associate vascular clinical medicine at Columbia, as well as Senior Vice President

and Chief Medical Officer at Stamford Hospital. Thank you for this opportunity to address OHCA on this important matter.

I'd like to present just a couple of highlights from my testimony. We will have a lot of time to discuss the other things in a minute. First, I think it's clear to everyone, both statewide as well as the proposed service area volumes are flat to declining in both PCI and cardiac cath. For PCI, while there are limitations in estimates about patient volumes there's no better source to estimate outpatient volume then the CHAPCR database, which shows PCI flat to slightly declining.

For cardiac cath. the stagnant trend continues. And the inpatient data from time and the utilization trends posted on OHCA's website in every way we looked at this data we did not see any trend that was going in another direction.

We agree very clearly that if a patient wants local care and that can be provided safely and effectively that they should have it. Since the time that we received approval in 2008 though White Plains Hospital has also received approval in New York to serve Westchester County elective angioplasty. We believe that

patients in the service area can get this care now. So within 10 miles to the west and six miles to the east of the service area the applicant proposes Greenwich Hospital seeks to serve in an area where there are two elective angioplasty programs as well as one full-service cardiac program, Stamford Hospital. We feel that this meets that need the community has now into the future given the current volume projections.

The applicant identifies the Connecticut service area for this elective angioplasty CON, which is identical to Stamford Hospital's primary, secondary service area. Access is just not an issue in the service area proposed in this application. In fact, both White Plains and Stamford Hospital programs are not at capacity and there is no issue of wait times that we've been able to identify. Based on the 50 patients per year currently going to Yale, local programs could assume these patients very easily.

We also agree that, while physician referral patterns are not fixed, telephone surveys and letters of intention to refer patients to program are speculative. We've learned that in our own programs. These do not estimate to true volume. Even with its inherent limitations the consistency between the various

utilization data that we have provided gave us no reason to think that volumes in these areas would grow.

Further, there's no reason that our two institutions cannot collaborate in achieving this, as we do in other areas. As a level two trauma center, Stamford has been a partner in the community in the care of most sick patients for years and in the past 21 months our trauma program has admitted over 270 patients from Greenwich. That said, Stamford Hospital maintains an open medical staff and we welcome any physician to admit and care for patients in any of our facilities. In fact, 30 percent of the cardiologists on staff at Stamford have privileges at Greenwich, 27 percent to be exact. In addition, there are other primary care providers, as well as other subspecialists.

The applicant also points out that 11 percent of their cardiologists have practices in Stamford. It's important to note that we are committed to serving the community for the long-term. This means delivering programs that the community needs. This is why we came before the agency in 2005 to address the need for elective PCI. Stamford is also preparing for the needs of the future, and as you know, we're building a new, state-of-the-art hospital for long-term benefit of

our community.

So I'll conclude with the basis of my position on this matter, which is that there is no need for this program. PCI volume is not growing. The proposed program does not improve access. There is no access issue. The proposed program is not cost-effective, in fact, there will more likely to be a potential for pressure for over utilization. It will not improve quality, is more likely to dilute the quality of the current programs that exist in the service area.

I'll leave the specifics of C-PORT-E to Dr. Gray. However, no one can argue that patients are better off without surgery on-site. The need for urgent surgery, when in fact it happens, is immediate, and cardiac surgery must be performed quickly such as in a perforated coronary artery. In no way do patients benefit from such a program without cardiac surgery as they would with one with cardiac surgery backup. And I know what I would prefer for my own family.

In conclusion, nothing has changed since 2009 when my colleagues presented their opposition to this expansion, it's really a discussion about a shift in volume and I don't believe there's any void to fill.

Thank you for this opportunity to present

this to the Agency. And now I'd like to introduce my colleague, Dr. Gray.

HEARING OFFICER YANDOW: And we'll give any opportunity for cross after they both provide their testimony and to make sure you have sufficient time to review what was filed this morning.

MS. GROVES: Um-hmm.

HEARING OFFICER YANDOW: Good morning Dr. Gray.

DR. WILLIAM GRAY: Good morning. How are you?

HEARING OFFICER YANDOW: Fine. Thank you.

WILLIAM GRAY

having been called as a witness, having been duly sworn, testified on his oath as follows:

HEARING OFFICER YANDOW: You have filed some prefiled testimony earlier in the hearing, a couple of days ago, and then also this morning. Do you adopt that testimony as your own?

DR. GRAY: I do, yes. I am William Gray, I'm associate professor of clinical medicine at New York Presbyterian Columbia University and I'm director of

vascular services there at that institution. Our institutions work closely with Stamford Hospital in the operation of both selective and open heart surgery programs. I'm here today in place of my colleague, Michael Collins, who wishes he could be here, but had a scheduling conflict. I wish he could be here --

(Laughter)

DR. GRAY: -- you wish he could be here because he's much taller and better looking. But nevertheless, I know he joins me in supporting Stamford Hospital's opposition to this CON application.

I guess my most important message in this testimony is that the science around this is still evolving and the safety and efficacy of providing PCI without surgery on-site. And this is reflected in the change in the guidelines statements, which were previously eluded to.

Prior guideline statements from 2005 demonstrated that PCI without surgery on-site, a class C recommendation, there's likely harm to doing so. That's been upgraded because of the C-PORT trial results. And as you've heard already, C-PORT trial was a randomized trial of about 18,000 patients and found there's no difference in mortality at six months and no overall

difference in efficacy at nine months, although there was a trend towards improved efficacy in sites that had surgery.

Incorporating that into the most recent guideline statement in 2011 the PCI without surgery on-site was raised from a level 3 to a level 2B, which means that there's potential benefit, that the risk doesn't outweigh the potential benefit, but there's substantial uncertainty and the level of evidence that supports that recommendation actually is still in conflict or supported by small or conflicting trials. So it's not -- it's not a level one indication as we might've hoped.

The guideline also states, and it's kind of epilogue that the PCI program without surgical on-site backup really should be intended to fill a clinical need in the community. That's well stated within the document. Competition within the same geographic area for PCI, especially with an established program without surgical backup, and I quote, "may not be in the best interest of the community." This appears to be a relevant consideration in this regard, in this case.

Based on the data discussed by Dr. Kiely it's clear that the proposed program does not fill a void in the current healthcare needs of lower Fairfield County

whose residents have ample access to PCI in the same service area as Stamford Hospital in White Plains. There's been an update released as of a month or two ago that PCI programs without surgery on-site should be established only when programs improve access to a higher level of cardiovascular care than otherwise would be available, which in this community would not be the case.

In addition to the flat or declining volume of the data from this area and from the state largely related to new therapy use Greenwich Hospital's proposed program would not likely exceed a couple of hundred cases per year and PCI volumes in Stamford and White Plains Hospital could fall below that number with the addition of Greenwich's program. I know there's an argument out there that says that there is difference in referral patterns, but in fact, you can't really fabricate procedures out of think block. These patients come from somewhere and they're fungible, and they transfer from one hospital to another. So it is a relevant consideration.

I recognize that it's been struck, but I will say that in New York State this would not be an issue by regulation. The New York State regulations would not allow a site without backup to do PCI if an

adjoining site was doing less than 300 a year.

In the end, at issue is not whether the applicant can provide excellent services, I'm sure that they can, in concert with Yale-New Haven, but whether results in the net health benefit to that community at large. I thank the Office of Health Care Access for the opportunity to speak on behalf of Stamford Hospital and I welcome any questions.

HEARING OFFICER YANDOW: Thank you. And are those your only two witnesses Attorney Cowherd?

MR. COWHERD: Those are the only two prefiled testimony and rebuttal witnesses depending on the scope of cross, there may be other witnesses, but --

HEARING OFFICER YANDOW: Okay. Well, we'll address that as it comes. Do you need time to review what's been filed?

MS. GROVES: I do. I mean, just as a wrap up matter I would like to just put an objection on the record to the reference to the (indiscernible, too far from mic.) regulations. They have been stricken in this matter. I didn't want to interrupt Dr. Gray while he was speaking. I had relatively few cross questions but I would like to have five minutes if I can to just confer with my clients. So can we take a short break? And like

I said, I don't think my cross will take long. If everyone is prepared with their questions would help us in getting Ms. Borgstrom's questions asked before 11:00 if that's possible?

HEARING OFFICER YANDOW: Okay. So will be back at 25 of.

(Off the record)

HEARING OFFICER YANDOW: Okay. We're going to do things a little out of order. OHCA does have some questions. We're going to ask some of those questions of the applicant's witnesses now, based on prefiled testimony and some of the testimony we've heard today. And then we will, you know, do cross after we finish with that. We'll sort of make a determination at that point when we're done with our questions regarding -- we're very sensitive to, you know, you need to leave. But let's get through our questions and see where we are, okay?

MS. GROVES: Okay. That's fine.

HEARING OFFICER YANDOW: All right. So we're going to go ahead with some of the OHCA questions.

MR. LAZARUS: Good morning again. This is Steven Lazarus, OHCA staff. I'll start off with a couple of questions for the intervenors first. And they're a

couple of general questions, so you can, you know, choose the best person to answer it. Okay. My first question is considering the fact that over the past three years there's only been a minimal number of transfers from Greenwich Hospital to Stamford Hospital. Can you provide a discussion as to why you feel there's a direct impact of the proposed PCI -- elective PCI program on your particular program?

HEARING OFFICER YANDOW: And if you could come up to the mic. whoever answers?

MR. LAZARUS: Yes. And please introduce yourself the first time?

DR. KIELY: I'm Dr. Sharon Kiely, Chief Medical Officer at Stamford. Could you repeat the question, please?

MR. LAZARUS: Sure. Considering the fact that over the past three years, there have been only a minimal number of transfers from Greenwich Hospital to Stamford Hospital, can you provide some discussion as to why you feel there is a direct impact of this proposed elective PCI program on your particular program?

DR. KIELY: I think on a couple of grounds. I think that first of all, we talked a little bit about the referral patterns within the community, and

how flexible those are. We've also pointed out that a third of the cardiologists on our staff have privileges at Greenwich. So I don't believe that the cases that went to Yale couldn't have been done at Stamford. I don't understand why that didn't happen, other than the referral patterns that were in place, and as I've pointed out, I think there's an opportunity for us to work locally with the patient's and the medical staffs collaboratively to think about ways to deliver care locally.

MR. LAZARUS: They mentioned that you have -- a third of the physicians have privileges at Greenwich Hospital?

DR. KIELY: Of our cardiologists.

MR. LAZARUS: Of your cardiologists?

DR. KIELY: Correct.

MR. LAZARUS: Why have they not been transferring their patients to Stamford, you know, for the past three years? What would change?

DR. KIELY: Yeah. Several of our cardiologists admit -- hospitalize patients to the hospitalist service. And I will point out in Dr. Howes' chart, where he pointed out that the top physicians who were pointing out this exact point, that the medical

staffs are distinct, 12 physicians on that list were hospitalists. Those are employees of Stamford Hospital that admit any patient, whether they are, you know, have a physician on staff at Stamford or Greenwich, or if they have no physician or are uninsured. So they take care of our clinic population, any patient that comes to the hospital. That's why they have such a large volume. And on that list 12 physicians were hospitalists.

MR. LAZARUS: And what about the cardiologists that you mentioned, do they refer to Stamford from Greenwich Hospital?

DR. KIELY: Did they refer to Stamford from Greenwich?

MR. LAZARUS: Like the patients that may have required certain services?

DR. KIELY: Yes. Certain of them do. Doctor Schuster (phonetic), a couple of others.

MR. LAZARUS: Okay. And that includes the volume that was transferred, say, the last three years?

DR. KIELY: I don't have those data, so I wouldn't be able to know who those 50 patients were that left. I would have to clarify that.

MR. LAZARUS: Okay. Following up on that question and your statement of being collaborative. The

applicants had brought up the matter having discussions with Stamford Hospital regarding a collaborative cardio program, almost like a regional approach. Can you, or somebody from Stamford Hospital, talk about -- give us details on that and talk about what happened?

DR. KIELY: Sure. I was not directly involved in these deliberations, so my colleague, David Smith, is here. David is referenced and he's here to speak about that. But I think essentially the discussions didn't go further. We have a partnership, as you know, with New York Presbyterian. New York Presbyterian knows about this. And we had asked to have some time to work with our current partner. We felt -- we had worked with them over all the years. It wasn't really something that we were going to, you know, turn our back on without exploring further, and those negotiations have not taken place, those discussions haven't taken place. But if you'd like, David certainly can answer more about that.

MR. LAZARUS: Sure, that would be great.

HEARING OFFICER YANDOW: OHCA calls Dr. David Smith to the stand.

MR. COWHERD: Just a correction for the record. Mr. Smith is not a doctor.

HEARING OFFICER YANDOW: Oh, I'm sorry, David Smith to the stand. Can we swear the witness and please?

(Witness sworn)

COURT REPORTER: Please state your name for the record.

MR. DAVID SMITH: David Smith.

COURT REPORTER: Thank you.

DAVID SMITH

having been called as a witness, having been duly sworn, testified on his oath as follows:

MR. SMITH: So, in answer to your question, we have been approached by Greenwich Hospital to support their application for a freestanding elective angioplasty program and on further reflection, we got back to them and said that we would consider supporting only within the context of a regional program, a regional collaboration, that benefited both the community at large and also help support our full-service programs, specifically our open-heart surgery program. And so we began a process of discussing how that collaboration might work.

At the same time, we had expressed some concern with our existing partner, New York Presbyterian, and began to develop a process for vetting out what those concerns were and seeing if there was an opportunity to enhance that relationship. So parallel tracks. And the relationship, the discussions with Yale, then proceeded to the development of a set of principles and a draft term sheet, which I had indicated Yale did a good job of actually addressing our concerns, however, I did then also indicate that we needed to continue to vet that set of terms and talk about internally how this program could be enhanced further to support the open-heart program. And that we don't exit existing partnerships lightly, that we had an ethical responsibility to continue to discuss with New York Presbyterian and Columbia, how they could further support our program.

And that in any case, for us to continue discussing the application would need to be withdrawn because there would be a new application where we are part of it. So, when the hearing was scheduled, we received an updated set of terms. I indicated that our CEO was on vacation, couldn't you know, really reflect on those terms, and that we needed to proceed with both these discussions to get to a point where this

collaboration could be really conceptualized and quantified. And that would be beyond any time that the hearing called for.

And that we needed to continue these discussions with New York Presbyterian and had a number of meetings scheduled. We needed to play out the process to really decide for us and for the community what was the best option for the hospital.

HEARING OFFICER YANDOW: Mr. Smith, could you just give us what your title is now? A little bit of your background and how -- what your experience is that you've based your opinion on and your role with Stamford for the intervenor?

MR. SMITH: Again, my name is David Smith, I'm a Senior Vice President for Strategy and the Chief Strategy and Network Development Officer. I've been with Stamford Hospital for 10 years. I've been a Senior V.P. for Strategy for the last 25 years in three different organizations and have worked with a number of hospitals and organizations to develop joint ventures and collaborations, both here and in Maryland.

MS. KIMBERLY MARTONE: So Mr. Smith, in your opinion, with or without the proposed program, these collaborations could continue and with the open medical

staff with transferring of patients, so there should be no reason why there wouldn't be a collaboration between the two hospitals? Or the hospital and the medical staff?

MR. SMITH: Well, there could be, although we would have to take a step backward there because given -- in light of the fact that these negotiations were to be confidential and not disclosed without mutual consent, I think we would have some concerns moving forward.

MR. LAZARUS: That's all of the questions I had for the intervenor.

HEARING OFFICER YANDOW: And, Mr. Smith, if you would please just -- you don't have to stay at the witness stand, but please stay at the hearing. There may be cross-examination later, but applicants' counsel.

MR. LAZARUS: I have a few questions and I'll start with Ms. Borgstrom. I don't know if you have your prefiled testimony in front of you? I'll try to cite the pages.

MS. BORGSTROM: Okay.

MR. LAZARUS: Starting at page 632, the first question involves a clarification. I know several times in your prefile, and this happened to be one of the times that other prefilers as well and witnesses, and a

couple of times when we see an application, it's referred to this particular CON as a satellite program of Yale-New Haven Heart and Vascular Center. And I understand that's probably some form of an internal thing, but this particular CON is not actually a CON for Yale-New Haven Hospital and Greenwich Hospital, it's not going to be on Yale-New Haven's license as a satellite location, it's going to be under Greenwich Hospital's license for service if approved?

MS. BORGSTROM: The provider number is Greenwich Hospital's provider number. If that's what you're asking?

MR. LAZARUS: Yes. Okay. I just wanted that clarification. Thank you. Also, on your testimony you state that -- I'm saying on page 632 that our vision for Yale-New Haven Heart and Vascular Center is to develop cost effective services in certain geographic locations, which will ensure delivery of high quality of patient care. Can you please explain what you meant by certain geographic locations, and if you could provide some sort of example for that?

MS. BORGSTROM: Well, our aspiration for certain of our service lines is to have a broad geographic service area. In some cases it's throughout

the state of Connecticut and in other cases we're looking at other collaborations, so it is not specifically defined. You know, I think it was to avoid being audacious and, you know, having a vision that went beyond what we could comfortably do. But, you know, it is with the belief that taking variation out of care consistency by having some of the key providers be the same in both providing oversight and providing the actual service can enhance care.

MR. LAZARUS: And so certain geographic regions, they would depend on type of service?

MS. BORGSTROM: It would depend the type of service and it would also depend on the opportunities for collaboration.

MR. LAZARUS: From page 632 and onto page 633, you say the proposed Greenwich Hospital meets -- the proposed program at Greenwich Hospital will meet or exceed all the programs, you know, requirements identified by professional organizations. When you state, meet or exceed the program requirements, and when you elude to say, and this duplicates EHE (phonetic) and ACC, do you -- is the goal to let the minimum proposed guidelines, or is this more towards the ideal as when you're talking about quality, in this particular

statement?

MS. BORGSTROM: I would defer that to Doctors Cabin and Howes to be that precise about your question, if that's all right?

MR. LAZARUS: That would be fine. But I just want to know, when you were doing your prefiled testimony what is it that you meant in that?

MS. BORGSTROM: What I meant was that we would meet or exceed the minimum guidelines for these organizations.

MR. LAZARUS: Thank you. And I will follow-up with that with Dr. Howes.

MS. BORGSTROM: Thank you.

MR. LAZARUS: Why don't we just switch over to Dr. Cabin at this point?

MS. MARTONE: One moment Ms. Borgstrom, I just have one question.

MS. BORGSTROM: Oh, yes.

MS. MARTONE: I'm sorry. He's moving very quickly. In terms of you had made a statement when you were testifying in terms of collaborating in good faith with Stamford Hospital. Did those discussions and collaborations also mean you worked in good faith with New York Presbyterian? Were they involved in the

conversations? Was there any discussion at all held? Or was it just between -- maybe, who were the entities at the table? Maybe I want to say it that way.

MS. BORGSTROM: You know, and I was not personally at these, but the discussions were among Greenwich Hospital, Stamford Hospital and Yale-New Haven.

MS. MARTONE: Okay. And that's physicians, management, all-inclusive, I'm assuming? Cardiologists and so forth? Or is it just --

MS. BORGSTROM: Yes, I believe that's correct.

MS. MARTONE: -- okay. All right. Thank you.

MR. LAZARUS: Dr. Cabin, good morning.

DR. CABIN: Good morning.

MR. LAZARUS: Can I direct you to your prefiled testimony, page 636? First of all, let me just back up a little bit. Ms. Borgstrom had responded to a question talking about what the goal would be as far as looking at national organizations and looking towards minimum guidelines, exceeding minimum guidelines. Are you of the same thought?

DR. CABIN: So, I think the minimum guidelines basically are defined by the threshold at

which outcomes are similar regardless of volume. So I think that the two issues are really the same issue. The societies say that if you achieve this minimum level then your quality, based upon studies that compare numbers of cases done at different hospitals, are comparable. If you're below that minimum, then there are issues that are raised as to whether or not your outcomes would be comparable based upon, you know, looking at large studies.

So, in my mind, what minimum means is that if you achieve that number, then you are ideal. Your outcomes are comparable to a program that did five times as many.

MR. LAZARUS: And is that -- I mean, I understand that. Is that also the goal of WNNHB? Is that like the goal, you know, for quality, you know, that was one of the statements in there I've heard, you know, that -- is that to ensure the proposed program is to exceed -- is that the quality of that aspect or is it just meeting the minimum is the goal at this point?

DR. CABIN: I'm not sure I understand the question.

MS. MARTONE: Well, what we're trying to get at Dr. Cabin is the fact that the guidelines, you

know, specifically say that institutions with a volume of fewer than 200 procedures per year, and we're actually looking at 50 actual transfers, unless in a region that is under served because of geography should carefully consider whether it should continue to offer this service. So that's kind of what we're looking at. That's a minimum standard. In looking at what the proposed program we're not really getting to even the minimum. So if you could address that concern?

DR. SMITH: So, I think the proposal is based upon an expectation that we will exceed that minimum number. And that's documented in a variety of prefiled testimonies that have been submitted. I don't think -- I know we wouldn't be going forward with this if our expectation was that we wouldn't do that number of cases. Based upon the transfers, you're absolutely right, and that's not what we based our projections upon. That's part of the projection, the other parts of the projection are based upon the fact that many patients are sent for cardiac catheterization's elsewhere because the physicians who refer those patients want to have everything done at one sitting. And I know that to be the case because they told me that, they'll send them to me at Yale. That doesn't show up. A patient who is seen

in a doctor's office in the Greenwich service area and calls me when I'm at Yale and not a Greenwich and says, this patient wants the procedure done at Yale, that wouldn't be considered in that 53 cases.

MS. GROVES: Just for clarification, she said to meet the 200 we only have 50, the existing primary cares are included in that 200 as well.

MS. MARTONE: Yes, the 30 currently being done?

MS. GROVES: Yes.

MS. MARTONE: The primary --

DR. CABIN: So, it's based upon what we're referring out, what the PAMI's are, and what our expectation is of patients who are cared for by Greenwich referring physicians who send them elsewhere, either to New York or to Yale, and also new docs, and that's been documented by the supporting letters that have been submitted.

MS. MARTONE: -- right. So then in essence, we're shifting volume from existing providers to a new program to be offered in the state?

DR. CABIN: Yeah. My sense is probably they would be shifted from high-volume programs in New York and from Yale. That's my best judgment having

worked for years in that Greenwich area, as well as working at Yale. That Yale will lose some cases, Columbia will lose some cases, New York Hospital will lose some cases. I don't anticipate any of the adjacent programs, certainly not Stamford, as you've pointed out in your questions, there are no referrals essentially, from Greenwich Hospital to Stamford Hospital. And so would we take something out of White Plains? Possibly. But I think that most of the patients would be coming out of the high-volume programs that I mentioned.

HEARING OFFICER YANDOW: Just a question. You made reference to other prefiled testimony and letters of support. Is there anything else that's been filed that you're aware of that would support your testimony?

MS. GROVES: I think the prefiles --

HEARING OFFICER YANDOW: Of the testimony.

MS. GROVES: -- the testimony and the exhibits including the letters?

HEARING OFFICER YANDOW: The letters. Is that yes, made up of the letters and testimony and stuff? I just didn't know if there were other attachments that specifically supported what your testimony is on that question?

DR. CABIN: I would include the entire scope of what we're looking at.

HEARING OFFICER YANDOW: Yeah. We'll look at the whole -- right, but I was just looking for a little -- if you had any direction, we look at everything and give it careful consideration.

MS. MARTONE: So, Dr. Cabin, just to confirm in your clinical opinion, so the clinical need for this proposed program is basically based on the fact that you know, or you've spoken to your own patients, and other physicians' patients, that would prefer to have all of their cardiac services done in one place, is that my understanding?

DR. CABIN: Yes. Yes. That's essentially what I'm saying. And the fact that I and Chris and others in our group, are in Greenwich Hospital on any given day, the Yale full-time intervention cardiologists are there because of the acute M.I. need, and we do a cath. and we can't do the elective angioplasty and now we have the backing of the national organization saying that it is okay, to me it makes no sense that we can take care of the sickest, but we can't take care of the elective patients, particularly since that's now sanctioned and exists in most other states in the United States.

MS. MARTONE: Okay. One more question, Doctor. Now in terms of access being limited, which there's been a lot of testimony about, this is an elective procedure where you have 72 hours, and correct me if I'm wrong, in your clinical expertise that patients have 72 hours to get to another program, which obviously I'm assuming is not a problem in getting to Yale from Greenwich in 72 hours. Could you address that, being an access issue?

DR. CABIN: So, you know, I think it's, you know, if you can do it at Greenwich with the exact same docs and the same safety that they would have at a place that's 30, 40 miles away, then to me it makes no sense to do that transfer. You could, you know, I've seen you at many, many hearings, for many, many years, and, you know, we used to have a limited number of programs and Yale would sit here and say, why do we need these other programs because people can drive -- and the Commission has consistently said that having local access is important. That was what was said at the Stamford hearing Danbury, Waterbury, all of those hearings that I was part of and you were part of, and the Commission has consistently said sure, you could drive from Waterbury to Yale or Danbury to Yale or Stamford to Bridgeport, you

know, and yet local access has been something that the Commission has valued. And we are now coming and saying that Greenwich also deserves that opportunity.

MS. MARTONE: And local access isn't there even with the provider six miles away and another one 11 miles away?

DR. CABIN: Right. There are a variety of reasons why patients are transferred to the hospitals that they are transferred to. It can be patient preference, physician preference and for whatever the reasons are -- we could get into that if you want, the patients are not transferred from Greenwich to Stamford.

MS. MARTONE: Okay.

MR. LAZARUS: Now, back on page 636, the second paragraph, first line. You say, not all hospitals are equipped to offer safe, high-quality, elective angioplasty services. Can you please explain what you meant by that statement?

DR. CABIN: I think that we truly value the uniqueness of what we've done at Greenwich Hospital, what Yale-New Haven Hospital and Greenwich Hospital have done in providing the exact same physicians for doing the cases at Yale doing them at Greenwich. So not only will

the Yale physicians be providing oversight by being directly there and not at a distance like some other tertiary center supervised programs, but we actually are embedded in the hospital in which we are talking about. And to me, that generates a level of quality that is unique.

MR. LAZARUS: Can you provide open samples of hospitals in Connecticut that would not fit that statement?

DR. CABIN: Yes, I could, but I won't.

(Laughter)

MR. LAZARUS: Thank you.

HEARING OFFICER YANDOW: Is that -- I mean, do you -- he's choosing not to answer. Is that --

MS. GROVES: Is that information that -- if that's information that's relevant we'll absolutely --

MR. LAZARUS: No.

DR. CABIN: You had a smile on your face, so I figured you didn't really want me --

MR. LAZARUS: No. It is a question, but if you -- feel free to answer if you wanted to, but, you know, you don't have to.

MS. GROVES: (Indiscernible, talking over each other) the types of hospitals that might not be --

DR. CABIN: -- I think there are different levels of oversight that, you know, each of these programs that have come to you have said they are sponsored, or supported, or mentored, or supervised by a tertiary center. And I think that what Yale-New Haven has done is unique. I don't think there's any other center, maybe there's one, but where the actual doctors themselves are embedded in the practice at that hospital from the mentoring, the supervising, or whatever you want to label that hospital, each one of those programs I'm hearing that doctors from tertiary centers who never set foot in the hospital testifying as to the level of quality that would be existing at that hospital. I don't know that any other program has come before you where somebody like myself, who is a professor at Yale, and runs the program at Yale, actually sleeps overnight at Greenwich Hospital on a regular basis, or Chris Howes, who comes up 40 percent of his time at Yale.

MS. MARTONE: And that's how you operate all of the satellite programs?

DR. CABIN: Yes. In the heart and vascular. I can't speak to --

MS. MARTONE: Right. Yes, I know, heart and vascular. Thank you.

DR. CABIN: -- there may be others, but that's the one I'm in.

MR. LAZARUS: I'm all set. Thank you. If I can have -- I have a couple of questions for Dr. Howes. Good morning Dr. Howes.

DR. HOWES: Good morning.

MR. LAZARUS: If I could point you to your prefiled testimony, page 671? You state on page 671 that these physicians have committed to bringing 80 to 105 angioplasty cases per year. Can you please tell us where these 80 to 105 cases currently are being serviced?

DR. HOWES: I can't say with specifics, but I can probably surmise, and you know, I think I have a pretty good sense of the, you know, local environment. Two specific physicians that have written these letters. One of the physicians currently does all of his procedures at New York Presbyterian, that was the smaller number. The other physician is an interventional cardiologist for a, you know, very large, multi-center, multi-specialty group in the Westchester area and he does cases at White Plains and at New York Presbyterian and I would be misleading if I could really tell you what the breakdown of that was, but my personal instincts is the majority of those cases are being done at New York

Presbyterian at this point. But I don't have any definitive data. Can I ask someone who has had some other discussions?

HEARING OFFICER YANDOW: Well, why don't you just tell us who, and then if we want to call that person, but you --

DR. HOWES: Okay. Some of our administrators, Marc Kosak and Brian Doran, had more specific conversations with those physicians. They might be able to say more about that.

HEARING OFFICER YANDOW: -- okay. And if we need to call them we will.

MR. LAZARUS: We'd be happy to. okay. All right. Thank you for now. And on page 671 you state that this will reduce costs of angioplasty care. Can you please elaborate a little bit on that and provide a better understanding to us of how this will reduce cost?

DR. HOWES: Right. It kind of echoes what Dr. Cabin was saying. All of us, we really want to do the best by patients and I think although there's kind of a political feel to this at the end of the day, we really are interested in patient care. And I don't think anyone in this room would compromise the patient's well-being for any of this, for volume or any of that. But that

said, we have patients that we call elective angioplasty. And sometimes those patients coming to the emergency room with stuttering chest pain and EKG changes and positive troponin, they're having a heart attack. And Ms. Martone, you're right, but technically by some criteria you can say that this could wait for 24 or 48 hours. But no interventional cardiologist in North America would wait 48 hours. We'd do an angiogram, we'd get to the bottom of it, we'd find out whether they have medical disease, cardiac surgical disease, or interventional disease.

Currently at Greenwich if that patient has ST elevation we can do an angioplasty, 20, 30 minutes later they're in the ICU, their family is there and we tell them, we aborted the heart attack. The same patient, but it's a circumflex artery and they have ST segment depression, we have to stop, we have to say, listen, we don't -- we have the capability, but we can't do it in the setting. We have to arrange transfer through an ambulance or a helicopter. We have to, you know, so there's obvious costs right there. And then there's the redundancy of care. They're going to a new hospital, they get admitted by a new nursing staff, a new medical staff, and even though we're the same group of

physicians it's reinventing the wheel for that patient and then the trauma for the family that has to, you know, travel.

And whether they have to travel five miles or 50 miles, it's a trauma. They have to kind of leave that hospital and go to the next hospital. So there's psychological costs on family, but I think you can see some of the medical costs there of the transportation costs, and the re-admitting the patient, and then they're going to go to another care plan. You have to open up another packet, it's another procedure, and you know, we have left the sheath in the artery most of the time so they can just pick up where we left off, but they're restarting the procedure. It's an inefficient redundancy.

MS. MARTONE: Now, is that because of the STEMI criteria that are established or your own protocols at Greenwich on angioplasty or both?

DR. HOWES: No. The private protocol, you know, what we were approved by this Board, you know, whenever that was, eight years ago, we have privilege to do primary angioplasty. And it's very strict criteria and as you know, we've had these discussions ourselves. We stick by those criteria, we respect the requirements,

and often the majority of patients who have a heart attack don't have a STEMI, they have a non-STEMI.

MS. MARTONE: And could you offer some expertise in terms of the new hybrid OR's that we're hearing about?

MS. GROVES: I'm sorry, before you answer the question --

MS. MARTONE: Yes?

MS. GROVES: -- is it okay if Ms. Borgstrom leaves? Do you guys have more questions of her, or should we have her stay?

MR. LAZARUS: We do have some questions that are of a general nature, but they go to the overall need of the application. So as long as, I mean, we feel that she may be the best person, but --

HEARING OFFICER YANDOW: I think right now we're going to wait until we finish with that question --

MS. GROVES: Okay.

HEARING OFFICER YANDOW: -- and then we will -- I mean, we'll leave some questions for the end of the hearing and then I will leave it up to you whether you want to, you know, that's a decision you want to make. But I think we may need her available for the questions that are coming and we are trying to -- we are

aware --

MS. GROVES: I understand. I'm sorry for interrupting. I just noticed the time. I'm sorry.

MS. MARTONE: Because the hybrid OR's appear to be a new advancement in technology, I don't know if that -- if that advancement would alleviate somewhat of this issue? So I just wanted your expertise on that.

DR. HOWES: I don't think it would have any impact on Greenwich Hospital, because, you know, if you're talking a hybrid OR then you're talking, you know, full-service program with open heart surgery capabilities. And I know Dr. Gray mentions it in his testimony, and I agree, there are cases where a hybrid case has advantage to one or the other. I think those cases that are going to have complex multi-vessel coronary disease, those are patients that we did not include in counting our numbers, those are patients that would still transfer. Those are patients that are reported in the C-PORT Study represent about 12 percent of the total population of PCI patients. There will still be some patients that are either too complex, too high-risk, or need something else that wouldn't be done at an elective center and I don't know, maybe not even

done at Stamford Hospital. Those patients might be going to New York Presbyterian right now.

So there's a role for it, it's an evolving role. You have to always sort through whether it's marketing versus a real need, but there certainly is some role for it.

MS. MARTONE: Thank you.

MR. LAZARUS: On page 672, you say, increased utilization of existing cardiac catheterization and angioplasty infrastructure is completely consistent with health reform and efforts of OHCA to improve assets and financial feasibility. Please provide a little discussion on that as far as what you base that on?

DR. HOWES: We have a full-service cath. lab that's very up-to-date. It's all -- not all, most every technology that's needed during acute intervention, because we do primary angioplasty, these are very sick patients, we've got to be able to take care of them. But the rest of the day that lab is sitting there and as Dr. Cabin said, we're full-time interventional academic cardiologists, but we're not doing elective angioplasties. The cath. lab team and the cath. lab equipment is not being fully utilized.

As this application clearly states,

there's really no incremental capital costs to moving forward with this project. All of the resources are there, so that seems like a better utilization if we can do more procedures. And from a very personal perspective I think we do a very good job. I take pride in my work, but we are limited by the fact that we do between 38 and 40 cases every year. And I really think our staff would be better if we could do elective cases as well.

As it is, again, as Dr. Cabin has said, in a very unique way our entire staff, not just our physicians, but our nurses, our x-ray techs, our scrub techs, they all go to Yale on a routine basis, because we feel we need to do that to maintain their criteria.

If you look at the ACCNCDR documents only 18 percent of all electric hospital, all elective programs, farm out their staff to keep them up to skills. This is a very unique relationship that we take seriously. And I think doing more volume and more cases will make us better.

MR. LAZARUS: Just a quick clarification. The two letters that you submitted in the part of your exhibit as part of your testimony, those physicians are not here today, right?

DR. HOWES: That's correct.

MR. LAZARUS: All right. Thank you.

DR. HOWES: I think we had relatively short notice. And they are fully clinical physicians. I think they had patient, you know, requirements.

MR. LAZARUS: Thank you.

HEARING OFFICER YANDOW: I have a couple questions. What's the plan if you need backup?

DR. HOWES: We already have backup. You know, again, we're a hospital, we have an emergency room, we have patients who have aortic dissection. It has nothing to do with angioplasty, but they need to get to the OR as quickly as possible. We have long-standing relationships where we have had to transfer patients during an acute MI. It turns out they have left main disease. So it already is in existence, and we have transfer arrangements with Westchester Medical Center, one of the forgotten entities in this whole discussion, they are in the neighborhood. We have some relationships with Greenwich, and I think there was to pursue that further and that might be --

A MALE VOICE: I think you might mean Stamford.

DR. HOWES: -- Stamford, and then obviously we have very strong transfer relationships

actually to New York Presbyterian and to Yale-New Haven Hospital. So we have arrangements to transfer patients to lots of centers. And we do it, it happens not infrequently already, not because of a complication in the care plan, but because of the clinical necessity of medical patients and we're actually fairly facile at transferring these patients out.

HEARING OFFICER YANDOW: Regarding the EMS, do you know who your primary service area responder is?

DR. HOWES: EMS?

HEARING OFFICER YANDOW: Yes. To deliver by ambulance transport?

DR. HOWES: Gems is the primary one for Greenwich and then the Westchester communities have similar --

MS. GROVES: I don't think she means to get to the hospital, who transports and things like that.

DR. HOWES: -- oh, Access Care and -- they're one transfer, and we have very strong relationship with it. They actually have an on-site presence at our hospital. And then Life Star is another entity that, you know, the air support.

HEARING OFFICER YANDOW: So you would work

with the EMS coordinator at Yale on the transport?

DR. HOWES: We do that because Yale has to know about the transfer, but we actually at the same time are taking on the transfer part from our end already. And, you know, like I said, we have very direct relationships with Access, the ambulance company that transports these patients already. And similarly, in less frequent occurrences with Life Star, which provides helicopter transport.

HEARING OFFICER YANDOW: Okay.

DR. HOWES: And, you know, we initiate those transfers at the same time that we're communicating to the referring hospital. And again, it could be -- not referring, the receiving hospital, and again, it could be Westchester Medical Center, it could be Columbia, it could be Yale.

HEARING OFFICER YANDOW: Okay. And perhaps you're not the one to answer this, but as far as on an emergency transfer and who's called regarding the statutes and regulations on transport, has any of that and consider?

MS. GROVES: I'm sorry. (Indiscernible, talking over each other).

HEARING OFFICER YANDOW: My question is

just, I mean, I know there's a letter and I believe it's attached to Dr. Howes' testimony from maybe Access --

DR. HOWES: It's Access, yes.

HEARING OFFICER YANDOW: -- and I just -- and Access -- it starts with the PSA responder and who should be called in an emergency. I'm just wondering, has that been discussed and considered?

MS. GROVES: (Indiscernible, too far from mic.).

DR. HOWES: No, no, no.

MS. GROVES: The PSA responder would be if you had to call through 911, but this is for transfers. These are arranged?

DR. HOWES: Yeah. This is what these companies provide as a service. They provide inter-hospital transfer and that's going on on a regular basis already. And we have these established relationships and, you know, not infrequently we transfer patients urgently and emergently already.

MS. GROVES: It's arranged transfer, different than if you were to pick up the phone and call 911, you're getting the primary service area responder, which would be Gems or Sims (phonetic) versus an arranged transfer and short of an emergent situation that occurs

during medical care, correct?

DR. HOWES: Yes.

HEARING OFFICER YANDOW: Any other questions of Dr. Howes?

MS. MARTONE: No.

MR. LAZARUS: Thank you. I have a couple questions of Mr. Corvino. Good morning Mr. Corvino.

MR. CORVINO: Good morning.

MR. LAZARUS: On page 681 of the prefile, you state, that this program will reduce overall costs of angioplasty care in the Connecticut health system. What did you mean by that when you state that?

MR. CORVINO: In addition to what Dr. Howes has already said, you know, when we talk about transferring patients out there is a cost to that. And I think he articulated very well in that we've got to redo another admission and there's an ambulance charge to transfer the patient. So we calculate the value of that to be somewhere around $8,000. And if you multiply that by the number of cases we transfer out it's close to half a million dollars that could be saved. Without counting all of the subjective savings that would go into the patient's psyche for not having to be transferred.

MR. LAZARUS: What's the percentage of

patients that come in for cath. or some sort of a need, an elective that's considered to be emergency transport?

MR. CORVINO: I don't have that number. Does somebody else have a number?

MR. LAZARUS: I know you mentioned -- for example, in 53 cases, for example, you have based your testimony on, those 53 cases, what's the total number of cases that you put those 53 cases on?

MS. GROVES: Are you talking about the number that still need to be transferred anyway and wouldn't be able to stay?

MR. LAZARUS: Well, is that what you're referring to in your testimony, when you say emergency transport?

MR. CORVINO: Procedures that could not be done at Greenwich under the current regulations.

MS. GROVES: Under the current protocols.

MR. LAZARUS: Okay. Under the current protocols. But I'm saying, considering that this is an elective procedure, not every -- not every procedure that can be done at the hospital is considered an emergency transport, am I correct on that?

MR. CORVINO: Can Chris answer that? He's got more expertise.

MR. LAZARUS: Sure.

DR. HOWES: Again, when we use the term elective, it is a misnomer, I mean, no one elects to have a heart procedure, you know, this is serious stuff. And there are different things. Patients who come in with an acute coronary state syndrome and are sick, and you know, may end up hypotensive with a balloon pump, they're still being called elective angioplasties in this realm, in this discussion. So they're not all elective. Now, that said, some of them are much more stable and in fact are outpatients. I would say about half of the outpatients that we do a diagnostic cath. on in Greenwich, we end up transferring because we've already put, you know, entered arterial access, we have access to the arterial system, we transfer them and they'll end up getting the angioplasty the same day. The other half, we stopped, we regroup, and they go back up to New Haven or to New York Presbyterian some other day. So that's of the outpatient elective angioplasties, about half of them.

And then about half of those patients are actually inpatient, you know, not stable patients. So I'm making these numbers up, I don't have them off the top of my head, but my sense is of those, 53 number that's being reported, I would say about three quarters

of those patients go by ambulance or helicopter or something like that. Does that answer, what your asking?

MR. LAZARUS: That helps, yes. That gets it. Thank you. Mr. Corvino, are you -- let's just say those 53 cases you mentioned, you said there is about an $8,000 cost. $1,000 for the transport and about 7,000 for the admission and angioplasty. What's made up of the $7,000 cost that you're talking about?

MR. CORVINO: You know, that's the -- that's the charge, the average charge that goes along with that procedure.

MR. LAZARUS: Would that charge --

MR. CORVINO: And, you know, it may not be one-to-one with costs at the second facility we're talking about.

MR. LAZARUS: -- would there not be a charge at your facility if the service was here?

MR. CORVINO: But it would be much less because of the lack of transportation cost.

MR. LAZARUS: So it would be a savings of $1,000, not 8,000?

MR. CORVINO: Yeah, but you're also duplicating services at the other place.

MR. LAZARUS: Okay. So you're duplicating

services, I understand --

MR. CORVINO: Plus transportation.

MR. LAZARUS: -- but only the charge for the angioplasty, if it was approved, an elective angioplasty at Greenwich Hospital would be less than 7,000?

MR. CORVINO: I don't know that we have a charge code for that yet.

MR. LAZARUS: You also made a statement on the same page that, you know, we're committed to provide services that our community have come to rely on us and will need in the future. Was there a community needs assessment done for you to figure out what the community needs? Was there a study that the hospital had performed?

MR. CORVINO: Well, yes. I mean, we've done many community needs assessments throughout the years. Clearly, cardiology is a very important part of any institution's make up. And with the growing population and the incidence of heart attack in the U.S., you know, it's clear to us that we, you know, we have to improve and make sure that we've got all of the services that our community relies on on a regular basis. And we have saved many lives through the primary angioplasty

program from the communities we serve. And clearly, as Dr. Howes mentioned earlier, if we are able to do elective it'll make us better.

If you go back to when United Hospital closed in New York, about seven or eight years ago, we saw a huge increase in usage of our emergency room to the point where we went from 15 percent of our patients coming from Westchester to now 43 percent of our patients coming from Westchester County in New York, that made us a better institution. It made our emergency room better. It made our clinicians better. And we anticipate the same thing will happen here.

MS. MARTONE: Now, Mr. Corvino, to your knowledge the incidents of heart disease you just mentioned, is it higher in the Greenwich -- the Greenwich service area compared to other areas of the state?

MR. CORVINO: You know, I don't know the answer to that question. But what I can tell you is that when you look at heart disease and the potential for heart attack that's probably, number one, what frightens patients the most. And we've, you know, we've noticed that even through some of our fundraising efforts, even if people are affiliated with a New York hospital and they live in a local community they're are going to rely

on that local community to deal with their heart attack, if you will, in the middle of the night. They're not going to be traveling to another place. So having a strong heart program really bolsters your position in the community's eyes as a really good institution.

So regardless of whether the incidents is higher or lower, if you've got the illness you want to know that the very best is available in your community.

MR. LAZARUS: When was the last time, Mr. Corvino, a community needs assessment was done? Because you mentioned there were several done.

MR. CORVINO: I would say in the last three or four years.

MR. LAZARUS: And does it specifically discuss cardiac services?

MR. CORVINO: Yes.

MR. LAZARUS: Would you be able to provide OHCA a copy of that?

MR. CORVINO: Sure.

MR. LAZARUS: OCHA would like to accept that as --

HEARING OFFICER YANDOW: Okay. I'd like to order that to be produced. How much time do you need to produce that?

MR. CORVINO: A couple of weeks?

HEARING OFFICER YANDOW: Okay. Two weeks from today then?

MR. LAZARUS: Two weeks from today? Okay. And we'll call that Applicant Late File 1.

Again, you state in your prefiled testimony that, you know, we need to ensure providing care in a cost-effective and efficient manner. In relation to that, could you please state to whether you think a service that may be an additional program, for example, elective PCI in the region, would that be considered cost-effective, and/or how would you consider that to be efficient?

MR. CORVINO: Well, I think that having patients be treated in their community where they go for services and not having to leave the community and have a lot of duplication is very, very important. And there is a significant amount of cost savings when patients don't have to be transferred.

You know, I -- you know, I come to you today as the CEO of Greenwich Hospital, but I also come to you as a patient and I just want to relate a story, which I related the last time we were here. In 2005 I was one of those people who had chest pain, who went to

Greenwich Hospital, who was catheterized by Dr. Howes, who was asked if I had chest pain at that moment and I gave the correct answer and said no and was shipped to Yale-New Haven in an ambulance. I can't tell you what that experience is like unless you've experienced it yourself. You've got a catheter through your groin into your heart, your being moved in an ambulance 45 miles, you don't know what the outcome is going to be, your family is worried, they're following you -- they're trying to follow the ambulance, you get to a new place, okay? And Dr. Cabin is there to do the procedure. It just makes no sense in terms of efficiency, in terms of the burden we put on patient's. If we were not doing the difficult primary angioplasty cases you could make an argument that we're not, you know, potentially we're not equipped to do this. But how can we prevent us from doing the easier cases if we're doing the elective cases -- if we're doing the more difficult cases? It just makes no sense for patient care.

And until you've been in that position it's really hard to understand that we're not just talking about numbers here, we're talking about patients and families' experience and that is very, very important. If you can have that procedure done by the

same clinicians the first place you go without two or three hours of delay, and then repeating the whole process, that is the right thing to do for people. And in my mind, that's what it comes down to.

MR. LAZARUS: Thank you.

MS. MARTONE: Now Mr. Corvino, if your cardiologist had privileges at Stamford would you have chose to go there as opposed down to Yale?

MR. CORVINO: You know, I'm not sure it's an issue of my choice. I think that in my position, I'm going to go to Greenwich, no matter what, you know?

MS. MARTONE: Yes, yes.

MR. CORVINO: And if that doesn't work, I'm going to New Haven, which is exactly what happened.

MR. LAZARUS: All right. Thank you Mr. Corvino. Now I have a couple of questions and they're general need in nature. It's up to you who you want to address.

MS. GROVES: Frank.

MR. LAZARUS: Okay. The first question would be, why does Greenwich Hospital need to provide an elective PCI service considering that its patients have access in the region to the proposed services at Yale, Stamford, and nearby New York hospitals?

MR. CORVINO: You know, let me just -- Frank Corvino, let me just try on an answer. I guess you could ask the same question of why should we do brain surgery? Why should we do spine surgery? The issue is, this is a procedure that the community needs and wants on a regular basis. I think the numbers prove it out. And for somebody to not be able to go to their local hospital and get this service in today's environment, where it's pretty common now across the country, in our minds it's just not appropriate. If there are one or two patients a year, sure, they could get access everywhere else. But, you know, this is a significant life-threatening disease that I think we should be able to provide as a community regional institution who serve so many patients every year.

MR. LAZARUS: Well, considering the percentage of Greenwich Hospital patient volumes as received from New York, being Boulder (phonetic) Hospital, why does a new provider nearby in New York, about 11 miles away, that recently started providing elective PCI here does not effect Greenwich Hospital's projected volumes for the proposed program?

MR. CORVINO: Because we just looked at the patients that got transferred -- that we transferred

out, you know, we did not look at drawing from any other community.

DR. HOWES: And again, you know, service area is a geographic map and where the patients and the physicians go are completely different. I've been at Greenwich Hospital for eight years, and I'm actually the Chief of Cardiology at Greenwich Hospital, so I have a pretty good sense of who the docs and who the patients are coming from. Although 30 percent of the Stamford cardiologist may have privileges, to my mind there's only one Stamford cardiologist who ever comes to the hospital. I know him personally, I'm friendly with him. There is an open policy, but they're just -- they're two separate worlds. And White Plains Hospital, that's a third separate world. There has been no impact on any of the hospital's behavior, patient population with that White Plains, elective angioplasty program. It's a different environment. And I agree, in Nebraska hospitals are 300 miles apart. In this area people are accustomed to choice. Within 50 miles, they have six of the greatest hospitals in the world, so you know, it's a different kind of expectation of the patient's of the physicians.

MR. LAZARUS: Since the last decision, since the last time this came up, we realize the

guidelines have changed from making this service from class 3 to class 2B, and again, there's been an additional provider in New York that's come online. What else do you think that has changed that supports the need for this proposal that makes it different from, say, three years ago?

MR. CORVINO: You know, I think one of the main issues here is that it's become accepted in community hospitals, and we cannot meet our potential to our patients if we are not allowed to do this procedure. You know, I think we are handicapped, our cardiology department is being prevented from growing and we're not able to meet the needs of the patients who come to Greenwich Hospital. And I think in light of the new guidelines, in light of the fact that we've got Yale cardiologists and Yale trained staff sitting in our institution, more than ably being able to do this, and not being allowed to do it is just a disservice to patients.

DR. HOWES: Can I comment as well?

MR. LAZARUS: Sure.

DR. HOWES: About differences in the application? I think the fundamental difference is that last application, if you recall, we were postulating it

as a pilot program. It would be a completely Yale controlled program because at that time the guidelines were less firm that this is, you know, an acceptable course. Although it was being done and is growing nationwide, you know, as a class 3 indication, and clearly now it's class 2B classification, so there was some reluctance by referring physicians, and a lot of reluctance by other interventional cardiologists if they weren't going to be part of the application. The real difference here is this is now not a class 3 indication. I feel very strongly that the referring noninvasive cardiologists 100 percent support the hospital and the program, and that will translate into referrals. Not every patient every time is going to choose to go to Greenwich, some people will still choose to go to Columbia for sure. But a lot of patience and they're referring physicians will support a program like this.

And the second thing is, these interventional cardiologist who are showing their support through their letters. The last application did not have that kind of support of -- not caths., not theoretic prorations, but they are saying actual PCIs. And that's a big difference in the application.

MS. MARTONE: So you're saying that the

cardiology community is supporting a class 2B, which is in a class 2A, where the benefits outweigh the risks, the 2B, and correct me if I'm wrong, is -- might be considered? It's not a recommendation, it just might be considered under certain conditions. So the cardiology community feels comfortable with that, you're saying to your knowledge in Connecticut?

DR. HOWES: For our hospital.

MS. MARTONE: For Yale, I should say.

DR. HOWES: For our hospital, you know, our relationships and with that change, and that criteria. In addition, the C-PORT-E trial was published after that guideline. So that guideline came out even before the largest document ever on this topic and that document only reinforces the observation.

MS. MARTONE: Right, but to my knowledge, I mean, that's only one study. And there were differences in outcomes, correct?

DR. HOWES: Actually, statistically no, they had the exact same outcome.

MS. MARTONE: The opposing testimony had suggested there were differences in outcomes. Maybe you want to address that?

DR. HOWES: A study -- a study of 18,000

patients that doesn't show a P value of statistical significance, it shows no statistical difference. You can refer to trends, but no statistician would acknowledge it.

MS. MARTONE: Okay. But --

MR. CORVINO: If I could just add to the issue of need? We were turned down in 2000 because allegedly there was no need and since then two new programs have been approved and they are doing well. So, you know, I just wanted to put that on the record.

MS. MARTONE: -- Steve, are you all done?

MR. LAZARUS: Yes, I'm all set.

A FEMALE VOICE: (Indiscernible, too far from mic.).

MS. MARTONE: Yes. Ms. Borgstrom, I don't want you to think we kept you, you know, without asking you a question, but if you could just -- you can go back to a couple of questions ago where Mr. Lazarus had asked about the need for this program considering, you know, all of the evidence that's been presented, in terms of your position overseeing the system and looking at cardiac services on a regional basis, like a system, if you could address the need with those terms?

MS. BORGSTROM: I'm going to ask you to

clarify the question. You're saying that the need from the system's perspective?

MS. MARTONE: Yeah.

MS. BORGSTROM: Yeah.

MS. MARTONE: Yeah, please.

MS. BORGSTROM: I would say more the vision and the plan for our heart and vascular center, as for many of the other service lines that we are developing, is to provide services locally, where they can be done appropriately and safely because, you know, for as many generations of changes and projected changes we've been through in healthcare, healthcare remains fundamentally a local issue. You know, people will travel very selectively for services. And so, where services can be provided cost-effectively and safely locally from a system perspective, that's something that we want to endorse. What we are trying to do throughout the system though, is use the kind of oversight that Dr. Cabin referred to in the heart and vascular services, to look at consistency in practice, whether it's at Greenwich, whether it's at Bridgeport, whether it's at New Haven, or whether it's another program like Lawrence and Memorial where we're involved, because one of the things that has made healthcare arguably as costly and

fragmented as it is, is unnecessary variation. And so we also believe that this is an opportunity, and in fact, a responsibility to provide better care at lower cost by creating better guidelines and better consistency among our providers in the system. Does that help?

MS. MARTONE: It does. So just to clarify. So in terms of cardiovascular services, the system is looking at -- as opposed to centers of excellence, looking at satellite programs that are efficient and cost-effective and they're appropriate for that area, does that send that out correctly?

MS. BORGSTROM: Yes. Yes.

MS. MARTONE: Okay.

HEARING OFFICER YANDOW: Do you have anything else for Ms. Borgstrom?

MR. LAZARUS: No. I'm all set.

HEARING OFFICER YANDOW: Okay. I just want to make counsel aware, we will have questions later on. Whether or not Ms. Borgstrom would be the best witness to answer, I'm going to leave that up to you. As far as our questions, we don't -- we believe we can get our answers from the other witnesses you have. So I'm leaving it up to you as far as whether or not you'll need Ms. Borgstrom.

MS. BORGSTROM: And I really appreciate your sensitivity and obviously this just came up over the weekend. I learned about the arrangements yesterday. And I think that with the team we have here, they can do as well, or better than I can. And I think the two people that can answer most of the questions that you could reasonably direct to me would be Frank Corvino and Gayle Capozzalo, who's our System Executive Vice President for Strategy and System Development. She was sworn in at the beginning of this hearing and is extraordinarily knowledgeable.

HEARING OFFICER YANDOW: Okay. Well, I'll leave it up to you counsel. Thank you.

MS. BORGSTROM: Thank you.

(Discussion off the record)

HEARING OFFICER YANDOW: Well, we have some follow-up, we have some questions of the intervenors' witnesses based on some of the information that we received, and I'd rather ask those questions before you do your cross, so your cross can be based on our questions too. So I'm first going to ask Professor Kielty --

A MALE VOICE: Kiely?

HEARING OFFICER YANDOW: -- Kiely, I'm

sorry, Dr. Kiely please. I'll let you ask the questions and then I might have some follow-up.

MR. LAZARUS: I just have one question and it's more of a clarification. The letters that you submitted from New York White Plains Hospital, there's not a representative here to represent them, right, it's just you submitting letters on their behalf?

DR. KIELY: That's correct.

MR. LAZARUS: Okay. Thank you. I just wanted that for the record.

HEARING OFFICER YANDOW: Okay. And I -- Dr. Kiely, you sat here through the questions that Mr. Lazarus asked, and the answers, and I just wanted to based on your opinion, do you have an opinion based on the answers you heard in the questions that were asked that you could share that would be relevant to what we have to decide?

MR. COWHERD: I'm going to -- is there a specific area? There was a lot of testimony --

HEARING OFFICER YANDOW: There was a lot and that's why I'm just leaving it there -- she sat there and I didn't know and I can't think of anything specific and I'm not going to go through every question with her. I just didn't know, based on her position and what she

does, and her opinion, if there was anything that she wanted to based on, you know, from the questions from OHCA whether or not there was something she wanted to offer?

DR. KIELY: I would just say that I think that based on what I said earlier in my documents, there are opportunities for collaboration. And we do have -- made inroads in certain -- and again, as others have testified, these are personal relationships and as those personal relationships change, as affiliations change and merge and more, this is very, very fluid. You know, we have our cardiac surgery program at Stamford and we do have referrals to that cardiac surgery program from Greenwich physicians. So again, these things take time. Relationships, you know, are what they are. And so I just underscore that because I don't think that's as fixed as it may have seemed.

HEARING OFFICER YANDOW: Okay. Do you have anything Ms. Martone?

MS. MARTONE: Yeah. Regarding the testimony or heard about the level of oversight, that the Yale physician and cardiovascular center provides --

DR. KIELY: Yes.

MS. MARTONE: -- does New York

Presbyterian provide the same level of oversight for the Stamford program?

DR. KIELY: We have a different construct, if you will. We have talented interventional cardiologists on staff and they work very, very closely together. The folks from New York Presbyterian are available at any time, but we also have biweekly sessions with them, as well as monthly conferences where the data -- because as part of that system our data is also benchmarked, not only against New York Presbyterian, we have the local -- you have the state data, but we also have benchmarking against all of the New York Presbyterian as well. So that's done routinely. All of the complications are reviewed in real-time. You know, we've had issues, for example, even where we've had physicians, you know, who we felt that their skill level needed some improvement and so we've used them to help us with that. There's something called a Focus Professional Practice Evaluation, and so we work with them through our medical staff process. So what we've done is while they're not the operators, the physicians, but they are part of our team and Dr. Collins is certainly that person largely.

HEARING OFFICER YANDOW: And he's from New

York Presbyterian?

DR. KIELY: Correct.

HEARING OFFICER YANDOW: He is. So he's the main physician -- cardiologist?

DR. KIELY: He's our main -- yes, boots on the ground at Stamford. Is known to all members of our team, our nurse managers, others, can call Dr. Collins. Dr. Collins participates regularly. If I need him, he's there.

HEARING OFFICER YANDOW: Any other questions of this witness?

MR. LAZARUS: One question. Has the Stamford Hospital seen an impact on its cardiac volumes in either program since New York White Plains Hospital came online?

DR. KIELY: You know, I have to ask one of my colleagues about that particular question. I'm not certain just off the top of my head.

HEARING OFFICER YANDOW: Do you want to ask if she knows of anyone that's here today that could answer the question?

MR. LAZARUS: Sure. If anybody else will be available to answer that, that would be fine.

HEARING OFFICER YANDOW: And if they're

sworn in.

DR. KIELY: The impact of White Plains on our volume --

HEARING OFFICER YANDOW: If you could just identify who that -- who is the person, we would ask the question.

DR. KIELY: -- I'm trying to identify --

A MALE VOICE: I am.

MR. COWHERD: The volume -- the volume numbers for Stamford Hospital's PCI program are in the CON application. Are you asking what's responsible for decreases?

MR. LAZARUS: Well, partially that, but I meant, do you -- if any of the impact that you feel is directly attributed to the New York hospital coming online?

HEARING OFFICER YANDOW: And then if not, what is to be attributed to the volume? Can you answer those questions, Dr. Kiely?

DR. KIELY: If I can understand the questions first. The question first is, I think you said, if I can paraphrase, what was the impact of White Plains Hospital opening its program on the Stamford volume? And then I think there was a slightly different

question related to the volumes. And I'd like Kathy Silard to answer those questions.

HEARING OFFICER YANDOW: Okay. Let me just -- what was your last name please?

DR. KIELY: Silard, S-I-L-A-R-D, Kathleen.

HEARING OFFICER YANDOW: Okay. Any other questions of Dr. Kiely?

MR. LAZARUS: No.

MS. MARTONE: No, not Dr. Kiely.

HEARING OFFICER YANDOW: All right.

MS. MARTONE: Thank you very much.

HEARING OFFICER YANDOW: OHCA calls Kathy Silard please? Ms. Silard, have you been sworn in?

MS. SILARD: Yes.

KATHLEEN SILARD

having been called as a witness, having been duly sworn, testified on her oath as follows:

HEARING OFFICER YANDOW: Okay. And could you just state your full name for the record please and spell your last name?

MS. SILARD: Kathleen Silard, S-I-L-A-R-D.

HEARING OFFICER YANDOW: Okay. Great.

And your title please, your position?

MS. SILARD: I'm the Executive Vice President and Chief Operating Officer at Stamford Hospital.

MR. LAZARUS: Okay. Could you please address that question, or would you like me to repeat it?

MS. SILARD: Please repeat it?

MR. LAZARUS: Okay. Considering that White Plains Hospital has come online with their cardiac program in the last year or so, have you seen any direct impact on Stamford Hospital's cardiac volumes? And if not, if there have been any declines, what would you attribute your declines to?

MS. SILARD: I would say that because of the lags in data reporting we cannot draw a direct correlation between that program coming on board and decline in the amount of cardiac volume that we're seeing either in elective angioplasty or in open-heart surgery. But what I would state is that the declines are really because of the declines across the market in the incidents of heart disease and the demand for these elective services. And that's really the reason that we are seeing the declines in our program, as is happening across the state and across the nation.

MR. LAZARUS: Thank you.

MS. MARTONE: And it appeared from the letter of intent, I think that's what it's called, in the application between the two hospitals that having access to the physicians at Yale, there was a thought, or a hope, I guess, that they would contribute volume to Stamford and the volumes would increase, is that a correct statement?

MS. SILARD: That is a correct statement. I think that as Dr. Kiely indicated, we have an open medical staff and the physicians who are in our primary and secondary market, who would have an interest in performing those procedures at Stamford Hospital and met our criteria for credentialing we would welcome them to perform those procedures.

MS. MARTONE: Thank you.

HEARING OFFICER YANDOW: Any other questions of this witness?

MR. LAZARUS: No.

HEARING OFFICER YANDOW: And of course you will have the opportunity to cross her when we're done for the open questioning. Thank you very much. And I'd like to call Dr. Gray to the stand please? And Dr. Gray, I'm just going to give you the same broad question I gave

Dr. Kiely. You sat here through the testimony, through the questions that were asked. Based on your position, do you have an opinion on any of the questions that he asked, as far as anything that sticks out that you didn't -- that wasn't covered earlier by you?

DR. GRAY: I guess I would take up the position that I agree largely with what Mr. Corvino said. That access in a community is important. I guess it really, for this panel's consideration, depends on how you define community and what the limits of the community are both geographically and territorially. He may have had a bad, and with all due respect to his experience, which sounds like it was harrowing, and to his excellent physicians, it's equally possible that because he may have come to a low-volume hospital he might have had a bad outcome.

Part of my research efforts throughout my life have been to look at outcomes in multiple different arenas. And there's nothing that you can look at, there's no procedural or surgical procedure or form of medicine that isn't axiomatically related to volume. And so while we can achieve good outcomes at C-PORT style facilities volume is king when it comes to outcomes. So while the experience may not have been terrific, it could

have easily been as bad or worse had it gone to a low-volume hospital. And it's not just the operators, it turns out to be the facilities, because it's facility preparedness as you probably well know. So I guess that's my only comment. I think it's important to kind of contextualize those experiences.

HEARING OFFICER YANDOW: Steve, do you have any questions?

MR. LAZARUS: No. Thank you.

MS. MARTONE: Did you have anything further in terms of line of questioning for New York Presbyterian, the relationship, supply any volumes or anything as such?

DR. GRAY: No, not really. I mean, I think the Connecticut data speaks for itself in terms of volumes.

HEARING OFFICER YANDOW: Okay. Does OHCA have any further questions now of any of the witnesses?

MR. LAZARUS: No.

HEARING OFFICER YANDOW: Okay. You may have some more after cross, but if you would like to call Dr. Greg, he's on the stand, are you prepared to --

MS. GROVES: (Indiscernible, too far from mic.) I don't have that many questions. You've asked

most of my questions.

HEARING OFFICER YANDOW: Okay.

MS. GROVES: So, I'll be brief. Ms. Silard, I'm just trying to get a handle, I'm sort of asking a follow-up to the question that Ms. Martone asked about the impact of the White Plains' program on Stamford Hospital's angioplasty numbers. If you look at page 10 of Dr. Kiely's testimony --

HEARING OFFICER YANDOW: Do you have -- Attorney Cowherd, do you have that there for her?

MR. COWHERD: Page 10 of Dr. Kiely's testimony?

MS. GROVES: -- okay. She says at the top of that page, it's important to note that the White Plains Hospital, elective angioplasty program began operating in 2010, making the field of elective PCI providers in the applicant's proposed service area even more crowded than it was in 2009, is that correct?

MS. SILARD: That's correct.

MS. GROVES: Okay. And in her letter, the letter that Susan Fox from White Plains Hospital submitted, she talks about the fact that their program opened in 2010 and they did -- these are the revised numbers, 90 PCIs in 2010 and then 231 PCIs in 2011 -- the

revised letter --

MR. COWHERD: The revised letter?

MS. GROVES: -- and that -- do you see that?

MS. SILARD: Yes.

MS. GROVES: Okay. And during this period of time, and I'm trying to put together -- there's some conflicting data in your application. Am I correct that Stamford's PCI volume, in fact, increased after White Plains was added to the market? Because from what I see in your testimony on page 32 of --

MS. SILARD: Well, that's her testimony.

MS. GROVES: -- I'm sorry, of Dr. Kiely's testimony, there were 38 angioplasties done at Stamford in 2010 and then Dr. Gray says 250 in 2011, and in your petition for status, it says you're on track to do 277 in 2012, is that correct?

MS. SILARD: PCRs? I would have to go and look at that data to answer correctly.

MS. GROVES: Yeah.

MR. COWHERD: Can you refer the witness to the pages Ms. Groves?

MS. GROVES: To the pages? The pages I'm looking at are on page 32 of Dr. Kiely's testimony. And

this is the PCR data says that Stamford did 238 combined -- page 32 of the --

MR. COWHERD: You're showing the PCR data, page 32, Kiely?

MS. GROVES: -- yes.

MR. COWHERD: Okay.

MS. GROVES: Am I reading this correctly? That in 2010 total procedures, inpatient and outpatient, it says Stamford do 238 elective angioplasties?

MS. SILARD: That's correct.

MS. GROVES: Okay. Now, right next to that in 2011, it says you did 220. But if you turn to the testimony of Dr. Gray, at page eight, (indiscernible, too far from mic.) --

MS. SILARD: Page eight of Dr. Gray's?

MS. GROVES: -- I'm sorry, Dr. Gray.

MS. SILARD: Okay.

MS. GROVES: So on that page in the second to last paragraph, do you see where it says, if I'm reading this correctly, Stamford Hospital performed 250 PCIs in 2011, total?

MS. SILARD: Um-hmm.

MS. GROVES: So you've gone from 238, based on this, to 250. And then looking back again in

your Counsel's petition for testimony -- or petition for status, I believe he references the fact that you're on track to perform 277 in 2012 and that's at page five of the petition.

MR. COWHERD: Page?

MS. GROVES: Five of the petition. I'm sorry, I'm jumping all over the place, of the petition for status.

MR. COWHERD: Petition for status?

MS. GROVES: Yes.

MR. COWHERD: We don't have it.

MS. GROVES: Okay. Do you see that in paragraph three?

MS. SILARD: Yes.

MS. GROVES: Okay. So based on what we just looked at from 2010 when the White Plains program came to this already crowded market, Stamford's angioplasty volume went from 238 to 250 to 277?

MR. COWHERD: I'm going to object. I've let this go because in the interest of moving forward, but Ms. Silard is first of all being asked repetitive questions from Dr. Kiely's testimony. Ms. Groves is accurate on what she's pointing to, but nonetheless, Dr. Kiely is familiar with the different data sources that

she's pointing to and the limitations that are inherent in some of those. We're not disputing the numbers, but Ms. Groves is asking questions of a witness who did not provide testimony on these issues, Dr. Kiely did. Flipping back to Dr. Gray's testimony, Dr. Gray did, but Ms. Silard didn't. So in the interest of just getting a full vetting of the facts here I think the witness who submitted the prefiled testimony in which these figures are contained should be answering the question, not somebody who did not --

HEARING OFFICER YANDOW: I'm going to make my ruling. You will have the opportunity for redirect. If she can answer the question I'm going to allow it. So I'm going to overrule the objection.

MS. GROVES: Okay. And the only reason the questions were being addressed to Ms. Silard is because when Ms. Martone asked who had the most knowledge of the impact of the White Plains program on Stamford, Dr. Kiely said Ms. Silard should answer this question. She's answered my question. I just wanted to confirm the fact that those numbers suggest that there has been an increase in volume over those three years, which he confirmed.

HEARING OFFICER YANDOW: I made my ruling.

The question was asked. Do you withdraw the question? Are you --

MS. GROVES: Then you can answer that question. Do the numbers that I have just shown you show that there's been an increase angioplasty volume at Stamford Hospital from 2010 to the present?

MS. SILARD: Yes. But not correlated to the White Plains equation.

MS. GROVES: Okay. But it was a yes or no question. So you've answered my question. And I have no additional questions for you. Thank you. I do just have a few questions for Dr. Gray.

Good morning Dr. Gray. On page one of your testimony you state -- I'll just let you get there, that New York Presbyterian has worked closely with Stamford Hospital in the operation of selected angioplasty and open-heart surgery programs, is that correct?

DR. GRAY: Um-hmm.

MS. GROVES: Dr. Gray, do you --

COURT REPORTER: I'm sorry, you need to --

DR. GRAY: I'm sorry. I'll sit up. Yes.

COURT REPORTER: -- thank you.

MS. GROVES: -- Dr. Gray, do you

personally perform any elective angioplasty procedures at Stamford Hospital?

DR. GRAY: No.

MS. GROVES: Okay. Do you know if any of your New York Presbyterian colleagues perform -- personally perform elective angioplasty at Stamford Hospital?

DR. GRAY: No.

MS. GROVES: Okay. Do any of your New York Presbyterian colleagues take primary angioplasty call at Stamford Hospital?

DR. GRAY: They may have in the past, but I'm not certain about now.

MS. GROVES: Okay. Now flipping to page eight of your testimony, in the middle of that page, the paragraph that begins, first, given the lack of volume growth, you testified that there is a very real risk that Greenwich will not exceed the 200 PCIs per year required by the guidelines if approved. You don't know for certain that they won't exceed 200, correct?

DR. GRAY: I don't know for certain.

MS. GROVES: Okay. And further down, you suggest that there's also a very real risk that if the Greenwich program is approved that both White Plains and

Stamford will see their PCI volume drop below 200, is that correct?

DR. GRAY: That's correct.

MS. GROVES: But you don't know for certain if that will happen, correct?

DR. GRAY: I don't know for sure.

MS. GROVES: And in fact, based on the testimony that was just given, the documents in the record in this matter demonstrate that Stamford's volumes -- angioplasty volumes went up when White Plains was approved, correct? And if you don't know, you don't know.

DR. GRAY: Yeah. The answer is, according to the numbers we see here it did. But it would be hard to prove a negative. Who knows how much higher they may have gone.

MS. GROVES: Right. Understand. I have no further questions. Thank you.

HEARING OFFICER YANDOW: Okay. Did you have any questions of Dr. Kiely?

MS. GROVES: No, I don't think.

HEARING OFFICER YANDOW: Okay. Redirect?

MR. COWHERD: I'd like to call Dr. Kiely. Dr. Kiely in Stamford's efforts to try and get an

estimate of PCI volume in the various surface areas covered were there any issues that Stamford experienced in compiling the data?

MS. GROVES: I'm going to object. I mean, this is redirect examination and so my understanding is it can only be based upon the questions that I asked of the witness. I mean, I didn't ask any questions of Dr. Kiely, but if he's redirecting on the questions to Dr. Silard --

HEARING OFFICER YANDOW: We did -- OHCA asked questions. I'm going to allow redirect of OHCA's questions.

MR. COWHERD: Right. And in addition, I think the instruction was redirect could be made on this issue. So I'm asking Dr. Kiely, who submitted the testimony, to speak to that.

DR. KIELY: Would you mind repeating that question?

MR. COWHERD: Yes. My question is, in compiling the PCI volume data for purposes of determining volume in the service areas did Stamford Hospital experience any problems or obstacles in compiling that data?

DR. KIELY: The obstacles were working

with the data sets that are available, which you know, have different reporting requirements, different -- some are voluntary, so in the PCR data, I think about my prefile as well as my testimony today, I mentioned that they're just slightly different data sets. And so -- but what was striking was that in no cut of the data, no parsing of the data did we find any volumes increasing in any of the service areas.

MR. COWHERD: Okay. Dr. Kiely, can you speak to the physicians who now perform angioplasty procedures at Stamford Hospital, their affiliations and backgrounds?

DR. KIELY: Sure. I certainly would -- the cardiologists who largely do our call coverage for the elective -- or the primary angioplasty program and part of a call schedule for the greater part of I think close to eight or 10 years, physicians work collaboratively to cover calls as well as other hospital responsibilities. The primary individuals are Dr. Tom Nero (phonetic). Tom also on staff at Greenwich Hospital. Dr. Ted Portney (phonetic), Ted is with Cardiology Associates, which is in the larger Bridgeport area as well, Norwalk. And Dr. Corvia (phonetic), who is an employee of Stamford Hospital. So among those doctors

in particular, there's been collaboration around PCI. In particular, and testimony to their teamwork really is the fact that they have been able to drop our time to PCI to extraordinary levels, close to 60 minutes from door to balloon time in working with outside EMS services and others. And this has been a collaboration certainly with the New York Presbyterian team. And so those three physicians from three completely different groups have collaborated to really drive this team to where it is right now.

And in fact, our door to balloon times I will add, since January of '11 have been 100 percent less than 90 minutes through this incredible teamwork, which includes nurses, as well as EMS and our in-hospital services.

MR. COWHERD: I have no further redirect of Dr. Kiely.

HEARING OFFICER YANDOW: Okay. Redirect of the other witnesses?

MR. COWHERD: Of the other Stamford --

HEARING OFFICER YANDOW: Dr. Gray was called. We also -- do you have any questions of Dr. Gray?

MR. COWHERD: -- no.

HEARING OFFICER YANDOW: No. Okay. All right. Recross?

MR. COWHERD: No.

HEARING OFFICER YANDOW: Does OHCA?

(Discussion off the record)

HEARING OFFICER YANDOW: We'll just take a five minute break, we'll be back at quarter after.

(Off the record)

HEARING OFFICER YANDOW: I have one question. I'm going to let -- do you have --

MR. LAZARUS: I have one question for the applicant.

HEARING OFFICER YANDOW: -- okay.

MR. LAZARUS: Following up on those two letters that were submitted, I believe part of Dr. Howes' prefiled testimony from the two physicians, talking about the 8,200 implied. Beyond the letters is there some sort of contract with them that the hospital has or is it just the letters at this point that you have the commitment?

MR. CORVINO: Just the letters. Frank Corvino. That's all we have is the letters. There is no contractual arrangement.

MR. LAZARUS: All right. Nothing further.

HEARING OFFICER YANDOW: Dr. Howes, do you

have something to say?

DR. HOWES: Yeah. I think it's hard for physicians to commit to a theoretical concept. And I think that some of what we see, there are other physicians who do the procedures at not New York Presbyterian, but New York Hospital, who have expressed interest and may also join on if it comes to be, but they're just reluctant to give a commitment to something that's theoretical and they, you know, it's out there in the ether space or whatever. So -- and I think they're being honest, but other than that we can't say any more about it.

MR. LAZARUS: Do they have privileges at Greenwich Hospital at the moment?

DR. HOWES: Oh, yes.

MR. LAZARUS: They do, okay.

MS. MARTONE: So as you stated in your testimony, he's just had discussions about them wanting to bring their patients to the Greenwich facility? That's kind of what you stated in your testimony. So they prefer the setting of Greenwich Hospital? They prefer -- what more that they're not currently getting?

DR. HOWES: They can't do -- they can't do the procedure at Greenwich. These are, you know,

patients in the Westchester, northeastern Westchester communities, Larchmont, you know, Rye, that currently they end up going and having a diagnostic and elective angioplasty in New York City. And if they have the opportunity locally, they have admitting privileges to this hospital, they think a portion of their practice would respond to that.

MR. CORVINO: I could just add? Greenwich Hospital has the highest patient satisfaction of any hospital in the area and that has allowed us to draw from many areas, and including, you know, clearly Greenwich is our main area, but you know, patient satisfaction is high and there are patients who want to come to Greenwich who can't because of the current regulations.

HEARING OFFICER YANDOW: And just -- and I'm not sure which -- I'll start with Dr. Howes, and perhaps if there's another witness that has testified that wants to add to this, I'll allow it. The question, look beyond the guidelines, and we, you know, OHCA's job is to see that there's a clear public need by statute. So we've heard about the guidelines. So, beyond the guideline, beyond just a local need or having local convenience, cost efficiencies and beyond a shift of volume with picking, you know, from the other hospitals,

is there anything else -- and I know this is just simplifying it, but, you know, to establish clear public need?

DR. HOWES: I am a clinician, you know? I think all of us, the physicians here are clinicians. We take care of patients and that's what we take seriously. Every day of my life I have to go through this discussion, and this permutation of where are you going to have your procedure? And are we going to have to transfer you? And it's very disruptive to the continuity of care that patient and their family.

And one thing we haven't talked about is that patients with coronary disease, the vast majority of these patients are elderly and you're talking about doing an elective, let's really say it, outpatient elective diagnostic cath. on an 80-year-old, it's much easier for them to stay two miles from home at the hospital that they've been going to for the last 25 years with the same primary care physician and the same cardiologist. There is a need there for those patients to stay with their physicians. And so from a very personal perspective, my need is to take care of my patients and provide the quality that I'm confident that we provide and will continue to provide and that they can't get that service

when we're they're providing that service for similar patients. We have patients in the hospital, sharing a hospital bedroom, one guy has a primary angioplasty that night and, you know, he's had this procedure, and then the next guy came in with unstable angina, rather than a heart attack, and we say, we're sorry, we have to send you up to New Haven or down to Presbyterian and then, you know, we have to decide do we do a diagnostic cath. or not do the diagnostic cath.?

The other thing about those 53 patients that we transferred, those are the patients that got caths. at Greenwich Hospital and we confirmed they need and angioplasty. There are other patients who've transferred out but don't get the cath. and, you know, they do still translate into reed aspirizations (phonetic).

HEARING OFFICER YANDOW: Okay. Mr. Corvino, to have any comments on the (indiscernible, interference on mic.).

MR. CORVINO: Not anything more than we've already established I don't think. In that this is a service that will be utilized by the people and citizens of Greenwich and, you know, we need to be able to provide it for them because it's the right thing to do and it is

safe. We have invested an awful lot of money in this primary angioplasty program. These great clinicians do not come cheap and we have spent the capital on getting the cath. labs ready. Everything is there. We need to increase the utilization, make it more cost-effective, and allow us to do the easy cases when we're already doing the more difficult ones.

HEARING OFFICER YANDOW: Any follow up?

A FEMALE VOICE: No.

HEARING OFFICER YANDOW: Okay. I asked earlier if there was any public comment. Is there anyone here that has arrived during the morning that wants to provide public comment? Okay. The record will show that no one has come forward and that no one has signed up. Now I'd like to allow closing remarks. Attorney Cowherd?

MR. COWHERD: Thank you Hearing Officer Yandow. Thank you OHCA staff for the opportunity to make this closing argument on behalf of the Stamford Hospital. There's been a mountain of papers submitted to you in this proceeding, but it doesn't obscure the facts. One fact is that the law of Connecticut requires that the applicant in its certificate of need bears the burden of proof. The applicants, Greenwich Hospital and Yale, have failed to carry their burden that there is sufficient

volume in the service area to warrant the establishment of another elective PCI program in Fairfield County. To me, OHCA Exhibit 1, and the declining volumes say at all. You see the trend. But I have a lot more to say.

OHCA appropriately asked what would be the impact of Greenwich Hospital continuing to treat the patients that it transfers to Yale and bypasses Stamford if this application were approved. The problem with that and the impact on Stamford is that that estimate is 53 cases per year. You cannot support an elective angioplasty program on 53 cases per year. And look at the data, even those transferred cases have been declining since 2009.

So then applicants say, well, we're going to get these 80 to 105 cases from these other providers, West Med and Dr. Munson. Take a look at West Med's estimate three years ago when it said it would transfer 100 PCIs to Greenwich's program. That estimate now is 50 to 75. As much as a 50 percent reduction in volume. Let's take a look at Dr. Munson. Dr. Munson is an employed physician of Columbia's doctors group, the same group generally as employs Dr. Gray, who's here today, speaking on behalf of New York Presbyterian Columbia Medical Center in opposing this application. How likely

do we think that the 30 cases from Dr. Munson are coming?

Now, OHCA asked Dr. Cabin where the volume would be coming from. He said, high-volume centers. The West Med letter specifically states, we're going to take this volume from another hospital out-of-state and transfer it to Greenwich. There is testimony in the record that West Med's volume is at White Plains Hospital. So much for Dr. Howes' statements, these are three separate worlds. They don't effect each other. That's a volume shift. Dr. Cabin admitted that there was a volume shift here.

Ms. Groves tried to make a point that Stamford Hospital doesn't know whether it's volume will go up or down because of this program. Well, that's generally true, nobody can tell. But it's most likely the providers that are directly in the service area that are going to be impacted by the volume shift and the creation of this third unnecessary program within 16 mile radius. So when that happens, the house of cards starts tumbling down. If the volume is not reached with this promised volume from New York, which Mr. Corvino just said, that promise is as good as the paper that it's printed on, where do they start looking for volume in a static market? It starts being exactly what the

consensus documents say that shouldn't happen. These programs start cannibalizing each other and with the two programs in the service area who are doing less than 400 cases, they're not the high volume, Dr. Cabin can't predict that it's coming from the high-volume hospitals, because there is no certainty to that. And it's these low-volume, or are doing better than the 200 threshold hospitals, that are most likely to see the volume trend. And when that happens that proportion of volume is greater to them. And so then we set up the scenario where exactly we're looking at 200 under performing -- 200 level or under that performing PCI programs that are elective in the service area.

Another fact in this matter is that the applicant must prove clear public need for a proposal and satisfy the other CON guidelines. Those are under 19(a)-639(a) and the most relevant here are being that the applicant must demonstrate that the proposal will have a positive impact on access, quality and cost efficiencies for healthcare delivery in the region. The applicant must show that the identified population has a need for the services and the proposal will not result in the unnecessary duplication of existing services.

The applicants have not shown a clear

public need for their proposal because residents of the proposed service area already have two providers within the service area and then, what you can only describe as an abundance of riches in terms of the number of programs surrounding that service area, including three other, not just Stamford Hospital, three other full service programs that serve Fairfield County. It was the volume and the other providers in the area that OHCA focused on three years ago when volumes were higher for PCI, that determined this application could not be approved. Nothing's changed.

Well, one thing's changed. We've got another provider in the service area in White Plains Hospital. People in remote locations of the state would be happy with half the access to elective angioplasty services that residents of this service area already have. And the applicants have not carried their burden of showing that a single one of these many programs has any capacity problems in terms of quickly providing care to patients.

Yale and Greenwich have not shown that the quality of care is going to be improved by this proposal. To the contrary, they are advocating a model that the expert consensus documents the 2011 guidelines and the

2012 update say -- well, let's take the guideline. It's a class 2B recommendation, meaning the benefit is greater than or equal to the risk and these programs are only appropriate when they will clearly fill a void in the healthcare needs of the community.

The other guideline is exactly the same, the 2012 consensus document. The cardiology community should foster these programs only when such programs improve access to a higher level of care than would otherwise be available. You've got four full-service programs with no evidence in the record that they are not providing high-quality care to patients already in this service area.

The consensus documents are important. These are experts in the field. They have no stake in this particular CON. And they are using words like benefit may be equal to the risk and elective PCI without surgical backup must clearly fill a void and only appropriate when a higher level of cardiovascular care can be achieved.

Now, the experts here have determined that it's only appropriate to provide these services in this model under certain conditions. Yale and Greenwich have failed to show that the residents of the service area are

receiving anything but high quality care from what's in that geographic region right now. So OHCA has to ask itself, why should any risk at all be taken in establishing a program of this kind in this service area where there's already an abundance of providers. What void is being filled by putting in the service area an elective PCI program without cardiac surgery? There is none.

Far from improving the quality the same expert guidelines state that competition with another PCI provider, especially one that is a full-service provider in the geographic area, may not be in the best interest of the community. And that's because it is just common sense. Somebody said it, that complications are rare, but when they happen an elective PCI without a surgical backup team immediately available is going to result in possible exacerbation of that complication to the detriment of the patients.

Again, the experts who have no stake in this game -- if you look at Dr. Gray's testimony in Exhibit 2, page E39, have said that a small but valid fraction of patients undergoing elective PCI will experience a life-threatening complication that could be managed with the immediate on-site availability of

cardiac surgical procedures -- cardiac surgical support, excuse me, but cannot be managed effectively by urgent transfer. These complications haven't gone away. If you go back to the 2011 guidelines and you turn to page 159 and 160 they talk about all the possible complications from a PCI procedure.

The applicants have not shown a clear public need for their proposal because these residents are already well served. Yale and Greenwich make the, I think, nonsensical point that because Stamford's program in fiscal year 2012 may be able to reverse its course in recent years and have an upswing in PCI volumes and the W -- White Plains' program, that we provided the most up to date data that we could, is above 200 cases that that justifies the addition of a third program in the service area. If the overall volume in the service area in the state is not increasing, and we all know that applicants tried every which way to find growth and couldn't, they don't refute any of the data that's been provided by Stamford Hospital in this proceeding, then as Dr. Cabin said it's just volume shift. If you have the same finite amount of cases then any additional volume, I mean, at one hospital in the service area is to the detriment of another. You can't predict where this volume is going to

go from.

Any need for an additional capacity in the service area has been filled by both Stamford and White Plains' programs and there's simply no room for another provider in this such a concentrated area of 16 miles from each other. In a static shrinking market, one provider cannot grow without the expense of the other, and no one should be happy if that volume comes from a hospital anywhere, in Connecticut or New York, if it could result in a diminution in quality.

Lastly, applicants have not shown that their proposal is cost-efficient. The estimated $425,000 annually that Mr. Corvino says would be saved by patients and payers by not having to transfer those 53 cases to Yale-New Haven Hospital will be more than offset by the risk of over utilization if these low-volume programs have to compete against each other. It'll also be offset significantly if there is an exacerbation of even one complication in what Dr. Howes said is serious stuff, a coronary intervention procedure. If even one complication that could have been avoided by immediate on-site cardiac surgery were to occur, what's the cost to the patient and the health care system then?

The result of all of this is that Yale and

Greenwich have also failed to carry their burden of identifying that patients in this service area need the proposed elective PCI program without cardiac surgery on-site and that the project does not result in what it is, an unnecessary duplication of existing or approved healthcare service. OHCA has stated in precedent decisions that convenience does not equate to need. That is clear, that the convenience of 53 patients cannot merit the establishment of a program.

I've spent time up to this point, talking about what the applicants haven't shown. I just want to sum up what they have shown. They've shown that this proposal is driven in large part by the financial gains that Greenwich Hospital will realize by being able to subsidize their primary angioplasty program. A program they voluntarily established with elective angioplasty procedures. One look at page 15, the three primary factors on which they are determining need, tells you all you have to know on that score. And one look at page 164 of the 2011 guidelines, which is attachment six to their application, tells you that this is a wholly inappropriate basis for establishing an elective PCI program without on-site surgery in a service area.

For Yale and Greenwich to take the

position that the language about having to clearly fill a void, and that you should not establish a elective PCI program without on-site cardiac surgery, in the 2011 guidelines is basically ludicrous. They said that this was irrelevant to their application because they were proposing a class 2B instead of a class 3 harm, just not no benefit, possible harm under that classification. And so they said, that admonishment was only for class 3 programs. Well, I think if you read Dr. Gray's testimony he tells you exactly why that can't be the case.

I give you a couple of other sections maybe to look --

MS. GROVES: I'm going to at this point -- I'm sorry to interrupt, but I'm going to have to object. I mean, I think the order that OHCA made in this case was the applicant would give a, quote, unquote, "brief closing remark," which in OHCA parlance typically means two to three minutes, okay? Attorney Cowherd is going through -- his client had 10 minutes to present, he's now been spending 20 minutes arguing on behalf of his client. And we've prepared a brief remark for Mr. Corvino to give as we have in past CON hearings. I think this is entirely inappropriate, and I think Attorney Cowherd needs to conclude his closing expeditiously.

MR. COWHERD: -- there was no time limit set on the remarks.

HEARING OFFICER YANDOW: I'm going to make my ruling. Overruled. You can continue. You will have as long as you -- you will have whatever you need to make your closing argument.

MR. COWHERD: Appreciate it. So we were on what the guidelines say and don't say. Take a look at sections 5.21 -- 5.2.1, excuse me, and 5.2.2, and determine for yourselves whether the discussions under class 3, after they talk about the class 3 recommendation, pertains only to that specific recommendation rather than the recommendations that precede it. It's clear that the applicant's position on this has no merit.

The applicant's have also shown that they are in full control of remedying the situation where elective PCI patients who want to be treated locally are transferred instead 47 miles away to Yale-New Haven Hospital. Stamford's program, Dr. Kiely said, is ready, willing and able, as it was three years ago when the invitation was made for their interventionalist to apply for privileges, that invitation to my knowledge was ever taken up, it still outstanding. You can treat the

patients who you want to locally at Stamford Hospital. Your attendings are also welcome if they want to follow the patient.

This proceeding and the so-called cardiac wars -- the cardiac wars that have preceded it in this state also shows how misguided Dr. Howes' statements are that these hospitals don't compete with each other. He provides data that supposedly says that, look, their docs don't admit to our hospital. He neglects to tell OHCA that 12 of those doctors are hospitalists, they're not out in the community, they have no ability to direct patients anywhere but to their employer. When a physician in the community either -- the patient is unassigned, the physician in the community does not want to follow the patient into the hospital --

HEARING OFFICER YANDOW: I just want to make sure we get your argument is based on evidence that is in there and you're not putting in --

MR. COWHERD: -- it's in Dr. Kiely's rebuttal testimony.

HEARING OFFICER YANDOW: -- okay.

MR. COWHERD: For purposes of clarification on the evidence though we were busy bees yesterday, so we said 10 hospitalists. It's actually 12,

and we can provide the documentation to support that.

The truth of the matter is that service area residents are not stamped as Stamford Hospital patients and Greenwich Hospital patients as much as the applicants would like that to be the case. Referral patterns do influence where patients go, but those referral patterns change. In the blink of an eye, a cardiology group gets acquired by a hospital. A big referring cardiologist changes employers or a cardiac interventionist does the same thing, or there is a formation of an ACO that requires the primary care doc and the specialist to provide integrated services. That's going to create volume shifts.

The Yale system acquired a cardiology group recently in the Bridgeport area. There are other discussions in the Bridgeport area of another large cardiology group being acquired by a hospital. What is that going to do to the dynamic of these commitments of procedures from --

MS. GROVES: I'm going to object again. This is not information that is in the record. He's testifying.

HEARING OFFICER YANDOW: Yeah. And I don't want -- and I said that already, so if it's about

anything that I've stricken, you know, already, or evidence that's not in to the testimony I don't want to hear any of that in a closing argument as summation of the evidence. So if you could conclude in the next few minutes?

MR. COWHERD: Okay. I will. I will. I'll just then show, you know, if you look at the comparison --

HEARING OFFICER YANDOW: I will sustain the objection as far as evidence coming in that's, you know, as testimony from Counsel.

MR. COWHERD: -- withdrawn as to that. I think my point's proven by, look at Dr. Munson's letterhead. Three years ago affiliated with Westchester Medical Center, now with Columbia. That's the point. The point is, nothing is static in this healthcare environment today. Physicians are looking to align and with the cost pressures on hospitals the need to expand market share is ever present. That Stamford has a large share of the cardiology market in Stamford and that Greenwich Hospital presently has a large share of the cardiology market in Greenwich means nothing, means nothing. If approved, Greenwich Hospital is not going to erect billboards on I-95 that say, hey, all you folks

from Stamford and from Darien, you keep going to Stamford Hospital, and you folks from Rye and Port Chester, you come to our new program.

Likewise, Stamford is not going to be turning away patients from any of the service areas. These hospitals, if approved, are going to compete hammer and tong like they are in this proceeding. And because we agree, we agree wholeheartedly with what OHCA stated in its CON determination a few years ago that applicants cite. That OHCA does not have CON jurisdiction over what happens in New York. OHCA cannot control what's in New York. So if these referrals from New York don't materialize, for whatever reason, a new provider, these shifts that I've talked about, then the results could be devastating to programs in Fairfield County, because everybody is going to train their eyes on that service area population.

HEARING OFFICER YANDOW: If you could just take -- take a few -- I was interested in the evidence before when the objection came, but as far as argument, we'll certainly make that assessment. For the next few minutes if you could wrap up any evidence you haven't addressed and close?

MR. COWHERD: -- I will. Okay. In

closing, I'm there, this proposal does nothing to improve access, quality or cost efficiencies. In addition, Yale and Greenwich seek to establish an elective angioplasty program without cardiac surgical backup in a geographic site that the relevant clinical literature clearly finds to be inappropriate. Part of OHCA's mission is to help prevent excess capacity and under utilization of medical facilities. Limit the proliferation of services that would undermine the ability of other providers to maintain viability and lower the overall cost to the health care system by limiting duplication of services.

Three years ago OHCA followed these exact same policies and made the right decision in denying Greenwich and Yale's proposal, citing the decline in PCI volume and an abundance of providers in the service area. Nothing's changed. Those declines continue. Exhibit one is really all you need to look at. And, one more provider exists. OHCA should make the same decision on this application again and deny it. Thanks for your time.

COURT REPORTER: Attorney, if you would bring the microphone (indiscernible, interference on mic.).

MS. GROVES: Mr. Corvino is giving the

statement on behalf of Greenwich.

MR. CORVINO: Okay. Thank you Commissioners. Thank you all. I never went to closing argument school, so my closing argument will be a little different. I must have been at a different hearing this morning and for the past four hours because I think that the evidence is quite the opposite of what has been portrayed. And I think what you've heard over the last 20 minutes is an attempt to deflect attention from the facts and the truth, because, quite the opposite of what was said is true.

I guess we can distort numbers anyway we want to distort them to make them fit our needs, but we never talked about 53 cases. We talked about meeting the minimum standards and that other cases would come from other physicians. We have come in 2000, we've come in 2008, we've come in 2011, we come in 2012 again, because this program is very important to us. It has -- the primary angioplasty program that we provide has consistent unparalleled quality and what we are proposing is without any additional investment. We have already expended the funds. To say that we are doing this for financial improvement of three or $400,000 on a $330,000,000 budget is preposterous. We've already made

the investment and we feel this is a program that is absolutely essential for our community.

Every time that we have come new programs have been approved. We've been denied, other programs have been approved, those programs have done well I might add. As we mentioned in the beginning Greenwich Hospital tried to collaborate with Stamford Hospital in the area of cardiac services and they withdrew from the discussion. There was no confidentiality agreement signed. If there was we certainly would not have violated it. We have proven that we meet all the requirements, the class 2B requirements for elective angioplasty, without on-site surgery programs.

We have repeatedly tried to gain approval to offer cardiac services that are requested by our patient and physician community and that are cost-effective. We have submitted the CON again now, because as we have shown, there have been significant changes in the angioplasty environment. Elective angioplasty programs without on-site cardiac surgery exist all over the country and in the northeast. The clinical guidelines have changed and no longer view elective angioplasty programs without on-site cardiac surgery as a class 3 recommendation. With proper program development

and clinical oversight and expertise, elective angioplasty programs without on-site cardiac surgery can be safely provided.

I would also like to state that this program is unique. I cannot impress upon that enough. When we talk about risk in a community hospital we have minimized that risk to as low as it can possibly be minimized. We have trained, highly qualified cardiovascular interventionists from Yale-New Haven on site 24/7. They have chosen our equipment. They have in-serviced our nurses. They provide the program at Greenwich. And to think that there's a risk in coming to our community hospital, when the environment other than having a cardiac OR next door is identical to what is at Yale-New Haven is just an unfair characterization.

Our volume projections have been conservative. And to a large degree include cases already coming to the hospital that we have transferred out. Our conservative projections will allow the program to achieve the necessary institutional volumes as recommended by clinical practice guidelines. Our volumes do not assume a shift of cases from any Connecticut provider, particularly the intervenor, as demonstrated in the data that we supplied. There is no reason to assume

that practice referral patterns are going to change. If patients are not being referred to a particular institution now there's no reason to think that that's going to happen. Especially in this era of consolidation, systemization and system formation.

We talked about there being no capital cost required to institute this program. We offer this program again, and I can't repeat this enough, to patients who are more acutely ill than we are asking for, more acutely ill than we are asking for. And if you look at our quality it has been impeccable. By offering this program we also eliminate many of the costs with patients having to undergo two invasive procedures.

And I will tell you that with reference to my own situation I did not go to a low-volume provider in the beginning because we had Dr. Howes, we had Dr. Cabin working at Greenwich Hospital, and others, who do hundreds of these procedures a year. So, the geography is the issue, but the provider is not the issue. And I think that what is also critical is that even when Stamford's program was approved PCI volumes were declining. And it seems that, you know, we're in a position where we can provide this great service, we already have everything in place and our patients are

being shut out of this market. And I think that the time has really come for OHCA to approve this application.

It's what's happening across the country, it's what safe for patients, and I just urge you to think about the patient experience, number one. And to think about the mechanics of this program and how great it is. We don't have people in our program who just show up and are affiliates who get their name put on the letterhead, we have dedicated interventional cardiologists from an institution like Yale-New Haven Medical Center who live at our institution 24/7, who are housed at our institution 24/7.

And I asked you to look at this with an open mind from the patient's perspective. Thank you very much for your attention.

HEARING OFFICER YANDOW: Thank you. So we have the late file exhibit coming within two weeks from today.

MR. LAZARUS: Two weeks from today.

HEARING OFFICER YANDOW: We have -- OHCA will go through the testimony to see what needs to be stricken regarding those attachments. Any other matters that need to -- so even though the hearing ends today the record is remaining open for those limited purposes at

this time. Okay? All right. So we will close for today.

Whereupon, the hearing adjourned at 1:09 p.m.)

RE: YALE-NEW HAVEN HOSPITAL AND GREENWICH HOSPITAL
JULY 17, 2012

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UKS
MERITAS LAW FIRMS WORLDWIDE

Jennifer L. Groves
(t) 203.786.8316
(f) 203.772.2037
jgroves@uks.com

August 10, 2012

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HEALTH CARE ACCESS

VIA ELECTRONIC MAIL & FEDERAL EXPRESS

Joanne V. Yandow, Esq.
Hearing Officer
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS #13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: Docket No. 12-31748-CON
Proposal to Establish & Operate an Elective Angioplasty Program at Greenwich Hospital

Dear Hearing Officer Yandow,

This office represents Greenwich Hospital and Yale-New Haven Hospital in connection with the above-referenced CON request. Attached is a copy of my clients' Reply to Intervenor Stamford Hospital's Objection to and Motion to Strike Applicants' Late File Submission. An original and two (2) copies of the reply have been sent via Federal Express for Monday delivery.

Please let me know if you require anything further.

Very truly yours,

Jennifer L. Groves

cc: Gayle Capozzalo
Frank Corvino
Stephen M. Cowherd, Esq.

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AUG 13 2012
DEPARTMENT OF PUBLIC HEALTH
PUBLIC HEALTH HEARING OFFICE

Updike, Kelly & Spellacy, P.C.
One Century Tower ▪ 265 Church Street ▪ New Haven, CT 06510 (t) 203.786.8300 (f) 203.772.2037 www.uks.com

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS DIVISION

IN RE: ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM AT GREENWICH HOSPITAL	)	DOCKET NO. 12-31748-CON
	)	AUGUST 10, 2012

GREENWICH HOSPITAL AND YALE-NEW HAVEN HOSPITAL'S REPLY TO INTERVENOR STAMFORD HOSPITAL'S OBJECTION TO AND MOTION TO STRIKE APPLICANTS' LATE FILE SUBMISSION

Greenwich Hospital ("Greenwich") and Yale-New Haven Hospital ("YNHH") (collectively "Applicants"), Applicants in the above-referenced matter, submit this reply to the Intervenor Stamford Hospital's Objection to and Motion to Strike Applicants' Late File Submission, dated August 2, 2012 ("Objection"). The Objection, which is replete with inaccuracies and omissions and is not supported by law or the practices of OHCA, should be overruled and The Stamford Hospital's ("TSH") Motion to Strike should be denied.

TSH makes the following claims and arguments in its Objection: (1) Applicants failed to serve TSH with a copy of their late file submission; (2) Applicants' late file submission does not include a "community needs assessment" and therefore is non-responsive to OHCA's request; (3) Applicants are not entitled to late file any information that existed at the time of the initial CON submissions and could have been included in those submissions; (4) Applicants seeks to modify the

sworn testimony given by Greenwich Hospital President Frank Corvino at the July 17, 2012 public hearing; (5) Applicants' late file submission improperly references information already in the record of this matter; and (6) Applicants' late file submission does not support a clear public need for an elective angioplasty program at Greenwich Hospital. Each and every one of TSH's claims and arguments is without merit. None should be considered by OHCA in evaluating this proposal.

1. Applicants Served TSH With a Copy of Their Late File Submission

TSH claims that Applicants "failed to contemporaneously serve" the hospital with their late file submission and that TSH "only recently learned" of the filing (Objection, p. 2). Applicants hand delivered their late file submission to OHCA on Friday, July 27th, four days before the July 31st filing deadline set by Hearing Officer Yandow. Also on July 27th, Applicants sent Attorney Stephen M. Cowherd, counsel of record for TSH, a copy of the late file submission via United States mail. Service by United States mail is permitted by Section 19a-9-6(c) of the Regulations of Connecticut State Agencies. This is the same form of service used by Attorney Cowherd to transmit the Objection to the undersigned counsel. In the unlikely event that Attorney Cowherd did not receive Applicants' mailing, TSH was clearly able to obtain a copy of the Late File submission from OHCA and had sufficient time to formulate and file a response.

2. Applicants Have Provided OHCA With "Community Needs Assessments" and Other Information Responsive To the Agency's Request

TSH goes to great lengths arguing that the documents submitted by Applicants as late file do not constitute a "community needs assessment" and are not responsive to OHCA's request. This argument fails on both fronts. First, there are no specific requirements for a "community needs

assessment" set forth in any of the OHCA statutes or regulations, so TSH cannot claim that the requirements have not been met. Second, the documents provided by Applicants were entirely responsive to OHCA's request, which is apparent if you read the complete public hearing transcript around the question and not just the excerpt attached by TSH.

TSH makes the bold and entirely unsubstantiated statement that "[n]ot a single one of Applicants' submissions qualifies as a community needs assessment" for the CON proposal (Objection, p. 3). However, nowhere in its filing does TSH explain what a "community needs assessment" is and why Applicants' submissions are not considered community needs assessments. This is because the OHCA statutes and regulations do not prescribe a specific form of community needs assessment. Assessing community need is a process left to Applicants, who have the burden of supporting their request for permission to establish a service and proving their case-in-chief for a CON. For TSH to claim that the studies and assessments included in Applicants' late file submission are not community needs assessments, without providing any support for that proposition, is meaningless.

Moreover, Applicants' late file submission was entirely responsive to OHCA's request for information. A more complete excerpt of the public hearing transcript is attached as Exhibit A. It shows that the question regarding whether Greenwich Hospital conducted a community needs assessment originated with OHCA Analyst Steven Lazarus' review of Mr. Corvino's prefile testimony. Mr. Lazarus cites to (paraphrases) the following statement made by Mr. Corvino on page 682 of his testimony:

> *We are committed to providing the services that our communities have come to rely on us for and will need in the future.*

Mr. Lazarus then goes on to ask:

> *Was there a community needs assessment done for you to figure out what the community needs? Was there a study that the hospital had performed?*

Finally, Mr. Corvino responds:

> *Well, yes. I mean, we've done many community needs assessments throughout the years.*

Applicants' submission to OHCA included a number of documents, which comprise the "community needs assessment" to which Mr. Corvino was referring. These include studies done by or in association with Greenwich Hospital, which show among other things, that the community relies on Greenwich for cardiac care. The significance of each document to Applicants' assessment of "community need" is explained in the late file submission. These are analyses, studies and surveys that Greenwich Hospital relied on in making the decision to pursue an elective angioplasty program. They reflect the needs and preferences of the patient and physician communities around cardiac services and, by extension, the proposed program. It is true that some of this information was already provided in the CON, however, Applicants thought it would be worth highlighting and/or clarifying the information for OHCA, as it supports community need for the proposal. OHCA has historically given applicants tremendous latitude in determining what information is responsive to requests for supporting documentation in a CON proceeding (i.e. needs assessments, market share analyses, public health information, etc.) and Applicants ask that they be afforded the same latitude in this matter.

3. Applicants Are Entitled To Late File Information Upon OHCA's Request

TSH argues that Applicants should be precluded from offering the late file submission as evidence because the information should have been included in their CON application. As support, TSH cites the OHCA Policies & Procedures, which provided that all supporting evidence should be attached to the application and referenced therein. However, the very nature of a late file submission is to provide "late" evidence, after the CON has been deemed completed and the public hearing has taken place, at OHCA's request. As TSH and its counsel are well aware, OHCA often asks for information in a late file that existed at the time an application was filed (i.e. historical volume), but that was not included in the CON submissions. Here, OHCA asked for information that it knew to be as much as 3 to 4 years old (see Exhibit A attached). The agency clearly understood in making its request that the information could have been provided previously, but was not. Still, OHCA made the request of Applicants and they have responded, as ordered.

4. Applicants Do Not Seek To Modify the Sworn Testimony of Frank Corvino

TSH claims that by way of the late file submission, Applicants are attempting to modify the sworn testimony of Mr. Corvino through testimony from Gayle Capozzalo, Executive Vice President, Strategy and System Development for the Yale New Haven Health System. However, the very language of Ms. Capozzalo's letter belies this claim. Regarding Mr. Corvino's testimony about the community needs assessment, she states that upon further discussion with Mr. Corvino, "he indicated he was referring to several analyses which have been conducted either by or in association with Greenwich Hospital which he feels support public need for the requested elective angioplasty program." Mr. Corvino was simply clarifying what he meant when he offered to provide OHCA with

a "community needs assessment." As President and CEO of Greenwich Hospital, Mr. Corvino relied on planning and development staff to provide OHCA with the details of the assessments. Applicants do not claim that Mr. Corvino misspoke at the hearing, nor are they trying to alter the substance of his testimony in any way. The purpose of Ms. Capozzalo's letter was simply to clarify which documents Mr. Corvino was referring to when he said that several "community needs assessments" had been conducted over the years involving cardiac services.

5. Late File Information Already In the Record Should Not Be Stricken

Applicants included reference in their late file submission to certain information already contained in the record of this matter, either directly or through OHCA's administrative notice of past dockets. This information was included to show that Applicants had, in fact, assessed "community need" in advance of this CON application being filed. Applicants wanted to make this clear to OHCA, particularly given the agency's request for a copy of any "community needs assessment" undertaken by Greenwich Hospital. Reference to this information in the late file submission is not in any way prejudicial to TSH, which had an opportunity to rebut the information the first time it was presented, as well as through its latest submission.

6. Applicants' Late File Submission Supports the Clear Public Need For an Elective Angioplasty Program at Greenwich Hospital

TSH argues that the late file information submitted by Applicants has no relevance to an assessment of "community need" for the cardiac services that are the subject of the CON. Applicants stand by their submission and the relevance of each document contained therein to their evaluation of need for an elective angioplasty program at Greenwich Hospital. The information is reflective of a

need and desire on the part of physicians and patients to have access to high-quality elective angioplasty services within their community, where they are presenting for cardiac services now even without an elective angioplasty program in place. TSH's suggestion that Greenwich Hospital did not conduct any "community needs assessment," and that this somehow justifies denying the CON request, is not supported by the evidence.

WHEREFORE, for the foregoing reasons Applicants request that Intervenor Stamford Hospital's Objection to and Motion to Strike Applicants' Late File Submission be overruled/denied.

Respectfully Submitted,

GREENWICH HOSPITAL
YALE-NEW HAVEN HOSPITAL

By: _____

JENNIFER L. GROVES, ESQ.
Updike, Kelly & Spellacy, P.C.
265 Church Street
One Century Tower
New Haven, CT 06510
Tel: (203) 786-8300
Fax (203) 772-2037

CERTIFICATION

I hereby certify that a copy of the foregoing has been sent via email and United States mail, postage prepaid, this 10th of August, 2012 to the following:

Stephen M. Cowherd
Jeffers Cowherd
5 Walls Drive
Fairfield, CT 06824

Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.

EXHIBIT A

during medical care, correct?

DR. HOWES: Yes.

HEARING OFFICER YANDOW: Any other questions of Dr. Howes?

MS. MARTONE: No.

MR. LAZARUS: Thank you. I have a couple questions of Mr. Corvino. Good morning Mr. Corvino.

MR. CORVINO: Good morning.

MR. LAZARUS: On page 681 of the prefile, you state, that this program will reduce overall costs of angioplasty care in the Connecticut health system. What did you mean by that when you state that?

MR. CORVINO: In addition to what Dr. Howes has already said, you know, when we talk about transferring patients out there is a cost to that. And I think he articulated very well in that we've got to redo another admission and there's an ambulance charge to transfer the patient. So we calculate the value of that to be somewhere around $8,000. And if you multiply that by the number of cases we transfer out it's close to half a million dollars that could be saved. Without counting all of the subjective savings that would go into the patient's psyche for not having to be transferred.

MR. LAZARUS: What's the percentage of

patients that come in for cath. or some sort of a need, an elective that's considered to be emergency transport?

MR. CORVINO: I don't have that number. Does somebody else have a number?

MR. LAZARUS: I know you mentioned -- for example, in 53 cases, for example, you have based your testimony on, those 53 cases, what's the total number of cases that you put those 53 cases on?

MS. GROVES: Are you talking about the number that still need to be transferred anyway and wouldn't be able to stay?

MR. LAZARUS: Well, is that what you're referring to in your testimony, when you say emergency transport?

MR. CORVINO: Procedures that could not be done at Greenwich under the current regulations.

MS. GROVES: Under the current protocols.

MR. LAZARUS: Okay. Under the current protocols. But I'm saying, considering that this is an elective procedure, not every -- not every procedure that can be done at the hospital is considered an emergency transport, am I correct on that?

MR. CORVINO: Can Chris answer that? He's got more expertise.

MR. LAZARUS: Sure.

DR. HOWES: Again, when we use the term elective, it is a misnomer, I mean, no one elects to have a heart procedure, you know, this is serious stuff. And there are different things. Patients who come in with an acute coronary state syndrome and are sick, and you know, may end up hypotensive with a balloon pump, they're still being called elective angioplasties in this realm, in this discussion. So they're not all elective. Now, that said, some of them are much more stable and in fact are outpatients. I would say about half of the outpatients that we do a diagnostic cath. on in Greenwich, we end up transferring because we've already put, you know, entered arterial access, we have access to the arterial system, we transfer them and they'll end up getting the angioplasty the same day. The other half, we stopped, we regroup, and they go back up to New Haven or to New York Presbyterian some other day. So that's of the outpatient elective angioplasties, about half of them.

And then about half of those patients are actually inpatient, you know, not stable patients. So I'm making these numbers up, I don't have them off the top of my head, but my sense is of those, 53 number that's being reported, I would say about three quarters

of those patients go by ambulance or helicopter or something like that. Does that answer, what your asking?

MR. LAZARUS: That helps, yes. That gets it. Thank you. Mr. Corvino, are you -- let's just say those 53 cases you mentioned, you said there is about an $8,000 cost. $1,000 for the transport and about 7,000 for the admission and angioplasty. What's made up of the $7,000 cost that you're talking about?

MR. CORVINO: You know, that's the -- that's the charge, the average charge that goes along with that procedure.

MR. LAZARUS: Would that charge --

MR. CORVINO: And, you know, it may not be one-to-one with costs at the second facility we're talking about.

MR. LAZARUS: -- would there not be a charge at your facility if the service was here?

MR. CORVINO: But it would be much less because of the lack of transportation cost.

MR. LAZARUS: So it would be a savings of $1,000, not 8,000?

MR. CORVINO: Yeah, but you're also duplicating services at the other place.

MR. LAZARUS: Okay. So you're duplicating

services, I understand --

MR. CORVINO: Plus transportation.

MR. LAZARUS: -- but only the charge for the angioplasty, if it was approved, an elective angioplasty at Greenwich Hospital would be less than 7,000?

MR. CORVINO: I don't know that we have a charge code for that yet.

MR. LAZARUS: You also made a statement on the same page that, you know, we're committed to provide services that our community have come to rely on us and will need in the future. Was there a community needs assessment done for you to figure out what the community needs? Was there a study that the hospital had performed?

MR. CORVINO: Well, yes. I mean, we've done many community needs assessments throughout the years. Clearly, cardiology is a very important part of any institution's make up. And with the growing population and the incidence of heart attack in the U.S., you know, it's clear to us that we, you know, we have to improve and make sure that we've got all of the services that our community relies on on a regular basis. And we have saved many lives through the primary angioplasty

program from the communities we serve. And clearly, as Dr. Howes mentioned earlier, if we are able to do elective it'll make us better.

If you go back to when United Hospital closed in New York, about seven or eight years ago, we saw a huge increase in usage of our emergency room to the point where we went from 15 percent of our patients coming from Westchester to now 43 percent of our patients coming from Westchester County in New York, that made us a better institution. It made our emergency room better. It made our clinicians better. And we anticipate the same thing will happen here.

MS. MARTONE: Now, Mr. Corvino, to your knowledge the incidents of heart disease you just mentioned, is it higher in the Greenwich -- the Greenwich service area compared to other areas of the state?

MR. CORVINO: You know, I don't know the answer to that question. But what I can tell you is that when you look at heart disease and the potential for heart attack that's probably, number one, what frightens patients the most. And we've, you know, we've noticed that even through some of our fundraising efforts, even if people are affiliated with a New York hospital and they live in a local community they're are going to rely

on that local community to deal with their heart attack, if you will, in the middle of the night. They're not going to be traveling to another place. So having a strong heart program really bolsters your position in the community's eyes as a really good institution.

So regardless of whether the incidents is higher or lower, if you've got the illness you want to know that the very best is available in your community.

MR. LAZARUS: When was the last time, Mr. Corvino, a community needs assessment was done? Because you mentioned there were several done.

MR. CORVINO: I would say in the last three or four years.

MR. LAZARUS: And does it specifically discuss cardiac services?

MR. CORVINO: Yes.

MR. LAZARUS: Would you be able to provide OHCA a copy of that?

MR. CORVINO: Sure.

MR. LAZARUS: OCHA would like to accept that as --

HEARING OFFICER YANDOW: Okay. I'd like to order that to be produced. How much time do you need to produce that?

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

November 20, 2012

Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.
265 Chruch Street
Once Century Towner,
New Haven, CT 06510

RE: Certificate of Need Application; Docket Number: 12-31748-CON
Greenwich Hospital and Yale-New Haven Hospital
Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup
at Greenwich Hospital

Dear Attorney Groves:

Enclosed please find a copy of the Proposed Final Decision rendered by Hearing Officer Joanne V. Yandow, Esq. in the above-referenced case.

Pursuant to Connecticut General Statutes § 4-179, Greenwich Hospital and Yale-New Haven Hospital, the parties in this matter, may request the opportunity to file exceptions or a brief or a request to present an oral argument, in writing, with the Deputy Commissioner, OHCA of the Department within twenty-one (21) days from the mailing of the decision, or by December 11, 2012. If no such request is received by this date, the Deputy Commissioner will take those rights to be waived and will render a Final Decision in this matter.

If you wish to expedite the process and avoid the necessity that the Deputy Commissioner await the expiration of the aforementioned fourteen days, you may submit a written statement to the Deputy Commissioner affirmatively waiving those rights.

Sincerely,

Kimberly R. Martone
Director of Operations

Copy: Stephen M. Cowherd, Jeffers and Cowherd, PC.

Office of Health Care Access
Certificate of Need Application

Proposed Final Decision

Applicant:	**Greenwich Hospital and Yale-New Haven Hospital**
Docket Number:	**12-31748-CON**
Project Title:	**Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital**

Project Description: Greenwich Hospital and Yale-New Haven Hospital propose to establish and operate an elective angioplasty program without onsite surgical backup at Greenwich Hospital, with no associated capital expenditure.

Nature of Proceedings: On June 20, 2012, the Office of Health Care Access ("OHCA") received the Certificate of Need ("CON") application from Greenwich Hospital and Yale-New Haven Hospital to establish an elective angioplasty program without onsite backup at Greenwich Hospital, with no associated capital expenditure. The Applicants are health care facilities or institutions as defined by Section 19a-630 of the Connecticut General Statutes ("General Statutes").

Pursuant to General Statutes § 19a-638, a public hearing regarding the CON application was held on July 17, 2012. On July 2, 2012, the Applicant was notified of the date, time, and place of the hearing. On July 3, 2012, a notice to the public announcing the hearing was published in *The Greenwich Times*. Attorney Joanne V. Yandow served as Hearing Officer. The hearing was conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the General Statutes) and General Statutes § 19a-638.

By petition dated July 12, 2012, The Stamford Hospital requested Party or, in the alternative, Intervenor status with full rights of cross-examination regarding the Applicants' CON application. The Hearing Officer denied the request of The Stamford Hospital for Party status and designated The Stamford Hospital as an Intervenor with limited rights of participation.

The Hearing Officer heard testimony from the Applicants' witnesses and the Intervenor's witnesses and, in rendering this decision, considered the entire record of the proceeding. The public hearing record was closed on September 6, 2012.

OHCA's authority to review and approve, modify, or deny the CON application is established by General Statutes § 19a-638. The provisions of this section, as well as the principles and guidelines set forth in General Statutes § 19a-639, were fully considered by OHCA in its review.

Findings of Fact

1. Greenwich Hospital is a not-for-profit 174-bed acute care hospital located at 5 Perryridge Road in Greenwich, Connecticut. Exhibit A, p. 573 (CON Application).

2. Yale-New Haven Hospital is a not-for-profit, acute care hospital located at 20 York Street, New Haven, Connecticut. Exhibit A, p. 575 (CON Application).

3. The Yale-New Haven Heart and Vascular Center provides elective and emergency ("primary") angioplasty at Yale-New Haven Hospital and has established satellite primary angioplasty programs at Greenwich Hospital and Lawrence & Memorial Hospital in New London, Connecticut. Exhibit H, pp. 629&632 (prefiled testimony of Marna Borgstrom, President and CEO of Yale-New Haven Health System and CEO of Yale New Haven Hospital); OHCA CON Final Decision, DN: 03-30148.

4. Angioplasty is historically a procedure in which a balloon tipped catheter is advanced to an artery narrowed from the buildup of cholesterol-laden plaque, but has been expanded to include other devices that serve as adjuncts to the balloon catheter, such as stents. Percutaneous coronary intervention ("PCI") also refers to this broader group of technologies. PCI for patients that present on an emergency basis with ST-segment elevation MI or new onset left bundle branch block is referred to as a "primary" PCI. Other PCI procedures are referred to as "elective" PCI. *See*, OHCA CON Final Decision, DN: 08-31210.

5. As part of Yale-New Haven Heart and Vascular Center, Greenwich Hospital currently provides diagnostic cardiac services including echocardiography, nuclear cardiac imaging, stress testing, cardiac CT angiography, and diagnostic cardiac catheterization. Greenwich Hospital also provides PCI angioplasty services for patients that present on an emergency basis with artery blockage in the heart. Exhibit A, pp. 22-23 (CON Application).

6. The primary angioplasty program at Greenwich Hospital received permanent status approval from OHCA on July 25, 2008, after completion of a 3-year demonstration project. Exhibit A, p. 22 (CON Application); OHCA CON Final Decision, DN: 03-30148.

7. Elective angioplasty is the same procedure as primary angioplasty but is typically a scheduled procedure (within 72 hours) and is not an emergency. *See*, OHCA CON Final Decision, DN: 08-31210.

8. The Applicants are proposing to establish an elective angioplasty program at Greenwich Hospital without an on-site open heart surgery program. Exhibit A, p. 14 (CON Application).

9. The Applicants define the population to be served through this proposal as the residents of the towns that comprise 85% of Greenwich Hospital's inpatient volume. The Applicants claim that the proposed service area ("PSA") is as follows:

Table I: Greenwich Hospital's PSA for Elective PCI

State	Towns
Connecticut	Darien, Greenwich, New Canaan, Norwalk, Stamford, Weston, Westport and Wilton
New York	Armonk, Bedford, Bedford Hills, Harrison, Hartsdale, Katonah, Larchmont, Mamaroneek, Mount Kisco, Mount Vernon, New Rochelle, Port Chester, Pound Ridge, Purchase, Rye Scarsdale, South Salem, West Harrison and White Plains

Exhibit A, p. 24 (CON Application).

10. The Stamford Hospital ("Stamford Hospital"), the Intervenor in this matter, performs cardiovascular services, including primary and elective PCIs. *See*, OHCA CON Final Decision, DN: 04-30374.

11. The Applicants claim that based on the 2011 inpatient cardiovascular discharge volume by patients' towns of origin for Stamford Hospital and Greenwich Hospital, cardiovascular patients at Greenwich Hospital are the low volume communities for Stamford Hospital. Specifically, the communities of Greenwich, Port Chester and Rye comprise 80% of Greenwich Hospital's cardiovascular patient population but only 4.6% of Stamford Hospital's cardiovascular patient population. Additionally, patients who live in the city of Stamford and the town of Darien comprise 88% of Stamford Hospital's cardiovascular patient volume but only comprise 7% of Greenwich Hospital's cardiovascular patients. Exhibit H, pp. 668-669 (prefiled testimony of Christopher Howes, MD, Chief of Cardiology and Medical Director of the primary angioplasty program at Greenwich Hospital).

12. In 2010, OHCA issued a decision denying Greenwich Hospital's first proposal to establish and operate elective angioplasty program without on-site open heart surgery. The proposal was denied because the projected volume included New York patients, there was insufficient evidence to support the projected volumes, and there was an existing provider of elective PCI and full service cardiac program in the service area (Stamford Hospital). CON Final Decision 08-31210-CON.

13. In or about January 2012, White Plains Hospital in White Plains, New York began offering elective angioplasty service. . Exhibit I, p. 49-50 (Intervenor's prefiled documents, letter from Susan Fox, Executive Vice President, White Plains Hospital).

14. Stamford Hospital and White Plains Hospital are currently providing elective angioplasty procedures in Greenwich Hospital's claimed PSA. Exhibit A, p. 28 (CON Application).

15. White Plains Hospital states it services most of the Westchester County towns identified by the Applicants as towns in Greenwich Hospital's PSA. Exhibit I, page, 49 (Intervenor's prefiled documents, letter from Susan Fox, Executive Vice President, White Plains Hospital).

16. The Applicants assert that Greenwich Hospital is already performing angioplasty on more acutely ill patients through its primary angioplasty program and the staff and physicians are well prepared to perform elective angioplasty for less acute patients. Exhibit A, p. 14 (CON Application).

17. The Medical Director of the cardiac services program at Greenwich Hospital is appointed by Yale University School of Medicine, Department of Cardiology and is a member of the Yale School of Medicine's interventional cardiology faculty. Exhibit A, p. 14 (CON Application).

18. The Applicants claim that the previous OHCA approval for the primary PCI demonstrated clear public need for emergency angioplasty services at Greenwich Hospital and that the current proposal expands upon that approval to demonstrate that the same population, from which Greenwich Hospital's primary angioplasty patients originate, also have a clear need for access to their provider of choice for high quality elective angioplasty services. Exhibit A, p. 15 (CON Application).

19. The Applicants claim that the clear public need for this proposal is supported by the following three key factors:

    a. Local access to elective angioplasty care at Greenwich Hospital is needed and appropriate;
    b. Greenwich Hospital must address the cost-effectiveness of angioplasty services; and
    c. The proposed program will improve the quality of elective angioplasty services provided to Greenwich Hospital's PSA patients.

    Exhibit A, p. 15 (CON Application).

20. The Applicants assert that significant stress and strain are placed on Greenwich Hospital patients and their families when they receive either a diagnostic catheterization or an emergency angioplasty and then must undergo an elective angioplasty at another facility. Exhibit H, p. 671 (prefiled testimony of Christopher Howes, MD, Chief of Cardiology and Medical Director of the primary angioplasty program at Greenwich Hospital).

21. In November 2011, the American College of Cardiology/American Heart Association/The Society for Cardiovascular Angiography and Interventions ("ACC/AHA/SCAI") updated their guidelines regarding PCI without on-site surgical backup. These guidelines are intended to assist healthcare providers in clinical decision making by describing a range of generally acceptable approaches to the diagnosis, management, and prevention of specific diseases or condition. Exhibit A, pp. 139-239 (CON Application).

22. The Applicants claim that an elective PCI program at Greenwich Hospital would fall within the ACC/AHA/SCAI updated guidelines. Exhibit H, pp. 635-636 (prefiled testimonoy of Henry Cabin, MD, Clinical Chief of Cardiology at Yale School of Medicine and Medical Director of Yale-New Haven Heart and Vascular Center).

23. The ACC/AHA/SCAI updated guidelines recommend, in part, that:
> elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection.

Exhibit A, p. 164 (CON Application).

24. The ACC/AHA/SCAI guidelines also recommend, in part, that:
> [i]t is only appropriate to consider initiation of a PCI program without on-site backup if the program will clearly fill a void in the healthcare needs of the community. Competition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interests of the community.

Exhibit A, p. 164 (CON Application).

25. It is found that although OHCA is not bound to the ACC/AHA/SCAI guidelines, these guidelines are instructive. *See*, CON Final Decision 08-31210-CON.

26. The Applicants claim that angioplasty has become a fairly routine procedure, often performed in an outpatient setting at much lower risk than used to exist. Exhibit H, p. 632. (prefiled testimony of Marna Borgstrom, President and CEO of Yale New Haven Health System and CEO of Yale-New Haven Hospital).

27. The Applicants claim that this proposal eliminates the need for two invasive procedures, diagnostic cardiac catheterization and elective angioplasty, which adds hospital costs, clinical risk and expensive medical transportation costs. Exhibit H, pp.

632 and 671 (prefiled testimonies of Marna Borgstrom, President and CEO of Yale New Haven Health System and CEO of Yale New Haven Hospital, and Christopher Howes, MD, Chief of Cardiology and Medical Director of the angioplasty program at Greenwich Hospital).

28. The Applicants assert that Yale School of Medicine cardiovascular physicians have been actively involved in the primary angioplasty program at Greenwich Hospital since its inception and will continue to provide clinical oversight, direct patient care, and staff and physician education at the proposed program. Exhibit H, p. 632 (prefiled testimony of Marna Borgstrom, President and CEO of Yale New Haven Health System and CEO of Yale New Haven Hospital).

29. The Applicants state that Greenwich Hospital participates in the National Cardiovascular Data Registry NCDR-CathPCI Registry. Exhibit A, p. 36 (CON Application).

30. According to the Applicants, since Fiscal Year ("FY") 2008, 272 patients presented at Greenwich Hospital for elective angioplasty service. A total of 246 of the 272 patients were transferred to other providers for elective PCI. The following table illustrates the total of transfers by provider:

Table II: Historical Greenwich Hospital Elective PCI Transfers

FY	Yale	Westchester Medical Center	Cornell	Columbia	Stamford	West Haven VA	Total Transfers
2008	44	1	0	0	0	0	45
2009	71	0	1	1	1	0	74
2010	51	0	2	0	1	0	54
2011	53	0	2	1	0	1	57
2012*	16	0	0	0	0	0	16
Totals	**235**	**1**	**5**	**2**	**2**	**1**	**246**

*Number of transfers between 10/1/11 and 12/31/11

Note: The remaining 26 patients were discharged and referred for elective angioplasty at a future time. Exhibit A, p. 19 (CON Application).

31. The Applicants identified the following historical primary angioplasty volumes for Greenwich Hospital for FYs 2008-2011:

Table III: Greenwich Hospital Historical Primary PCI

	FY 2008	FY 2009	FY 2010	FY 2011
Greenwich Hospital	40	40	32	38

Exhibit A, p. 30 (CON Application).

32. Greenwich Hospital's angioplasty volume projections:

Table IV: Greenwich Hospital Projected Primary and Elective PCI

	FY 2012	FY 2013	FY 2014
Primary Angioplasty	38	38	38
Elective Angioplasty	**53**	**53**	**53**
New Referred Elective PCI	105	126	151
Total	196	217	242

Exhibit A, p. 31 (CON Application).

33. The Applicants based the projected primary angioplasty volumes on historical volumes, which have remained fairly steady for the past few years. The projected elective angioplasty volumes have been based on the historical elective angioplasty patients transferred to other facilities. Exhibit A, pp. 32-34 (CON Application).

34. The Applicants claim that half of the outpatients that have a diagnostic catheterization performed at Greenwich Hospital are transferred to other facilities for elective PCI. Exhibit H, p. 669-671 (prefiled testimony of Christopher Howes, Chief of Cardiology of Angioplasty Program at Greenwich Hospital).

35. The Applicants state that an increase in the PCI patient volume will result from the addition of New York interventional cardiologists who currently do not practice at Greenwich Hospital but have referral relationships with Greenwich Hospital medical staff and would utilize and refer elective angioplasty to Greenwich Hospital. Exhibit H, pp. 670-671, 675-676 (prefiled testimony of Christopher Howes, Chief of Cardiology of Angioplasty Program at Greenwich Hospital).

36. Although the Applicants provided letters of support from the two (2) physicians from the State of New York who state they would offer elective PCI at Greenwich Hospital if that were an option, the projected new PCI volumes are speculative and appear to be a shifting of the elective PCI patients from an area provider to Greenwich Hospital. *See*, Exhibit H, page 671 &675-679 (prefiled testimony of Christopher Howes, M.D Chief of Cardiology of Angioplasty Program at Greenwich Hospital).

37. Stamford Hospital claims that elective angioplasty volumes are flat to declining in the State, with no volume growth in the Applicants' proposed service area, and therefore, there is no clear public need for the establishment of elective angioplasty program without onsite surgical back up at Greenwich Hospital. Exhibit K, p. 1 (Intervenor's prefiled testimony of Sharon Kiely, M.D., Senior Vice President of Medical Affairs and Chief Medical Officer for Stamford Hospital).

38. The following table illustrates the historical overall statewide PCI (primary and elective combined) discharges by provider between Federal Fiscal Years ("FFY") 2002-2011:

Table V: PCI discharges by provider, FFYs 2002-2011

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	FFY 05-07 (3-yr)* % Change	FFY 09-11 (3-yr) % Change	FFY 10-11 (1-yr) % Change
Bridgeport	1,191	1,249	1,288	1,052	692	560	580	428	379	298	-47%	-30%	-21%
CT Children's								2	0		n/a	-100%	n/a
Danbury	0	0	0	0	453	409	330	326	277	292	n/a	-10%	5%
Dempsey	452	464	453	519	401	353	376	334	368	253	-32%	-24%	-31%
Greenwich	0	0	0	20	38	32	40	40	32	37	60%	-8%	16%
Hartford	1,312	1,483	1,321	1,282	1,246	1,206	1,093	1,031	1,122	1,195	-6%	16%	7%
Hospital of Central CT	0	0	0	26	61	70	60	74	69	97	169%	31%	41%
Lawrence & Memorial	0	0	0	0	41	-	29	74	74	70	n/a	-5%	-5%
New Milford	0	0	0	0	0	6	11	11	0		n/a	-100%	n/a
Norwalk								14	57	65	n/a	364%	14%
St. Francis	1,192	1,253	1,349	1,223	1,170	1,188	1,171	1,232	1,030	938	-3%	-24%	-9%
St. Mary's	0	0	0	59	297	246	251	255	291	314	317%	23%	8%
St. Raphael	715	970	924	708	680	632	595	534	523	444	-11%	-17%	-15%
St. Vincent's	1,063	1,035	1,085	1,150	1,181	1,101	1,124	958	925	509	-4%	-47%	-45%
Stamford	0	0	0	9	39	34	45	159	151	135	278%	-15%	-11%
Waterbury	0	0	0	61	347	373	325	361	361	379	511%	5%	5%
Yale	1,635	1,715	1,460	1,297	1,218	1,131	1,186	1,352	1,469	1,324	-13%	-2%	-10%
Total	**7,560**	**8,169**	**7,880**	**7,406**	**7,864**	**7,341**	**7,216**	**7,185**	**7,128**	**6,350**	**-1%**	**-12%**	**-11%**

***Source**: CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database.*

ICD-9-CM Procedure Codes: .66, 36.01, 36.02, 36.05, 36.06 and 36.07
Please note: unduplicated counts utilizing all procedure codes
*This column in OHCA's Exhibit 1, Table 2A, was mislabeled. No data from this column was relied upon to support the findings in this decision.

39. The statewide inpatient PCI volumes demonstrate the following: a five year historical decline of 1% between FY 2007-2011; a 12% overall decline between FY 2009 and 2011; and an 11% decline in statewide PCI volume between FY 2010-2011. *See,* Table V, above.

40. Stamford Hospital's PCI discharges have declined 15% between FY 2009-2011 and, therefore, Stamford Hospital has capacity to serve the needs of the community. *See*, Table V, above.

41. The Intervenor claims that discharges of residents from Greenwich Hospital's service area from Connecticut and New York hospitals show that from FY 2009 through 2011, inpatient ("I/P") cardiac catheterization and PCI volumes have decreased in the service area:

Table VI: FY 2009-2011, I/P PCI Volume in proposed Service Area

State	FY 2009	FY 2010	FY 2011
CT Service Area	598	610	429
NY Service Area	844	775	772
Total	**1,442**	**1,385**	**1,201**

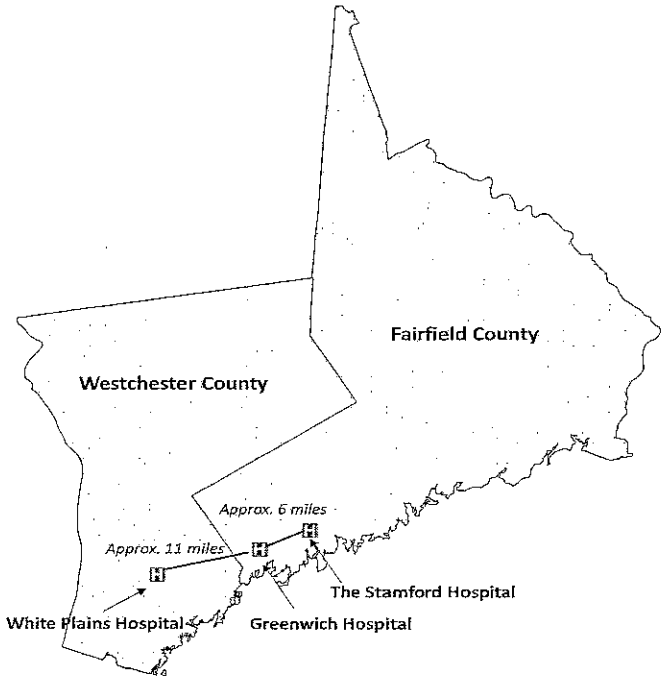
Exhibit K, p. 8 (Intervenor's prefiled testimony of Sharon Kiely, M.D., Senior Vice President of Medical Affairs and Chief Medical Officer for Stamford Hospital).

42. In light of the historical elective PCI transfers from Greenwich Hospital to existing providers and the declining statewide PCI volumes, OHCA finds that the Applicants have not provided sufficient evidence to support its projected PCI utilizations.

43. A letter from White Plains Hospital states that its elective PCI program presently has capacity to serve the needs of the community and they are not aware of any backlog of cases in their service area that would indicate patients are not receiving timely care. Exhibit I, pp. 49-50 (Intervenor's prefiled documents, letter from Susan Fox, Executive Vice President, White Plains Hospital).

44. White Plains Hospital is located approximately ten (10) miles west of Greenwich Hospital. If this application is approved, three (3) elective angioplasty programs will operate within sixteen (16) miles of each other. Exhibit K, p. 10 (Intervenor's prefiled testimony of Sharon Kiely, M.D., Senior Vice President of Medical Affairs and Chief Medical Officer for Stamford Hospital).

45. The map illustrates the location of Greenwich Hospital and the existing providers such as Stamford Hospital and White Plains Hospital, in Greenwich Hospital's proposed service area and their approximate distance to Greenwich Hospital:



46. There is no capital expenditure associated with this proposal. Exhibit A, p. 21(CON Application).

47. The Applicants assert that they estimate the unnecessary costs that now result and impact payers and patients total approximately $425,000 each year. This amount is based on an average of 53 elective angioplasty cases currently transferred that could be cared for by a Greenwich Hospital's elective angioplasty program multiplied by $8,000 ($7,000 for the average cost of an angioplasty admission at Yale New Haven Hospital plus $1,000 for emergency transportation). Exhibit H, p. 79 (prefiled testimony of Frank Corvino, President and CEO of Greenwich Hospital).

48. Greenwich Hospital's projected incremental revenue from operations, total operating expense and gain from operations associated with the CON proposal are as follows:

Table VII: Financial Projections Incremental to the Project

Description	FY 2013	FY 2014	FY 2015
Incremental Revenue from Operations	$2,935	$3,413	$3,976
Incremental Total Operating Expense	$2,353	$2,744	$3,222
Incremental Gain from Operations	**$582**	**$669**	**$756**

Note: figures are in thousands.
Exhibit A, p. 577 (CON Application).

49. The current and three-year projected payer mix for Greenwich Hospital is as follows:

Table VIII: Current & Three-Year Projected Payer Mix

Description	Current	Year 1	Year 2	Year 3
Medicare*	40.5%	40.5%	40.5%	40.5%
Medicaid*	5.4%	5.4%	5.4%	5.4%
CHAMPUS and TriCare				
Total Government	**45.9%**	**45.9%**	**45.9%**	**45.9%**
Commercial Insurers*	48.7%	48.7%	48.7%	48.7%
Self Pay	5.4%	5.4%	5.4%	5.4%
Workers Compensation	0%	0%	0%	0%
Total Non-Government	**54.1%**	**54.1%**	**54.1%**	**54.1%**
Total Payer Mix	**100%**	**100%**	**100%**	**100%**

* Includes managed care activity.
Exhibit A, p. 40 (CON Application).

50. The Applicants assert that Greenwich Hospital's primary angioplasty services are costing Greenwich Hospital approximately $1.78 million per year, as Greenwich Hospital has to pay Yale School of Medicine to provide 24/7 physician staffing for its existing program. The primary angioplasty program results in significant staffing costs to cover approximately 40 primary angioplasty cases treated at Greenwich Hospital each year. Utilizing the same physicians to perform elective angioplasty would be a cost-effective and efficient approach and would reduce the costs per case from the arrangement. Exhibit A, p. 20 (CON Application).

51. The Applicants claim that the proposed elective angioplasty program is cost effective as it maximizes use of the existing high-cost infrastructure of the primary angioplasty program and permits existing and available highly qualified expert physicians and staff to perform both primary and elective angioplasties for which they have been trained and are qualified to perform. In addition, as noted in the application, System-wide integration, coordination of care practices and standardization, more cost effectiveness and evidence-based care will be provided. Exhibit A, pp. 40-41 (CON Application).

52. OHCA is currently in the process of establishing its policies and standards as regulations. Therefore, OHCA has not made any findings as to this proposal's relationship to any regulations adopted by OHCA. (General Statutes § 19a-639(a)(1)).

53. OHCA is currently in the process of establishing the statewide facilities and services plan ("the plan"). The plan was not a published document at the time of this proposal was filed; however, even if the plan is published by the time this final decision is issued, it has no bearing on the outcome of this matter, as the Applicants have not sufficiently demonstrated a clear public need for this proposal. (General Statutes § 19a-639(a)(2)).

54. There is insufficient evidence to establish that there is a clear public need for the Applicants' proposal. (General Statutes § 19a-639(a)(3)).

55. The Applicants have not satisfactorily demonstrated how this proposal will impact the financial strength of the health care system in this state. (General Statutes § 19a-639(a)(4)).

56. The Applicants have failed to satisfactorily demonstrate that their proposal would improve the accessibility of health care delivery in the region but they have satisfactorily demonstrated a potential improvement in quality and cost effectiveness. (General Statutes § 19a-639(a)(5)).

57. The Applicants have shown that there would be no change to the provision of health care services to the relevant populations and payer mix. (General Statutes § 19a-639(a)(6)).

58. The Applicants have satisfactorily identified the population to be served by their proposal but have failed to satisfactorily demonstrate that this population has a need as proposed. (General Statutes § 19a-639(a)(7)).

59. The historical elective PCI discharges in the service area do not support this proposal. (General Statutes § 19a-639(a)(8)).

60. The Applicants have failed to satisfactorily demonstrate that their proposal would not result in an unnecessary duplication of existing elective PCI services in the area. (General Statutes § 19a-639(a)(9)).

Discussion

CON applications are decided on a case by case basis and do not lend themselves to general applicability due to the uniqueness of the facts in each case. In rendering its decision, OHCA considers the factors set forth in General Statutes § 19a-639(a) and the Applicant bears the burden of proof in this matter by a preponderance of the evidence. *Goldstar Medical Services, Inc., et al. v. Department of Social Services,* 288 Conn. 790 (2008); *Steadman v. SEC*, 450 U.S. 91, 101 S.Ct. 999, *reh'g den.*, 451 U.S. 933 (1981); *Bender v. Clark*, 744 F.2d 1424 (10th Cir. 1984); *Sea Island Broadcasting Corp. v. FCC*, 627 F.2d 240, 243 (D.C. Cir. 1980).

Greenwich Hospital is a 174-bed acute care hospital located at 5 Perryridge Road in Greenwich and Yale-New Haven Hospital is an acute care hospital located at 20 York Street in New Haven. Greenwich Hospital and Yale New Haven Hospital (collectively known as "Applicants") are proposing to establish and operate an elective angioplasty program without onsite surgical backup located at Greenwich Hospital. FFs 1, 2, 8.

Currently, Greenwich Hospital, as a satellite of Yale New Haven Hospital's Yale-New Haven Heart and Vascular Center, provides cardiac catheterization and primary (emergency) angioplasty services. Greenwich Hospital does not have an on-site open heart surgery program. FF 4-6.

The Applicants argue that there is a clear public need for elective angioplasty ("elective PCI") at Greenwich Hospital and that such a program would fall within the ACCF/AHA/SCAI updated guidelines regarding elective PCI without on-site surgical backup. FFs 18, 19, 21, 22. The ACCF/AHA/SCAI guidelines now state that elective PCI might be considered in hospitals without on-site cardiac, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection. FF 23.

The Applicants claim there is clear public need based on three key factors: local access, cost-effectiveness and improved quality. FF 19. Greenwich Hospital has transferred approximately 57 patients annually (between FYs 2008-2011) that required elective angioplasties to other providers over the each of the past three fiscal years. FF 30. Additionally, the Applicants claim that two new physicians (currently practicing in Westchester County, NY) will refer new angioplasty patients to Greenwich Hospital, if approved. FF 35.

Although the Applicants claim that there is need for elective PCI in the proposed service area, there are currently two providers of elective angioplasty service within its proposed service area, Stamford Hospital and White Plains Hospital. FFs 14, 44, 45. Each of the existing providers of elective angioplasty is approximately 6 and 11 miles away from Greenwich Hospital. FFs 44, 45. A letter from White Plains Hospital in Westchester County, NY, stated that its elective angioplasty program presently has capacity to serve the needs of the community and they are not aware of any backlog of cases in their service area. FF 43. Additionally, historical PCI discharge data shows that Stamford Hospital also has capacity to serve the needs of the community. FFs 37-40. Furthermore, based on OHCA's statewide hospital discharges, it's clear that since FY 2009,

the cardiac catheterization volume has declined 10% and the combined (emergent and elective) angioplasty volumes declined 12% at Connecticut providers. FFs 38-40.

The ACCF/AHA/SCAI updated guidelines state:

> It is only appropriate to consider initiation of a PCI program without on-site cardiac surgical backup if this program will clearly fill a void in the healthcare needs of the community. Competition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interests of the community.

FF 24. Regarding the proposal at hand, there is insufficient evidence to establish a void in the needs of the community for elective PCI services and that the Applicants' proposal is in the best interests of the community.

Based on the statewide decline at all Connecticut providers of cardiac catheterization and angioplasty programs, the speculative projected new cases, and the fact that there are two (2) existing providers currently providing elective PCI in Greenwich Hospital's proposed service area and that these providers have capacity to fulfill the needs of the community, OHCA finds there is access to elective angioplasty service for the residents within Greenwich Hospital's proposed service area and, further, that the Applicants failed to demonstrate and provide evidence of a clear public need for this proposal. Based upon the lack of sufficient evidence demonstrating that the Applicants' proposed project fulfills a clear public need for elective PCI, OHCA is unable to conclude that the Applicants' financial projections and volumes upon which they are based are reasonable and achievable, or that the project is financially feasible.

Based upon the foregoing Findings of Fact and Discussion, I respectfully recommend that the Certificate of Need application of Greenwich Hospital and Yale-New Haven Hospital for the establishment of an elective angioplasty program without onsite surgical backup at Greenwich Hospital, with no associated capital expenditure, be **DENIED**.

Respectfully submitted,

11/20/12
Date

Joanne V. Yandow
Joanne V. Yandow
Hearing Officer

JVY:swl

****
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TO: Jennifer Groves, Esq. ✔

FAX: (203) 772-2037

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TO: Stephen M. Cowhard

FAX: (203) 259-1070

AGENCY:

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Vice [4] 32:24 49:15 94:8 101:2
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York [52] 7:4 23:8 25:21 27:15 33:23 37:23 40:22 40:23 46:11 46:11 48:2 48:15 49:5 53:24 57:16 57:24 58:3 64:17 64:21 64:24 70:2 73:1 78:17 81:5 81:9 81:23 85:24 86:18 86:19 88:3 95:5 96:24 97:6 97:10 97:12 98:1 98:14 99:15 104:11 110:15 111:5 111:10 115:7 117:5 117:6 118:4 122:23 123:21 129:9 136:11 136:12 136:12
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yourselves [1] 132:10

CERTIFICATE

I, Paul Landman, a Notary Public in and for the State of Connecticut, and President of Post Reporting Service, Inc., do hereby certify that, to the best of my knowledge, the foregoing record is a correct and verbatim transcription of the audio recording made of the proceeding hereinbefore set forth.

I further certify that neither the audio operator nor I are attorney or counsel for, nor directly related to or employed by any of the parties to the action and/or proceeding in which this action is taken; and further, that neither the audio operator nor I are a relative or employee of any attorney or counsel employed by the parties, thereto, or financially interested in any way in the outcome of this action or proceeding.

In witness whereof I have hereunto set my hand and do so attest to the above, this 24th day of July, 2012.



Paul Landman
President

Post Reporting Service
1-800-262-4102

Greer, Leslie

From: Lazarus, Steven
Sent: Friday, July 27, 2012 8:35 AM
To: Greer, Leslie
Subject: FW: YNHH/Greenwich Hospital - Late File Submission DN: 12-31748-CON

Please add to the record.

Thank you,
Steve

Steven W. Lazarus
Associate Health Care Analyst
Office of Health Care Access
Department of Public Health
410 Capitol Avenue
Hartford, CT 06134
Phone (Direct): 860.418.7012
Fax (Main): 860.418.7053

From: Lazarus, Steven
Sent: Friday, July 27, 2012 8:35 AM
To: 'Karen Banoff'
Cc: Ahn, Jean (Jean.Ahn@ynhh.org); Jennifer Groves; Nancy Rosenthal (Nancy.Rosenthal@greenwichhospital.org); Nancy Hamson (nancy.hamson@greenwichhospital.org)
Subject: RE: YNHH/Greenwich Hospital - Late File Submission DN: 12-31748-CON

Good Morning Karen,

Thank you. I'll let our staff know.

Steve

Steven W. Lazarus
Associate Health Care Analyst
Office of Health Care Access
Department of Public Health
410 Capitol Avenue
Hartford, CT 06134
Phone (Direct): 860.418.7012
Fax (Main): 860.418.7053

From: Karen Banoff [mailto:kbanoff@kmbconsult.com]
Sent: Friday, July 27, 2012 8:15 AM
To: Lazarus, Steven
Cc: Ahn, Jean (Jean.Ahn@ynhh.org); Jennifer Groves; Nancy Rosenthal (Nancy.Rosenthal@greenwichhospital.org); Nancy Hamson (nancy.hamson@greenwichhospital.org)
Subject: YNHH/Greenwich Hospital - Late File Submission DN: 12-31748-CON

Good morning Steve-

I just wanted to let you know that the Late File submission for the above referenced docket will be delivered to OHCA via courier today. A copy will also be sent (via US mail) to Attorney S. Cowherd.

Please let me know if you have any questions. Thank you. Karen

Karen M. Banoff

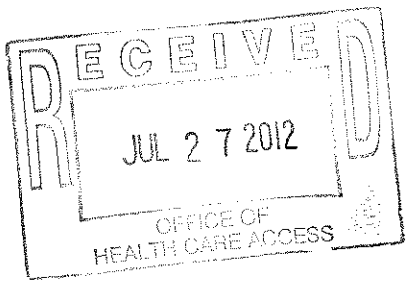
kmb consulting llc

91 Old Hollow Road
Trumbull,CT 06611
(203) 459-1601 (Phone/Fax)
kbanoff@kmbconsult.com

www.kmbconsultingllc.com

YALE NEW HAVEN HEALTH

July 26, 2012



Joanne V. Yandow
Hearing Officer
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P. O. Box 340308
Hartford, CT 06134

Re: Certificate of Need Application (CON); Docket Number 12-31748
Proposal to Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital – Late File Submission

Dear Hearing Officer Yandow:

As requested at the Public Hearing held on July 17, 2012 regarding the above referenced CON application, the following documents are being provided as Late File #1. OHCA staff asked Mr. Corvino whether Greenwich Hospital had performed any community needs assessments and Mr. Corvino replied in the affirmative. Upon further discussion with Mr. Corvino, he indicated he was referring to several analyses which have been conducted either by or in association with Greenwich Hospital which he feels support public need for the requested elective angioplasty program. A description of each analysis and/or report is provided below and relevant components have been attached.

- Market Strategies Consumer Survey:
  - Greenwich Hospital contracted with Market Strategies International, a market research company, to conduct a telephone and web survey in the summer of 2011. Some of the content of that survey involved cardiac services. The results of the survey highlight that Yale New Haven Health System/Greenwich Hospital is the preferred health care provider in a number of clinical areas, including the treatment of heart disease. This is quite significant since the survey was conducted well after Stamford Hospital established its full-service cardiac program. This survey provides additional support for Mr. Corvino's comments regarding the community's preference for access to cardiac services at Greenwich Hospital. Key pages from the survey report are provided in *Attachment I.*

- Navigant Physician Needs Assessment:
    - Greenwich Hospital contracted with Navigant Consulting to assess community needs for physicians in Greenwich Hospital's service area. Navigant determined that there is a deficit of 3.0 full time equivalent physicians in the area of invasive-interventional cardiologists. This deficit is projected to grow to 7.9 FTEs by 2017. The need for additional invasive/interventional cardiologists also supports the need for these services in the Greenwich Hospital service area. Key pages of this assessment are included in *Attachment II.*
- Physician Telephone Survey:
    - As described in the CON application on applicant pages 31-34 and 703, Greenwich Hospital's Planning Director personally contacted 18 physicians currently on Greenwich Hospital's medical staff in the area of cardiology and one internal medicine practice. These physicians were asked to estimate the number of cardiac catheterization patients they would send to Greenwich Hospital if it could offer elective angioplasty. *Attachment III* includes more detail about the physician survey and serves as another supporting analysis for the proposed elective angioplasty program. These 18 physicians have patients who require invasive cardiac procedures, would prefer to use Greenwich Hospital, but are sent elsewhere because of the absence of elective angioplasty.
- United Way Community Needs Assessment:
    - In January, 2011, the Greenwich United Way Community Planning Council published a comprehensive assessment of human service needs. Although this very broad and comprehensive assessment is not focused on cardiac services, the report does identify that the largest number of deaths for Greenwich residents was caused by heart and circulatory disease. A link to the full report can be accessed at http://www.unitedway-greenwich.com/needs-assessment2011-es.pdf.

In addition, the Applicants would like to highlight some information already included in the above referenced CON application and DN: 08-31210 which further contribute to Mr. Corvino's comments regarding community need.

- Other Physician and Patient Support:
    - Although part of both the above referenced CON application (see applicant pages 125-138, 675-676) and DN: 08-31210-CON (see applicant pages 119-125 and patient letters included in *Attachment IV*), letters of support from both patients and physicians also reinforce public need for the program. The Applicants would like to reiterate the presence of these letters in both CON applications and request OHCA consider them along with the other supporting data and information.
- Cardiovascular Health Statistics:
    - Public need for the proposed program is also supported by compelling statistics which identify the significance of heart disease. The Applicants would like to

direct OHCA to pages 24 – 26 of the CON application where relevant statistics on heart disease, hospitalizations, and deaths are provided for the state overall and Fairfield County. Fairfield County's heart disease death rate was higher than the rates in New Haven, Middlesex, Hartford and Litchfield counties and it had the third highest 65+ heart disease hospitalization rate per 1,000 in Connecticut.

The Applicants hope that the following materials are satisfactory to OHCA and want to thank you for your time and effort on the Applicants' behalf. Please do not hesitate to contact me with any questions or concerns.

Sincerely,

Gayle L. Capozzalo
Executive Vice President, Strategy and System Development

Enclosures

ATTACHMENT I

MARKET STRATEGIES CONSUMER SURVEY

Methodology

For the 2011 wave, Market Strategies conducted 2,301 telephone and web interviews from July 15, 2011, to August 7, 2011 among consumers:

Service Area	Sample Size	Sample Error
Yale-New Haven Hospital's Primary Service Area	384	+/-5.0% sample error at the 95% confidence level
Yale-New Haven Hospital's Secondary Service Area	383	+/-5.0% sample error at the 95% confidence level
Bridgeport Hospital's Primary Service Area	384	+/-5.0% sample error at the 95% confidence level
Bridgeport Hospital's Secondary Service Area	383	+/-5.0% sample error at the 95% confidence level
Greenwich Hospital's Primary Service Area	383	+/-5.0% sample error at the 95% confidence level
Greenwich Hospital's Secondary Service Area	384	+/-5.0% sample error at the 95% confidence level

The definition of each market area is shown on the following page. The data was weighted by geography to proportionately represent the distribution of the population. The telephone sample is a Random Digit Dial (RDD) design to ensure an equal probability of reaching unlisted as well as listed households. The sample is drawn Population-Proportionate-To-Size (PPS) across each geographic area to allow for proportionate representation. The sample for the web-based surveys is an online consumer panel. The mix of final completes was approximately 500 phone and 250 web completes for each hospital.

Respondents are consumers who are the adult head-of-the-household (i.e., 18 years or older), responsible for health care decisions for the household, and who reside in the defined market areas. Consumers with someone in their household who works within the healthcare industry or for a market research firm or an advertising agency were also excluded from the study.

Methodology

Service Area	Zip Codes
Greenwich Hospital Primary Market Area	10528, 10538, 10543, 10573, 10580, 06807, 06820, 06830, 06831, 06836, 06840, 06870, 06878, 06901, 06902, 06903, 06905, 06906, 06907
Greenwich Hospital Secondary Market Area	10504, 10506, 10507, 10576, 10577, 10583, 10601, 10603, 10604, 10605, 10606, 10607, 10801, 10804, 10805, 06850, 06851, 06853, 06854, 06855, 06880, 06883, 06897, 06852, 06856, 06857, 06858, 06859, 06860, 10590, 10802, 10530, 10536, 10549, 10550, 10552, 10553

MARKETSTRATEGIES INTERNATIONAL

Key Findings
Greenwich Hospital Leadership – Primary Service Area

Greenwich Hospital remains the service preference leader in the primary service area despite Stamford's improved ratings over time

- Greenwich continues to be the unaided awareness leader, however awareness of Stamford's offerings grows year over year
- Greenwich preference ratings strengthen for *maternity services, radiology and imaging, rare medical condition treatment,* and *heart disease*
- Stamford also makes directional improvements to challenge Greenwich for *rare medical condition* and *heart disease* treatment
- Overall, the competition between Greenwich and Stamford Hospitals remains close over time

	Attribute	Greenwich Hospital	Lead / Closest Competitor	Competitor	Ranked by Gap
Aware	Total Unaided	76 +3	61^ +8	Stamford	15
	Top-of-Mind Unaided	38 -3	33 +3		5
Preference	Maternity Services	45 +4	26	Stamford	19
	Age 65+	42	28		14
	Radiology or Imaging	34 +5	21 -5		13
	Women's Health	38	26		12
	Emergency Room	42	33		9
	Pediatric Services	33	24		9
	Rare Medical Condition	20 +3	16 +3		4
	Heart Disease	25 +4	24 +3		1
	Cancer Treatment	18	30	Sloan	-12

^ Indicates a significant difference at the 95% confidence level between the 2010 and 2011 scores. Faded numbers reference directional change >2% and circles identify potential opportunities to strengthen position.

Key Findings

Greenwich Hospital Leadership – Primary Service Area

As with service preferences, consumers also consider Greenwich and Stamford Hospitals close competitors on key brand positioning metrics

- Greenwich makes a dramatic improvement in consumers' impression of their *health education* offerings in 2011
- The gap between Greenwich and Stamford remains widest year over year on *caring and compassionate doctors, nurses and staff*

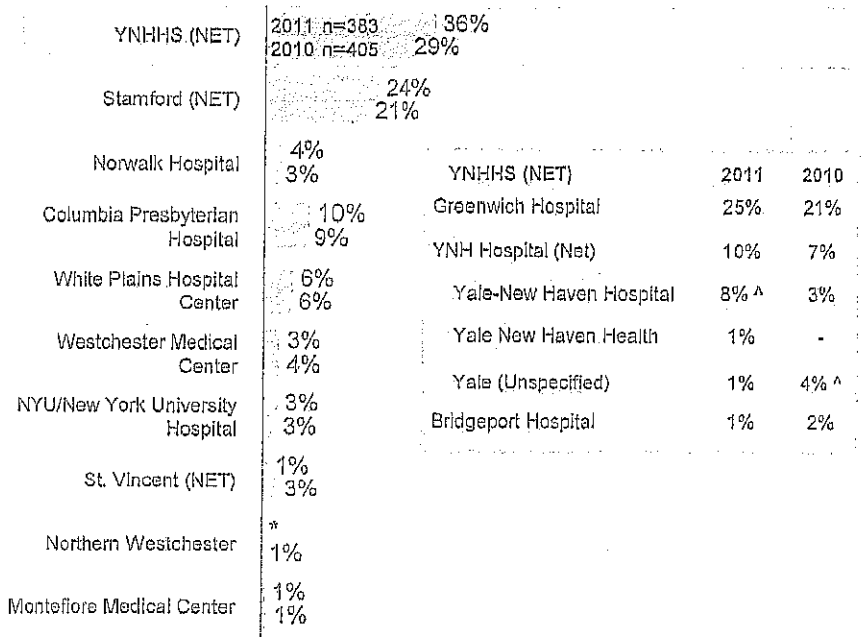
Attribute		Greenwich Hospital	Lead / Closest Competitor	Competitor	Ranked by Gap
Attributes	Health Education	37 +5	20 +3	Stamford	7
	Caring and compassion	35	19		6
	Highest quality care	30 -4	18 -4		2
	Having expert physicians	22 -3	15		7
	Cares About Entire Community	29	23		3
Overall Preference		41	26	Stamford	5

^ Indicates a significant difference at the 95% confidence level between the 2010 and 2011 scores. Faded numbers reference change >2% and circles identify potential opportunities to strengthen position.

Primary service area consumers prefer to be *treated for heart disease* either at Greenwich (25%) or Stamford (24%). Secondary service area consumers do not have a strong of a preference for *heart disease treatment*, although most mention Norwalk (16%).

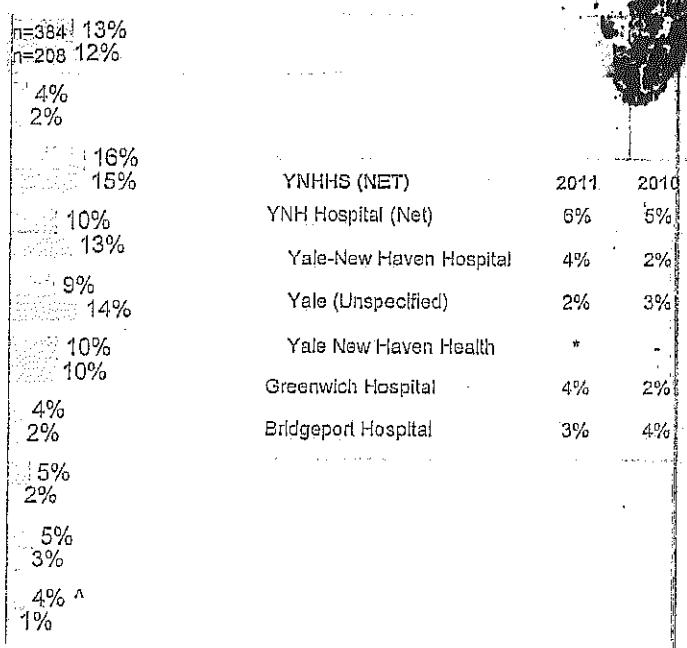
Heart Disease Preference

Primary Service Area



YNHHS (NET)	2011	2010
Greenwich Hospital	25%	21%
YNH Hospital (Net)	10%	7%
Yale-New Haven Hospital	8% ^	3%
Yale New Haven Health	1%	-
Yale (Unspecified)	1%	4% ^
Bridgeport Hospital	1%	2%

Secondary Service Area



YNHHS (NET)	2011	2010
YNH Hospital (Net)	6%	5%
Yale-New Haven Hospital	4%	2%
Yale (Unspecified)	2%	3%
Yale New Haven Health	*	-
Greenwich Hospital	4%	2%
Bridgeport Hospital	3%	4%

* Indicates less than 1%.
^ Indicates a significant difference at the 95% confidence level between the 2010 and 2011 scores.
Q4. If you or someone in your household had to be treated in a hospital for HEART DISEASE, what area hospital would you PREFER?

ATTACHMENT II

NAVIGANT PHYSICIAN NEEDS ASSESSMENT

NAVIGANT

30 S. Wacker Dr., Suite 3100
Chicago, IL 60606
312.583.4100 phone
312.583.4101 fax

Greenwich Hospital
Draft 2012 Community Needs Assessment
May 15, 2012

Introduction

Navigant has been asked by Greenwich Hospital to evaluate the current and future FTE demand and supply for physicians in the following specialties in the service area for Greenwich Hospital:

Primary Care	Medical Specialties	Surgical Specialties
Internal Medicine	Cardiology	CT Surgery
OB/Gyn	Endocrinology	Colorectal Surgery
Pediatrics	Gastroenterology	ENT
	Hematology-Oncology	General Surgery
	Nephrology	Neurosurgery
	Neurology	Oncology Surgery
	Pulmonary Medicine	Orthopedics
	Rheumatology	Spine Surgery
		Urology
		Vascular Surgery

Greenwich Hospital has requested and intends to use this evaluation by Navigant for the purpose of structuring Greenwich Hospital's physician recruitment programs in compliance with the federal Stark law (42 USC Section 1395nn), the federal anti-kickback statute (42 USC Section 1320a-7b) and the federal laws governing tax-exempt organizations.

Market Definition

Greenwich Hospital's Primary Service Area is comprised of the lowest number of contiguous zip codes located within the surrounding areas that account for at least 75% of Greenwich Hospital's inpatient admissions for the most recent 12 months available. In addition, Greenwich Hospital identified a Secondary Service Area (SSA) for study within this report. Please refer to Attachment A for a complete zip code listing of both areas. To determine the current population, Navigant utilized demographic data provided by Claritas, a nationally recognized

provider of demographic and other market intelligence information. Using data from these sources, the following current population was identified:

Population [1]	Greenwich Hospital PSA [2]		Greenwich Hospital SSA [2]	
	2012	2017	2012	2017
Total	404,136	409,242	407,622	411,616
65+	56,488	61,988	55,786	62,771
% 65+	14.0%	15.1%	13.7%	15.2%

[1] Source: Claritas – Data updated and projected based on 2010 Census.
[2] Zip Code Definition found in Attachment A

Assessing community need for a particular specialty involves calculating current and future demand on a FTE basis for each physician specialty, then comparing demand against current and projected physician FTE supply located and practicing within the service area.

Current Regional Service Area Physician Demand

To assess community needs for physician for the defined service area, Navigant performed a quantitative analysis using our customized actuarial-data based model for prediction physician demand. Based on the current demographic profile and specific healthcare market characteristics of the defined service area population, Navigant applied actuarially based use rates and MGMA practice capacity benchmarks to estimate the total number of FTEs by specialty required to serve the needs of the community.

Greenwich Hospital's service areas are located within the New York/Connecticut metropolitan area. Therefore an adjustment was made to reflect the healthcare utilization within the states of New York and Connecticut and is included in the model inputs.

Current Regional Service Area Supply

A physician roster of all FTEs for each of the selected specialties practicing in the market was created through the integration of information provided by Greenwich Hospital and information obtained by Navigant from American Medical Information, a division of InfoUSA. Additionally, other sources such as large local payer directories and competitor physician rosters were consulted to locate and aggregate all physicians that are practicing in Greenwich

Greenwich Hospital's Total Service Area (PSA+SSA)

Greenwich Hospital Total Service Area Specialty	2012 Demand (FTEs)	2017 Demand (FTEs)	2012 Supply (FTEs)	2017 Supply (FTEs)	2012 Surplus/ Deficit	2017 Surplus/ Deficit
Cardiology - Medical	21.0	22.6	66.2	48.4	45.2	25.8
Cardiology - Invasive & Interventional	16.1	17.3	13.2	9.3	(3.0)	(7.9)
Cardiology - EP	12.3	13.3	2.9	2.8	(9.4)	(10.6)

Attachment D

Overview of Navigant's Demand Calculation Methodology

Drivers of Physician Demand

Physician demand is defined as the number of physician FTEs by specialty required in a market to meet the healthcare needs of a community. The four primary drivers of physician demand include:

1.) Physician Utilization
   ⇒ How often do people visit a physician on an outpatient basis in a year?
2.) Market Demographics
   ⇒ Because different age and sex cohorts require different medical attention, what is the projected male/female population aged 85 years and older, 65-84 years, 45-64 years, 15-44 years and 0-14 years?
3.) Payor Mix
   ⇒ What is the mix of Commercial, Medicare and Medicaid/Public Aid in a community and how does this impact physician utilization?
4.) Physician Office Capacity (FTE)
   ⇒ How many patients does a typical full-time physician (by specialty) see in his/her office in a year?

1.) Physician Utilization

In order to project physician demand, it is necessary to understand how often people visit a physician on an outpatient basis in a year. Navigant worked with Milliman, a leading actuarial firm, to collect and analyze physician utilization rates. In general, the utilization data is based on Milliman USA's research, which is comprised of national data collected from insurance companies/HMOs and government sources. More specifically,

- The commercial encounter estimates are based on Milliman's recently updated research on professional costs by physician specialty and the Milliman USA Health Cost Guidelines. Milliman constructed a database from nationwide commercial group data from 10 HMOs, representing roughly 2.5 million members. Milliman's Health Cost Guidelines are widely recognized as a leading tool in the industry.
- The Medicare utilization data by specialty are primarily based on data obtained from the Centers for Medicare and Medicaid Services (CMS), which represents utilization in a fee-for-service environment and Milliman's Ages 65 and Over Health Cost Guidelines.
- The Medicaid encounter estimates are based on Milliman's research on professional costs by physician specialty and other Milliman research. Milliman constructed the database from Medicaid data from ten HMOs, representing 500,000 members.

Because certain CPT codes may not equate to a single outpatient encounter at a physician's office, the data were adjusted by specialty based on the judgment of Milliman's clinical division. Milliman's clinical division conducted thorough research and analysis at the CPT level to develop office encounter conversion factors by specialty and service category.

2.) Market Demographics

The second driver of demand is market demographics. The utilization rates in the database are based on a defined population and age mix. Because different age cohorts require different medical attention, the utilization rates need to be adjusted to reflect the age mix of the market being analyzed.

The Navigant Physician Requirements model adjusts the utilization rates for all specialties based on the market's percentage of male and female population over 85 years, 65-84 years, 45-64 years, 15-44 years, and under 15 years of age.

3.) Payor Mix

The third driver of demand is payor mix in the market. The utilization rates in the database contain three levels of utilization, one for commercial population (all ages and sex cohorts up to age 64), one for Medicare (both 65-84 and 85+), and one for Medicaid populations (all ages and sex cohorts up to age 64). Because different payor categories access health care differently and at different levels, the utilization rates need to be adjusted to reflect the payor mix appropriate for the market.

4.) Physician Office or Work Capacity

The fourth driver of physician demand is physician office or work capacity. Physician office capacity is the number of patients the typical physician can see in his/her office in a year,or other comparable unit of work productivity. Navigant collected office capacity assumptions by specialty from the 2011 MGMA Compensation and Production Survey based on 2010 median data. This data is updated yearly upon receipt of the most recent MGMA study.

Physician to Population Ratios

Methodology: Based on the four drivers of demand, the number of physician FTEs by specialty per 100,000 population is calculated.

Market Demand → Office Encounters per 100,000 population

Physician Capacity → Expected annual office visits per Physician FTE

= Physician Requirements per 100,000 Population (FTEs)

Example: Medical Cardiology

Office Encounters per 100,000 population → 5,630

Expected annual office visits per Physician FTE → 1,748

= 3.2

ATTACHMENT III

PHYSICIAN TELEPHONE SURVEY

DN: 12-31748 CON Elective Angioplasty Physician Survey and Projected Volumes

Physician Survey Results

Physician Key	Annual Caths at Any Hospital (#)	Caths Already at GH - FY11 (#)	Caths Currently Not at GH - FY11 (#)	Caths to GH Currently Not at GH (%)	Caths to GH Currently Not at GH (#)
A	100	50	50	100%	50
B	120	3	117	33%	39
C	36	3	33	100%	33
D	70	38	32	100%	32
E	100	1	99	25%	25
F	NA	NA	NA	NA	24
G	25	0	25	60%	15
H	50	4	46	30%	14
I	50	0	50	15%	8
J	20	3	17	33%	6
K	40	18	22	25%	6
L	53	1	52	10%	5
M	2	2	0	0%	NA
N	150	0	150	0%	0
O	20	2	18	0%	0
P	50	0	50	0%	0
Q	8	8	0	0%	NA
R	150	2	148	0%	0
Total	1044	135	909		257

Sources: Telephone surveys conducted in September 2011
Greenwich Hospital Finance Department Data

Note: Physician F is Cardiovascular Services of Greenwich and represents the patients sent directly to Yale

In September 2011, Greenwich Hospital conducted a telephone survey of cardiologists currently on the Hospital's medical staff. The Hospital also included in its survey the internal medicine practice on the medical staff that refers patients directly for cardiac catheterizations. The surveyed physicians have practices located in Greenwich, Connecticut or in Westchester County, New York. When asked where they currently send patients for cardiac catheterizations, the physicians cited Yale-New Haven Hospital, White Plains Hospital, Columbia, Cornell and Westchester Medical Center.

Physicians were asked to provide the number patients they refer to any facility on an annual basis for cardiac catheterizations. The physicians were asked for the number of patients they currently send to Greenwich Hospital annually for cardiac catheterizations. This was compared to the statistics available in the Greenwich Hospital database and the database statistics were used in the chart above. The physicians were then asked to estimate the number of additional cardiac catheterization patients they would send to

Greenwich Hospital that they currently do not send to Greenwich Hospital for care if the Hospital received approval to offer elective angioplasty without surgical backup and given the cardiac interventionalists on staff at Greenwich Hospital.

Based on the survey responses for the physicians, a calculation was made for each physician of the number of new cardiac catheterizations that each physician would send to Greenwich Hospital if the Hospital provided elective angioplasty. Each calculation was based on the physician's responses and any cardiac catheterizations currently seen at Greenwich Hospital were excluded so that double counting of cardiac catheterizations did not occur. Of the surveyed physicians, twelve (including the cardiology practice discussed below) physicians indicated they would bring new cases to the Hospital. Of the six physicians who do not show any additional volume, two of those physicians already send all their cardiac catheterization patients to Greenwich Hospital. Thus they do not have any additional cardiac patients to send to the Hospital so are listed as "NA". Two of the physicians practice primarily in Manhattan facilities. Two of the physicians are part of a large multi-specialty practice and are discussed below.

Of note, five of the surveyed physicians belong to a large multi-specialty practice in Westchester County. These physicians were asked for additional volume they would send based on the current cardiac interventionalists at Greenwich Hospital. The physicians each gave various volumes but also indicated they would be likely to send more patients if the cardiac interventionalist who is part of their practice was also on the Greenwich Hospital medical staff. As discussed in the CON, the cardiac interventionalist would be able to join Greenwich Hospital's medical staff and perform angioplasties subject to the policies and procedures of the Yale New Haven Heart and Vascular Center (YNHHVC). The cardiac interventionalist of the large multi-specialty practice subsequently submitted a letter to Greenwich Hospital indicating he would send angioplasties to Greenwich Hospital. Any additional cardiac catheterizations from the physicians as a result of their cardiac interventionalist joining the Greenwich Hospital medical staff were not included in the survey results and, therefore, were not double counted in the letter submitted by the cardiac interventionalist. Thus, the letter represents additional angioplasties to Greenwich Hospital not included in the projections included in the CON.

In addition to the above survey data, the cardiology practice that is part of the YNHHS cardiology program at Greenwich Hospital researched the number of patients each year that they send directly to Yale for cardiac catheterizations instead of to Greenwich Hospital. These patients numbered 25, 22, 21 and 25 in FY08-11 respectively for an average of 24 per year. These patients would use Greenwich Hospital if the Hospital provided elective angioplasty services and were, therefore, included in the survey results above listed as Physician F.

Based on the survey results and information above, 257 additional cardiac catheterizations were estimated to be sent to Greenwich Hospital for care if the Hospital provided elective angioplasty services.

The tables below summarize the CON projections as were previously provided.

Angioplasty Volumes at Greenwich Hospital
Historical and Projected Volumes

Volumes	FY08 Actual	FY09 Actual	FY10 Actual	FY11 Actual	Year 1	Year 2	Year 3
Primary Angioplasty Cases	40	40	32	38	38	38	38
Elective Angioplasty Cases To Be Performed at GH (currently sent to other facilities)	0	0	0	0	53	53	53
Elective Angioplasty Cases Transferred or Referred to Another Facility	54	79	64	59	0	0	0
New Referred Angioplasty Cases from Physicians	NA	NA	NA	NA	105	126	151
Total	94	119	96	97	196	217	242
Variance					99	21	25

Source: CHIME database, GH Cardiology Department, YNHH statistics, telephone survey of physicians

Volumes	Year 1	Year 2	Year 3
Inpatient Angioplasties (89.6%)	176	194	217
Outpatient Angioplasties (10.4%)	20	23	25
Total	196	217	242

Source: CHIME database

Greenwich Hospital used the results of the physician survey as well as other data to project the angioplasty volume expected at Greenwich Hospital if the CON for elective angioplasty were approved. The angioplasty projections include primary angioplasty cases currently treated at the Hospital and elective angioplasty cases currently not treated at the Hospital.

Greenwich Hospital currently provides primary angioplasty to patients that meet the criteria for care. For the past several fiscal years, this volume has remained fairly stable. In FY11, the Hospital had 38 primary angioplasty cases. This is the same number as the four year average number of cases. This volume was projected to remain stable over the next several years.

While the Hospital does not provide elective angioplasty at this time, there are patients who present to the Hospital each year that require elective angioplasty. These patients are either transferred or referred to another facility for care. The number of transfers or referrals for the past four fiscal years has been 54, 79, 64 and 59 respectively. Over the past four fiscal years, on average there had been 64 patients per year either transferred or referred to another facility for care. With the approval of this application, Greenwich Hospital would be able to provide elective angioplasty to the majority of these patients and thus save the patients an unnecessary transfer or referral to another facility. These patients are already part of the Greenwich Hospital physician referral patterns established at the Hospital that would continue when the Hospital is approved to provide elective angioplasty care. However, there is a small portion of patients that would need to be transferred or referred to another facility even if Greenwich Hospital was approved to provide elective angioplasty.

In the CPORT E trial, of patients who underwent primary angioplasty, 12% were excluded from randomization after consenting to the study, representing the subgroup who would be transferred to another facility. In reviewing the cases in FY09-11 that were either transferred or referred for care to another facility, it was felt that some of the cases would have been transferred or referred even if Greenwich Hospital was approved to provide elective angioplasty. These percentages for FY09-11 were respectively 12%, 16% and 22% for a three year average of 16.6%. For the projection of elective angioplasty at Greenwich Hospital, the conservative estimate of 16.6% was used, i.e. 83.4% of patients who had been transferred or referred to another facility in the past would be able to receive care at Greenwich Hospital. This percentage applied to the average of 64 patients per year transferred or referred to another facility yielded 53 patients in Year 1 who would be able to stay and receive their care at Greenwich Hospital. Again, to be conservative, this volume was projected to remain stable over the next several years.

Therefore, in Years 1, 2, and 3, there are 91 patients per year (38 emergency angioplasties and 53 elective patients currently transferred or referred elsewhere) who are projected to have either elective or emergency angioplasties at Greenwich Hospital. The projected 91 patients per year are based on the Hospital's actual historical experience and are patients who have come to Greenwich Hospital to seek care.

As discussed above, the Hospital conducted a telephone survey of cardiologists currently on the Hospital's medical staff as well as the large internal medicine practices on the medical staff who refer directly for cardiac catheterizations. These physicians were also asked to estimate the number of additional patients they would send to Greenwich Hospital. Lastly, the cardiology practice that is part of the YNHHS cardiology program at Greenwich Hospital estimated an average of 24 patients per year that would use Greenwich Hospital if the Hospital provided elective angioplasty services. Based on the information above, 257 additional cardiac catheterizations were estimated to be sent to Greenwich Hospital for care if the Hospital provided elective angioplasty services.

In order to estimate the number of angioplasties resulting from the additional cardiac catheterizations, the ratio of angioplasties to cardiac catheterizations was analyzed.

Since primary angioplasties and elective angioplasties have the same codes, it was not possible to separate them into two categories so angioplasty volume includes both primary and elective angioplasty cases. Angioplasty volume and cardiac catheterization volume includes both inpatient and outpatient cases. New York angioplasty and cardiac catheterization outpatient historical volumes were not available from the state of New York for CY08 and for CY11 only the first five months of inpatient and outpatient data was available. Therefore, CY11 New York data was flat line projected to estimate the entire year.

The ratios of angioplasties to cardiac catheterizations were determined for Greenwich Hospital (35.4%), Yale-New Haven Hospital (45.3%), the state of Connecticut (36.3%) and the Greenwich Hospital service area (41.2%). The Greenwich Hospital average included patients transferred or referred to another facility. While the program at Greenwich Hospital will follow all of the policies, procedures and guidelines of the Yale-New Haven Heart and Vascular Center, the New Haven facility is a tertiary hospital and may see a higher rate of angioplasty/sicker patients. To be conservative, an average ratio (41.0%) of the Yale-New Haven Hospital ratio and state of Connecticut ratio was used to estimate the number of angioplasties resulting from the cardiac catheterizations. The 41.0% ratio was applied to the 257 potential cardiac catheterizations to yield an estimated 105 new referred angioplasty cases to Greenwich Hospital in Year 1 from cardiologists on the Hospital medical staff who would previously have sent the cases either to Yale-New Haven Hospital or a New York hospital. It is expected that this volume would increase 21 and 25 angioplasties respectively in Years 2 and 3 as the Greenwich Hospital program becomes established. The increases would represent less than 1 angioplasty per year from the cardiologists on the medical staff of Greenwich Hospital. Since the patients will be referred by the cardiologists on the Greenwich Hospital medical staff, it is expected that the majority of patients will be from New York or Greenwich, Connecticut. The increase in volume will results from several factors including the addition of New York interventional cardiologists who currently do not practice at Greenwich Hospital but have referral relationships with the cardiologists on the Hospital medical staff, increased physician comfort with elective angioplasty care at the Hospital and patient preference for the high quality care offered at Greenwich Hospital. In FY11, inpatient angioplasties were 89.6% of total angioplasties according to the latest available data from the CHIME database. This percentage was used to estimate the distribution of angioplasties at Greenwich Hospital.

ATTACHMENT IV

PATIENT LETTERS OF SUPPORT

Honorable Cristine A. Vogel, Commissioner
Office of Health Care Access
410 Capitol Ave
MS #13HCA
PO Box 340308
Hartford, CT 06134-0308

RECEIVED
2009 FEB 20 P 3:29
CONNECTICUT OFFICE OF
HEALTH CARE ACCESS

February 20, 2009

Dear Commissioner Vogel:

I am forwarding to you by fax letters that have been written to you by patients from Greenwich Hospital in support of the proposed Elective Angioplasty program. These patients are unable to participate in the hearing in Hartford on February 24, 2009 and asked that their letters be delivered to you.

Thank you.

Sincerely,

George Pawlush
VP, Public Relations

LAW OFFICES
SISCA AND SISCA, P.C.
461 WESTCHESTER AVENUE
PORT CHESTER, NY 10573
(914) 937-5000

FRANCIS J. SISCA
PETER F. SISCA*

ARNOLD I. BERNSTEIN
THOMAS E. DECEA*
OF COUNSEL

ANA L. VALENCIA, PARALEGAL

*ADMITTED NY AND CT

TELECOPIER
(914) 937-3019

CT MAILING ADDRESS
P.O. BOX 4461
GREENWICH, CT 06831
(203) 661-4900

February 13, 2009

Honorable Cristine A. Vogel, Commissioner
Office of Health Care Access
410 Capitol Ave.
MS #13HCA
PO Box 340308
Hartford, CT 06134-0308

Re: Elective Angioplasty Program
Greenwich Hospital

Dear Commissioner Vogel,

I am writing to you to request your support for Greenwich Hospital's application to establish an elective angioplasty program as a satellite of the Yale New-Haven Heart and Vascular Center.

As a cardiac patient and as a family member of a cardiac patient (my father), it is very important to me and my family that elective angioplasty be available close to home. The proposed program would ensure that the procedure is administered by highly skilled interventional cardiologists at Greenwich Hospital where we can be followed and cared for by our own doctors. Greenwich Hospital is our hospital of choice. It is proximate to our homes. Being required to go to another hospital for this procedure is very stressful and burdensome, especially to family members. More important, we lose the continuity of care provided by our own doctors.

I was recently hospitalized this past holiday season after failing a stress test in my doctor's office. I had a mild heart attack seven months earlier in Florida where angioplasty was performed and heart damage was virtually nil (luckily the hospital was 5 minutes from my location). In my most recent experience, I was hospitalized on a Tuesday evening the week before Christmas. I was confronted with the choice of having a catheterization in Greenwich Hospital to see whether and where angioplasty was needed (all involved were confident that it was required) requiring a second procedure at another hospital location for the angioplasty to remove any blockages or to be transported to another hospital where the catheterization and angioplasty could be performed as part of the same procedure. I viewed this as no choice and had to leave my doctors and seek

the required procedures at another hospital, with unfamiliar doctors, an hour away from my home. I spent two additional nights in a hospital for a total of three nights (where only one was needed to complete the procedure through discharge) because Greenwich Hospital was not permitted to perform this lifesaving (albeit elective) procedure. My doctors routinely perform these procedures at their other affiliated hospitals. Not only was this a waste of valuable professional time, hospital staff services and resources and but I was caused to expend co-pays for 2 hospitals, other professional care and transportation to the new hospital. Most important, it subjected me to an additional level of risk, i.e. not only the potential risk of undergoing somewhat duplicative invasive procedures for the catheterization and follow-up angioplasty (which I avoided) but the risk attendant to a delay in having the procedure performed and the required transport to another hospital. Thankfully, my doctor's staff and the hospital staff were extremely competent which provided for a smooth, seemless transition to the new hospital.

Greenwich Hospital has proven its ability to provide emergency angioplasty services under life-threatening circumstances. There is no doubt that the hospital can provide the same high quality for an elective angioplasty program. It is my opinion, as a patient and a member of the community served by Greenwich Hospital, that the current status that the Hospital is operating under is stressful and inordinately risky and the community would be much better served and more confident in our hospital if the elective angioplasty program was approved.

Please approve Greenwich Hospital's application to offer elective angioplasty services.

Sincerely,

Peter F. Sisca

ROBERT C. WILLIS

February 17, 2009

Honorable Cristine A. Vogel, Commissioner
Office of Health Care Access
410 Capitol Ave.
MS #13HCA
PO Box 340308
Hartford, CT 06134-0308

Dear Commissioner Vogel,

I am writing to you to express my urgent support for Greenwich Hospital's application to establish an elective angioplasty program as a satellite of the Yale New-Haven Heart and Vascular Center.

As a cardiac patient, it is indeed very important to me as well as my family that elective angioplasty be available close to home. The proposed program would ensure that the procedure is administered by highly skilled interventional cardiologists at Greenwich Hospital where I can be followed by my own doctors. Greenwich Hospital is my hospital of choice. The idea of going to another hospital for this procedure is very stressful and a burden to me and my family. Most importantly, if I am forced to go to another hospital, we would lose the continuity of care provided by my own doctors.

Having had two cardiac events in 2008, that required transfer from Greenwich Hospital to Yale New-Haven Hospital, I can personally attest to the enormous stress of a one hour ambulance ride coupled with the further stress of a new hospital and staff. I should also comment that my family was forced to travel this distance several times a day during my hospital stay. It is an unpleasant experience for the entire family.

Greenwich Hospital has proven its ability to provide emergency angioplasty services under life-threatening circumstances. There is no doubt in my mind that the hospital can provide the same high quality for an elective angioplasty program.

I would appreciate an immediate approval of Greenwich Hospital's application to offer elective angioplasty services.

Sincerely,

Robert C. Willis

88 Silo Circle
Riverside, CT 06878

February 17, 2009

Honorable Cristine A. Vogel, Commissioner
Office of Health Care Access
410 Capitol Ave.
MS #13HCA
PO Box 340308
Hartford, CT 06134-0308

Dear Commissioner Vogel,

I am writing to you to express my support for Greenwich Hospital's application to establish an elective angioplasty program as a satellite of the Yale New-Haven Heart and Vascular Center.

As a cardiac patient it is very important to me and my family that elective angioplasty be available close to home. The proposed program would ensure that the procedure is administered by highly skilled interventional cardiologists at Greenwich Hospital where we can be followed by our own doctors. Greenwich Hospital is our hospital of choice. The idea of going to another hospital for this procedure is very stressful and a burden to me and my family. Most importantly if we are forced to go to another hospital, we would lose the continuity of care provided by our own doctors.

Please know my own situation and when making your decision do take into consideration my own reasons to have an angioplasty program at Greenwich Hospital:

- Twice I have been taken to Greenwich Hospital and then sent to Yale by ambulance through heavy traffic. This is hardly safe for a heart patient.
- Each time I have a need for an angiogram I have to go all the way to Yale even if it is then determined that I do not need the angioplasty after all. I have about two angiograms a year.
- I have missed work and lost income several times because I had to go all the way to Yale.
- When I did have angioplastys at Yale I had to have someone drive me there (about1 hour) and then come back to bring me back home when I was done. This means someone else had to take time off from work also.

- The nearest hospital that recently started doing angioplastys is Stamford Hospital but we are not familiar with it at all. I really don't want to change my Greenwich Hospital doctor at this stage and after he has known me and my case for over ten years.

- I have had many complications since my bypass in 2005 and would be very uncomfortable with another doctor who did not know me and my whole history. I had been to two other cardiologists before I was comfortable with my present doctor.

- We need our cardio care to be convenient for us and not have to travel miles or deal with new doctors . This is not something to be taken lightly.

- Several Greenwich Hospital doctors already perform angioplastys at Yale on a regular basis. They are qualified to do the same in Greenwich.

- Greenwich Hospital is the one we always use. We have the hospital. We need it to be full service for us heart patients so it properly meets our needs. We really need you establish an elective angioplasty program as a satellite of the Yale New-Haven Heart and Vascular Center.

Greenwich Hospital has proven its ability to provide emergency angioplasty services under life-threatening circumstances. There is no doubt that the hospital can provide the same high quality for an elective angioplasty program.

Please approve Greenwich Hospital's application to offer elective angioplasty services.

Sincerely,

Rameela Patel

Rameela Patel

88 Silo Circle
Riverside, CT 06878

February 16, 2009

Honorable Cristine A. Vogel, Commissioner
Office of Health Care Access
410 Capitol Ave.
MS #13HCA
PO Box 340308
Hartford, CT 06134-0308

Dear Commissioner Vogel,

I am writing to you to express my support for Greenwich Hospital's application to establish an elective angioplasty program as a satellite of the Yale New-Haven Heart and Vascular Center.

As a cardiac patient, it is very important to me and my family that elective angioplasty be available close to home The proposed program would ensure that the procedure is administered by highly skilled interventional cardiologists at Greenwich Hospital where we can be followed by our own doctors. Greenwich Hospital is our hospital of choice. The idea of going to another hospital for this procedure is very stressful and a burden to me and my family. Most importantly if we are forced to go to another hospital, we would lose the continuity of care provided by our own doctors.

Please consider my personal situation when making your decision and please establish an angioplasty program at Greenwich Hospital.

- It was suggested that I have an angiogram at Greenwich and then if it was determined that I needed angioplasty I would be sent to Yale by ambulance with the catheter and an anesthesia iv already in me. This is not a safe situation for a heart patient. What if there was traffic or an accident on the way to Yale?

- It is my understanding that between Bridgeport and New Haven there are at least four full service hospitals providing every aspect of cardio treatment. In our area Stamford hospital is the only other hospital that does angioplastys and my cardiologist does not work there

- I have six stents (angioplastys) and have needed emergency treatment on many occasions. I have had to go to Greenwich hospital and then be transferred to Yale. It would have been less traumatic for me to be treated at Greenwich hospital.

- Greenwich hospital should serve its community. It should not have to send its patients to another hospital.

- Cardio care is serious, sensitive and long drawn out. I really don't want to switch from a doctor who has treated me for over ten years and knows my history and knows me well.

- We would really appreciate your allowing Greenwich Hospital to provide us with the services we need. Several Greenwich doctors also perform the same angioplasty procedure at Yale, they are experienced and well qualified.

Greenwich Hospital has proven its ability to provide emergency angioplasty services under life-threatening circumstances. There is no doubt that the hospital can provide the same high quality for an elective angioplasty program.

Please approve Greenwich Hospital's application to offer elective angioplasty services.

Sincerely,

Salim Patel

02/20/2009 FRI 15:07 FAX 203 863 4784 PUBLIC RELATIONS 002/003
02/20/2009 FRI 13:57 FAX 203 622 1872 CARDIOVASCULAR SERVICES 002/003

PETER K. KNUDSEN
1 Spezzano Drive
Riverside, CT 06878
203-637-4104

Honorable Cristine A. Vogel, Commissioner
Office of Health Care Access
410 Capitol Avenue
MS #13HCA
PO Box 340308
Hartford, CT 06134-0308

February 17, 2009

Dear Commissioner Vogel,

I am writing to you to express my support for Greenwich Hospital's application to establish an elective angioplasty program as a satellite of the Yale New-Haven Heart and Vascular Center.

As a cardiac patient, it is very important to me and my family that elective angioplasty be available close to home The proposed program would ensure that the procedure is administered by highly skilled interventional cardiologists at Greenwich Hospital where we can be followed by our own doctors. Greenwich Hospital is our hospital of choice. The idea of going to another hospital for this procedure is very stressful and a burden to me and my family. Most impoitantly if we are forced to go to another hospital, we would lose the continuity of care provided by our own doctors.

In my own personal experience, when I had to undergo a procedure to see if my arteries were blocked they had to do a catherization (die test). Once they did the catherization (die test) and they found I needed a stent I had to have that procedure done in New Haven. There fore, I had to remain lying flat and not moving until I got to New Haven and the second procedure was preformed. The first procedure in Greenwich was in the morning. By the time I got to New Haven for a stent to be put into place it was in the evening. Traffic was at a stand still and my wife was in a car behind the ambulette. The traffic was so bad that the monitors and batteries in the ambulette were going dead. There was not any air conditioning in the ambulette and they ended up having to put the sirens and lights on to get there after a while. My wife traveling

behind me was a emotional wreck by the time we got to New Haven. If the ambulette was in an accident I could have bled to death. The thought of having to go through that all over again is stressful for all involved. If I had the opportunity to have it all done in Greenwich it would have been less of a burden on my family and friends that I had to involve because it was in New Haven. It was my understanding that if I was just 10% more blocked that Greenwich could have done the procedure right there as an emergency basis. I am not sure what the difference is. A person can die on the way to another hospital because of the stress involved in going from one place to another, not to mention the discomfort of not being able to move that part of your body for so many hours. Once I got to New Haven I met with a Doctor that did not know me and I in turn did not know him either. I would have been more comfortable if my own Doctor that started the procedure had been able to finish it.

Greenwich Hospital has proven its ability to provide emergency angioplasty services under life-threatening circumstances. There is no doubt that the hospital can provide the same high quality for an elective angioplasty program.

Please approve Greenwich Hospital's application to offer elective angioplasty services.

Sincerely,

Peter K. Knudsen

PKK/jmk

Public Relations
5 Perryridge Road
Greenwich, CT 06830
Phone: (203) 863-3126
Fax: (203) 863-4784

RECEIVED
2009 FEB 23 P 2:56
CONNECTICUT OFFICE OF HEALTH CARE ACCESS

GREENWICH HOSPITAL
YALE NEW HAVEN HEALTH

Fax

To: HON. CRISTINE A. VOGEL
OFFICE OF HEALTH CARE ACCESS

From: George Pawlush
Vice President
Public Relations

Fax: 860-418-7053

Date: 2/23/09

Phone:

Pages:

Re:

CC:

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

•Comments:

HERE ARE TWO ADDITIONAL LETTERS IN SUPPORT OF OUR ELECTIVE ANGIOPLASTY PROGRAM at GREENWICH HOSPITAL.

GEORGE PAWLUSH
VP, Public Relations

This message originates from Yale New Haven Health System. The information contained in this message may be privileged and confidential. If you are the intended recipient, you must maintain this message in a secure and confidential manner. If you are not the intended recipient, please notify the sender immediately and destroy this message. Thank you.

RECEIVED
2009 FEB 23 P 2:56
CONNECTICUT OFFICE OF
HEALTH CARE ACCESS

Honorable Cristine A. Vogel, Commissioner
Office of Health Care Access
410 Capitol Ave.
MS #13HCA
PO Box 340308
Hartford, CT 06134-0308

February 20, 2009

Dear Commissioner Vogel,

I am writing to you to express my support for Greenwich Hospital's application to establish an elective angioplasty program as a satellite of the Yale New-Haven Heart and Vascular Center.

As a cardiac patient it is very important to me and my family that elective angioplasty be available close to home The proposed program would ensure that the procedure is administered by highly skilled interventional cardiologists at Greenwich Hospital where we can be followed by our own doctors. Greenwich Hospital is our hospital of choice. The idea of going to another hospital for this procedure is very stressful and a burden to me and my family. Most importantly if we are forced to go to another hospital, we would lose the continuity of care provided by our own doctors.

The difference between elective and emergency may seem trivial, however, here is my real life example of the vast difference: on Monday at 6pm my cardiologist said that he was certain that I had blockage in my artery and needed immediate surgery the next day. I was scheduled to go to Yale Tuesday at 7am. He said, "go home...if you have a heart attack tonight I can operate in Greenwich on an emergency basis, otherwise I'll see you at Yale tomorrow." I'm not sure what was worse: the stress of waiting for a heart attack to happen at home so that I could be treated immediately or the stress of waiting what felt like a lifetime to drive to Yale and be treated.

I'm 45. I had 95% blockage in the LAD. I don't smoke, drink or have genetic problems. I have no other blockage. Chances are between 45 and say 75, despite a good diet, exercise and lower stress, I may be back. I would like to go to Greenwich.

Greenwich Hospital has proven its ability to provide emergency angioplasty services under life-threatening circumstances. There is no doubt that the hospital can provide the same high quality for an elective angioplasty program.

Please approve Greenwich Hospital's application to offer elective angioplasty services.

Sincerely,

Stephen J. Petuck

Honorable Cristine A. Vogel, Commissioner
Office of Health Care Access
410 Capitol Avenue
MS # 13HCA
P.O. Box 340308
Hartford, CT 06143-0308

February 19, 2009

Dear Commissioner Vogel,

I am writing to express my support for the Greenwich Hospital's application to establish an elective angioplasty program as a satellite of the Yale New Haven Heart and Vascular Center.

I recently had to be transported to Yale New Have Hospital to have an angioplasty performed. The circumstances were not life-threatening; I had an angiogram which resulted in a blockage at Greenwich Hospital. Rather than completing the process with an angioplasty, it was required that I be transported to Yale New Haven. At the time I was stable and this was part of routine procedure. However, having to go far from home to undergo this procedure was very stressful to me and my family. It seems to me that transporting patients for routine procedures could be avoided by simply implementing the angioplasty program.

Greenwich Hospital has proven its ability to provide emergency angioplasty services under life-threatening circumstances. It would seem that there is no doubt that the hospital can provide the same high quality for an elective program.

As a cardiac patient, it is critical to me and my family that angioplasty be available to me close to home. The proposed program would ensure that the procedure is administered by highly skilled cardiologists at Greenwich Hospital where patients could be monitored by their own physicians. Greenwich Hospital is most convenient to my home and the hospital of my choice. More importantly, if I have no other option but to go to another hospital, I would be losing continuity of care provided by my own physicians.

Please approve Greenwich Hospital's application to offer elective angioplasty services.

Sincerely,

Ed Nelson

JEFFERS COWHERD

RECEIVED
AUG - 2 2012
OFFICE OF HEALTH CARE ACCESS

JEFFERS COWHERD P.C.
ATTORNEYS AT LAW

55 WALLS DRIVE
FAIRFIELD, CT 06824
203-259-7900
203-259-1070 FAX
WWW.JEFFERS-LAW.COM

FACSIMILE TRANSMITTAL SHEET

TO: Joanne V. Yandow, Esq. Hearing Officer	FACSIMILE NO.: 860-418-7053
CC: Kimberly Martone	FACSIMILE NO.: 860-418-7053
FROM: Stephen M. Cowherd, Esq.	DATE: 8/2/12
RE: 12-31748-CON	TOTAL NO. OF PAGES INCLUDING COVER: 11

NOTES/COMMENTS:

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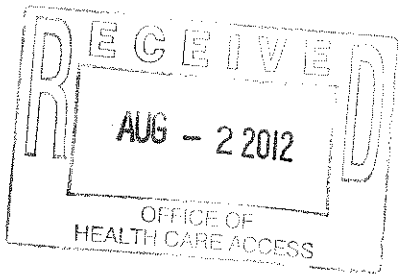
JEFFERS
COWHERD

JEFFERS COWHERD P.C.
ATTORNEYS AT LAW

55 WALLS DRIVE
FAIRFIELD, CT 06824
203-259-7900
203-259-1070 FAX
WWW.JEFFERS-LAW.COM

STEPHEN M. COWHERD
Email: scowherd@jeffers-law.com

August 2, 2012



VIA FACSIMILE (860) 418-7053

Joanne V. Yandow, Esq.
Hearing Officer
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS#13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: Docket Number: 12-31748-CON; Proposal to Establish and Operate an Elective Angioplasty Program without Onsite Surgical backup at Greenwich Hospital – Late File Submission

Dear Hearing Officer Yandow:

Attached please find Intervenor Stamford Hospital's Objection to and Motion to Strike Applicants' Late File Submission in the above-referenced docket. The original and two (2) copies are being sent to the Office of Health Care Access via Federal Express for delivery tomorrow.

Please contact the undersigned should you have any questions.

Respectfully submitted,

Stephen M. Cowherd

SMC:am
Enclosures

(5134-038-00038445.DOC -)

BEFORE THE OFFICE OF HEALTH CARE ACCESS DIVISION OF THE DEPARTMENT OF PUBLIC HEALTH	:	Docket No. 12-31748-CON
IN RE APPLICATION OF YALE-NEW HAVEN HOSPITAL AND GREENWICH HOSPITAL TO ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM AT GREENWICH HOSPITAL	:	August 2, 2012

INTERVENOR STAMFORD HOSPITAL'S OBJECTION TO AND MOTION TO STRIKE APPLICANTS' LATE FILE SUBMISSION

Pursuant to Regulations of Connecticut State Agencies (R.C.S.A.) § 19a-9-6(c)(3), Intervenor The Stamford Hospital hereby objects to and moves to strike Applicants' Late File 1 and accompanying correspondence, dated July 26, 2012 (collectively, "Late File 1") submitted on behalf of Applicants Yale-New Haven Hospital ("YNHH") and Greenwich Hospital ("Greenwich"). Applicants have failed to file a copy of a community needs assessment for cardiac services as ordered by OHCA. (Transcript, pages 82-83, Attachment A) Instead, Applicants attempt to modify Greenwich CEO Frank Corvino's sworn testimony at the Public Hearing that Greenwich had conducted such an assessment within the past four years and to submit other documents which they claim support the need for the proposed elective angioplasty program. As more fully set forth below, since the material submitted is non-responsive to OHCA's order, Late File 1 should be stricken in its entirety and OHCA should find that no community needs assessment was done in connection with Applicants' proposal.

OHCA'S REQUEST FOR COPY OF COMMUNITY NEEDS ASSESSMENT

At the Public Hearing, Mr. Corvino testified that Greenwich had done several community needs assessments, the last one specifically discussing cardiac services having been completed within the previous three to four years (*see* Transcript, pages 82-83, Attachment A). OHCA staff then asked Mr. Covino if Greenwich would be able to provide OHCA with a copy of this community needs assessment and Mr. Corvino responded in the affirmative. *Id.* Hearing Officer Yandow then ordered that a copy of Greenwich's community needs assessment be submitted as Applicants' Late File 1 within two weeks. *Id.*

APPLICANTS' LATE FILE 1

Because Applicants' failed to contemporaneously serve Stamford Hospital with Late File 1 as contemplated by R.C.S.A. § 19a-9-6(c), Intervenor only recently learned of the letter from YNHH's Executive Vice President for Strategy and System Development addressed to Hearing Officer Yandow which attempts to explain that when Mr. Corvino testified that Greenwich had conducted a community needs assessment for cardiac services within the last three or four years, he was actually "referring to several analyses which have been conducted either by or in association with Greenwich Hospital which he feels support public need for the requested elective angioplasty program." Correspondence from Gayle Capozzalo to Hearing Officer Yandow, dated July 26, 2012. Intervenor respectfully points out that a witness' sworn testimony at public hearing cannot be modified by a letter from another member of Applicants' staff. Accordingly, Ms. Capozzalo's correspondence purporting to clarify Mr. Corvino's testimony should be stricken.

It is clear from Applicants' Late File 1 submission that, contrary to Mr. Corvino's testimony (Transcript, pages 82-83, Attachment A), Greenwich has not undertaken a community

needs assessment for cardiac services. In the absence of a document responsive to OHCA's request, Applicants seek to late file other documents which they claim support their Application, as follows: (1) a Marketstrategies consumer survey; (2) a draft Navigant Consulting report on physician supply in the Greenwich service area; (3) a document with a footer dated July 20, 2012 (three days after the public hearing) that expands on the telephone survey referenced at page 33 of Applicants' CON Application; (4) a 2011 Greenwich United Way Community Planning Council report that Applicants appear to have had no hand in producing (only an internet link to this document was provided); and (5) a series of patient letters from 2009 apparently written in support of Applicants proposal under Docket No. 08-31210-CON that OHCA previously denied.

LATE FILE 1 IS WHOLLY UNRESPONSIVE

Not a single one of Applicants' submissions qualifies as a community needs assessment for cardiac services generally, no less a needs assessment for the hospital-based elective angioplasty program they have proposed. To the degree that Applicants believe the non-responsive materials in Late File 1 support their proposal, the documents should have been included in their CON Application.

OHCA's Policies and Procedures at Section VIII(a)(5) specifically requires that "[t]he [CON] application form should be filled out in its entirety and all supporting documents should be attached to the application and referenced as either an attachment or exhibit in the order in which they appear in the application." (emphasis added) The Applicants had every opportunity to submit materials supporting their Application prior to the Public Hearing, and in fact, some of the material contained in Late File 1 is duplicative of material previously furnished. To submit this largely unsupported documentation now as a non-responsive Late File exhibit is improper and ignores the procedural rules OHCA has established.

Additionally, as noted above, the material contained in Late File 1 has no relevance to assessing community need for the cardiac services that are the subject of the CON Application. The first attached document is a marketing survey which purports to reflect consumer preference for hospital providers in the Greenwich area and the close competition between Greenwich and Stamford Hospitals for cardiac patients, but it says nothing about the need for services. The second document is a consultant's report apparently prepared as part of Greenwich's physician recruiting programs which does not speak to community need for any hospital-based services. The third document provides additional information regarding Applicants' physician telephone survey which again does not speak to "community need" for the proposed service. The link to the United Way document, which does not appear to have any association with Applicants, also does not speak to any needs for elective angioplasty, and the letters relating to the previous CON Application that OHCA denied in 2009 certainly do not qualify as a community needs assessment. In sum, submitting these extraneous materials now, under the veil that they somehow relate to a community needs assessment, is unresponsive to OHCA's request and improper.

Finally, Ms. Cappozzalo's letter argues that other information in the record supports Mr. Corvino's testimony. Once again, there is nothing in the record to support Mr. Corvino's sworn testimony at the Public Hearing that Greenwich undertook a community needs assessment for cardiac services within the last four years. Ms. Cappozzalo's arguments are non-responsive to OHCA's order and should be stricken as well.

CONCLUSION

WHEREFORE, for the foregoing reasons, Intervenor's objection should be sustained and Applicants' Late File 1 should be stricken in its entirety and OHCA should find no community needs assessment was done in connection with Applicants' proposal.

THE STAMFORD HOSPITAL

BY _____

Stephen M. Cowherd
Jeffers Cowherd P.C.
55 Walls Drive
Fairfield, CT 06824
Tel.: 203-259-7900
Fax: 203-259-1070
scowherd@jeffers-law.com
Its Attorney

CERTIFICATE OF SERVICE

This is to certify that a true and accurate copy of the foregoing was sent by U.S. Mail, postage prepaid this 2nd day of August 2012 to:

Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.
265 Church Street
New Haven, CT 06510
jgroves@uks.com

Jean Ahn
System Director
Yale-New Haven Hospital
Planning & Business Development
20 York Street (Howe 3)
New Haven, CT 06504
jean.ahn@ynhh.org

Stephen M. Cowherd

Attachment A

on that local community to deal with their heart attack, if you will, in the middle of the night. They're not going to be traveling to another place. So having a strong heart program really bolsters your position in the community's eyes as a really good institution.

So regardless of whether the incidents is higher or lower, if you've got the illness you want to know that the very best is available in your community.

MR. LAZARUS: When was the last time, Mr. Corvino, a community needs assessment was done? Because you mentioned there were several done.

MR. CORVINO: I would say in the last three or four years.

MR. LAZARUS: And does it specifically discuss cardiac services?

MR. CORVINO: Yes.

MR. LAZARUS: Would you be able to provide OHCA a copy of that?

MR. CORVINO: Sure.

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HEARING OFFICER YANDOW: Okay. I'd like to order that to be produced. How much time do you need to produce that?

MR. CORVINO: A couple of weeks?

HEARING OFFICER YANDOW: Okay. Two weeks from today then?

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Again, you state in your prefiled testimony that, you know, we need to ensure providing care in a cost-effective and efficient manner. In relation to that, could you please state to whether you think a service that may be an additional program, for example, elective PCI in the region, would that be considered cost-effective, and/or how would you consider that to be efficient?

MR. CORVINO: Well, I think that having patients be treated in their community where they go for services and not having to leave the community and have a lot of duplication is very, very important. And there is a significant amount of cost savings when patients don't have to be transferred.

You know, I -- you know, I come to you today as the CEO of Greenwich Hospital, but I also come to you as a patient and I just want to relate a story, which I related the last time we were here. In 2005 I was one of those people who had chest pain, who went to

Greer, Leslie

From: Greer, Leslie
Sent: Friday, August 03, 2012 10:29 AM
To: 'JGroves@uks.com'
Cc: Lazarus, Steven
Subject: Yale New Haven Hospital and Greenwich Hospital - Objection to Motion
Attachments: 31748.pdf

Tracking:

Recipient	Delivery	Read
'JGroves@uks.com'		
Lazarus, Steven	Delivered: 8/3/2012 10:29 AM	Read: 8/3/2012 10:36 AM

Attached is an objection to motion and to strike applicant's late file submission for Yale New Haven Hospital and Greenwich Hospital (DN: 31748-CON).

Leslie M. Greer
CT Department of Public Health
Office of Health Care Access
410 Capitol Avenue, MS#13HCA
Hartford, CT 06134
Phone: (860) 418-7013
Fax: (860) 418-7053
Website: www.ct.gov/ohca

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COWHERD

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ATTORNEYS AT LAW

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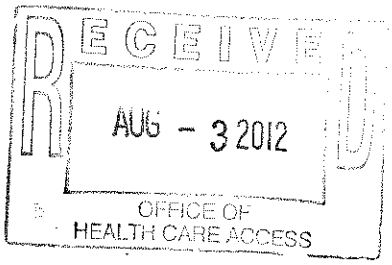
August 2, 2012



VIA FEDERAL EXPRESS

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SMC:am
Enclosures

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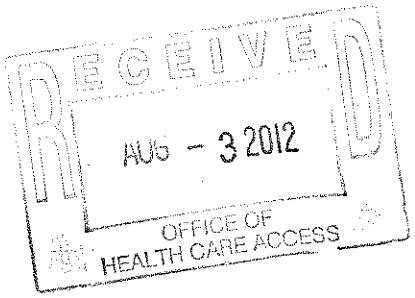

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Its Attorney

CERTIFICATE OF SERVICE

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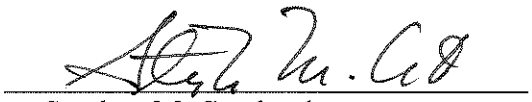
Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.
265 Church Street
New Haven, CT 06510
jgroves@uks.com

Jean Ahn
System Director
Yale-New Haven Hospital
Planning & Business Development
20 York Street (Howe 3)
New Haven, CT 06504
jean.ahn@ynhh.org



Stephen M. Cowherd

Attachment A

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Greer, Leslie

From: Lazarus, Steven
Sent: Monday, August 13, 2012 7:11 AM
To: Jennifer Groves; Stephen Cowherd (SCowherd@jeffers-law.com)
Cc: Nancy Rosenthal (Nancy.Rosenthal@greenwichhospital.org); 'Nancy Hamson' (Nancy.Hamson@greenwichhospital.org); Ahn, Jean; Marc Kosak (Marc.Kosak@greenwichhospital.org); Karen Banoff; Greer, Leslie
Subject: RE: Greenwich Hospital Elective Angioplasty - Docket No. 12-31748-CON

Thank you Attorney Groves. We'll place a copy of this in the original file.

Steven

Steven W. Lazarus
Associate Health Care Analyst
Office of Health Care Access
Department of Public Health
410 Capitol Avenue
Hartford, CT 06134
Phone (Direct): 860.418.7012
Fax (Main): 860.418.7053

From: Jennifer Groves [mailto:JGroves@uks.com]
Sent: Friday, August 10, 2012 4:24 PM
To: Lazarus, Steven; Stephen Cowherd (SCowherd@jeffers-law.com)
Cc: Nancy Rosenthal (Nancy.Rosenthal@greenwichhospital.org); 'Nancy Hamson' (Nancy.Hamson@greenwichhospital.org); Ahn, Jean; Marc Kosak (Marc.Kosak@greenwichhospital.org); Karen Banoff
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Steve,

Attached is Applicants' Reply to Intervenor Stamford Hospital's Objection to and Motion to Strike Applicants' Late File Submission. An original and two (2) copies have been sent via Federal Express for Monday delivery. **Attorney Cowherd is copied on this email and was served by regular mail as well.**

Please feel free to call with any questions.

Thanks,
Jen

Jennifer L. Groves, Esq.
Principal
Updike, Kelly & Spellacy, P.C.
One Century Tower
265 Church Street
New Haven, CT 06510
Office (203) 786.8316
Cell (203) 927.8122
Fax (203) 772.2037
www.uks.com



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Greer, Leslie

From: Lazarus, Steven
Sent: Monday, August 13, 2012 11:27 AM
To: Greer, Leslie
Subject: FW: Greenwich Hospital Elective Angioplasty - Docket No. 12-31748-CON
Attachments: 20120810152418465.pdf

Please add to the file.

Steve

Steven W. Lazarus
Associate Health Care Analyst
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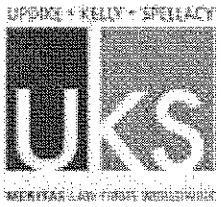

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(f) 203.772.2037
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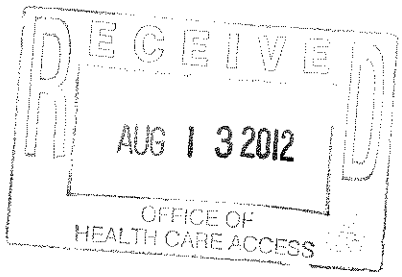
VIA ELECTRONIC MAIL & FEDERAL EXPRESS



Joanne V. Yandow, Esq.
Hearing Officer
Office of Health Care Access
Department of Public Health
410 Capitol Avenue, MS #13HCA
P.O. Box 340308
Hartford, CT 06134-0308

Re: Docket No. 12-31748-CON
Proposal to Establish & Operate an Elective Angioplasty Program at Greenwich Hospital

Dear Hearing Officer Yandow,

This office represents Greenwich Hospital and Yale-New Haven Hospital in connection with the above-referenced CON request. Attached is a copy of my clients' Reply to Intervenor Stamford Hospital's Objection to and Motion to Strike Applicants' Late File Submission. An original and two (2) copies of the reply have been sent via Federal Express for Monday delivery.

Please let me know if you require anything further.

Very truly yours,

Jennifer L. Groves

cc: Gayle Capozzalo
Frank Corvino
Stephen M. Cowherd, Esq.

Updike, Kelly & Spellacy, P.C.
One Century Tower • 265 Church Street • New Haven, CT 06510 (t) 203.786.8300 (f) 203.772.2037 www.uks.com

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS DIVISION

IN RE: ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM AT GREENWICH HOSPITAL	DOCKET NO. 12-31748-CON
	AUGUST 10, 2012

GREENWICH HOSPITAL AND YALE-NEW HAVEN HOSPITAL'S REPLY TO INTERVENOR STAMFORD HOSPITAL'S OBJECTION TO AND MOTION TO STRIKE APPLICANTS' LATE FILE SUBMISSION

Greenwich Hospital ("Greenwich") and Yale-New Haven Hospital ("YNHH") (collectively "Applicants"), Applicants in the above-referenced matter, submit this reply to the Intervenor Stamford Hospital's Objection to and Motion to Strike Applicants' Late File Submission, dated August 2, 2012 ("Objection"). The Objection, which is replete with inaccuracies and omissions and is not supported by law or the practices of OHCA, should be overruled and The Stamford Hospital's ("TSH") Motion to Strike should be denied.

TSH makes the following claims and arguments in its Objection: (1) Applicants failed to serve TSH with a copy of their late file submission; (2) Applicants' late file submission does not include a "community needs assessment" and therefore is non-responsive to OHCA's request; (3) Applicants are not entitled to late file any information that existed at the time of the initial CON submissions and could have been included in those submissions; (4) Applicants seeks to modify the

sworn testimony given by Greenwich Hospital President Frank Corvino at the July 17, 2012 public hearing; (5) Applicants' late file submission improperly references information already in the record of this matter; and (6) Applicants' late file submission does not support a clear public need for an elective angioplasty program at Greenwich Hospital. Each and every one of TSH's claims and arguments is without merit. None should be considered by OHCA in evaluating this proposal.

1. Applicants Served TSH With a Copy of Their Late File Submission

TSH claims that Applicants "failed to contemporaneously serve" the hospital with their late file submission and that TSH "only recently learned" of the filing (Objection, p. 2). Applicants hand delivered their late file submission to OHCA on Friday, July 27th, four days before the July 31st filing deadline set by Hearing Officer Yandow. Also on July 27th, Applicants sent Attorney Stephen M. Cowherd, counsel of record for TSH, a copy of the late file submission via United States mail. Service by United States mail is permitted by Section 19a-9-6(c) of the Regulations of Connecticut State Agencies. This is the same form of service used by Attorney Cowherd to transmit the Objection to the undersigned counsel. In the unlikely event that Attorney Cowherd did not receive Applicants' mailing, TSH was clearly able to obtain a copy of the Late File submission from OHCA and had sufficient time to formulate and file a response.

2. Applicants Have Provided OHCA With "Community Needs Assessments" and Other Information Responsive To the Agency's Request

TSH goes to great lengths arguing that the documents submitted by Applicants as late file do not constitute a "community needs assessment" and are not responsive to OHCA's request. This argument fails on both fronts. First, there are no specific requirements for a "community needs

assessment" set forth in any of the OHCA statutes or regulations, so TSH cannot claim that the requirements have not been met. Second, the documents provided by Applicants were entirely responsive to OHCA's request, which is apparent if you read the complete public hearing transcript around the question and not just the excerpt attached by TSH.

TSH makes the bold and entirely unsubstantiated statement that "[n]ot a single one of Applicants' submissions qualifies as a community needs assessment" for the CON proposal (Objection, p. 3). However, nowhere in its filing does TSH explain what a "community needs assessment" is and why Applicants' submissions are not considered community needs assessments. This is because the OHCA statutes and regulations do not prescribe a specific form of community needs assessment. Assessing community need is a process left to Applicants, who have the burden of supporting their request for permission to establish a service and proving their case-in-chief for a CON. For TSH to claim that the studies and assessments included in Applicants' late file submission are not community needs assessments, without providing any support for that proposition, is meaningless.

Moreover, Applicants' late file submission was entirely responsive to OHCA's request for information. A more complete excerpt of the public hearing transcript is attached as Exhibit A. It shows that the question regarding whether Greenwich Hospital conducted a community needs assessment originated with OHCA Analyst Steven Lazarus' review of Mr. Corvino's prefile testimony. Mr. Lazarus cites to (paraphrases) the following statement made by Mr. Corvino on page 682 of his testimony:

> *We are committed to providing the services that our communities have come to rely on us for and will need in the future.*

Mr. Lazarus then goes on to ask:

> *Was there a community needs assessment done for you to figure out what the community needs? Was there a study that the hospital had performed?*

Finally, Mr. Corvino responds:

> *Well, yes. I mean, we've done many community needs assessments throughout the years.*

Applicants' submission to OHCA included a number of documents, which comprise the "community needs assessment" to which Mr. Corvino was referring. These include studies done by or in association with Greenwich Hospital, which show among other things, that the community relies on Greenwich for cardiac care. The significance of each document to Applicants' assessment of "community need" is explained in the late file submission. These are analyses, studies and surveys that Greenwich Hospital relied on in making the decision to pursue an elective angioplasty program. They reflect the needs and preferences of the patient and physician communities around cardiac services and, by extension, the proposed program. It is true that some of this information was already provided in the CON, however, Applicants thought it would be worth highlighting and/or clarifying the information for OHCA, as it supports community need for the proposal. OHCA has historically given applicants tremendous latitude in determining what information is responsive to requests for supporting documentation in a CON proceeding (i.e. needs assessments, market share analyses, public health information, etc.) and Applicants ask that they be afforded the same latitude in this matter.

3. Applicants Are Entitled To Late File Information Upon OHCA's Request

TSH argues that Applicants should be precluded from offering the late file submission as evidence because the information should have been included in their CON application. As support, TSH cites the OHCA Policies & Procedures, which provided that all supporting evidence should be attached to the application and referenced therein. However, the very nature of a late file submission is to provide "late" evidence, after the CON has been deemed completed and the public hearing has taken place, at OHCA's request. As TSH and its counsel are well aware, OHCA often asks for information in a late file that existed at the time an application was filed (i.e. historical volume), but that was not included in the CON submissions. Here, OHCA asked for information that it knew to be as much as 3 to 4 years old (see Exhibit A attached). The agency clearly understood in making its request that the information could have been provided previously, but was not. Still, OHCA made the request of Applicants and they have responded, as ordered.

4. Applicants Do Not Seek To Modify the Sworn Testimony of Frank Corvino

TSH claims that by way of the late file submission, Applicants are attempting to modify the sworn testimony of Mr. Corvino through testimony from Gayle Capozzalo, Executive Vice President, Strategy and System Development for the Yale New Haven Health System. However, the very language of Ms. Capozzalo's letter belies this claim. Regarding Mr. Corvino's testimony about the community needs assessment, she states that upon further discussion with Mr. Corvino, "he indicated he was referring to several analyses which have been conducted either by or in association with Greenwich Hospital which he feels support public need for the requested elective angioplasty program." Mr. Corvino was simply clarifying what he meant when he offered to provide OHCA with

a "community needs assessment." As President and CEO of Greenwich Hospital, Mr. Corvino relied on planning and development staff to provide OHCA with the details of the assessments. Applicants do not claim that Mr. Corvino misspoke at the hearing, nor are they trying to alter the substance of his testimony in any way. The purpose of Ms. Capozzalo's letter was simply to clarify which documents Mr. Corvino was referring to when he said that several "community needs assessments" had been conducted over the years involving cardiac services.

5. Late File Information Already In the Record Should Not Be Stricken

Applicants included reference in their late file submission to certain information already contained in the record of this matter, either directly or through OHCA's administrative notice of past dockets. This information was included to show that Applicants had, in fact, assessed "community need" in advance of this CON application being filed. Applicants wanted to make this clear to OHCA, particularly given the agency's request for a copy of any "community needs assessment" undertaken by Greenwich Hospital. Reference to this information in the late file submission is not in any way prejudicial to TSH, which had an opportunity to rebut the information the first time it was presented, as well as through its latest submission.

6. Applicants' Late File Submission Supports the Clear Public Need For an Elective Angioplasty Program at Greenwich Hospital

TSH argues that the late file information submitted by Applicants has no relevance to an assessment of "community need" for the cardiac services that are the subject of the CON. Applicants stand by their submission and the relevance of each document contained therein to their evaluation of need for an elective angioplasty program at Greenwich Hospital. The information is reflective of a

need and desire on the part of physicians and patients to have access to high-quality elective angioplasty services within their community, where they are presenting for cardiac services now even without an elective angioplasty program in place. TSH's suggestion that Greenwich Hospital did not conduct any "community needs assessment," and that this somehow justifies denying the CON request, is not supported by the evidence.

WHEREFORE, for the foregoing reasons Applicants request that Intervenor Stamford Hospital's Objection to and Motion to Strike Applicants' Late File Submission be overruled/denied.

Respectfully Submitted,

GREENWICH HOSPITAL
YALE-NEW HAVEN HOSPITAL

By: _____

JENNIFER L. GROVES, ESQ.
Updike, Kelly & Spellacy, P.C.
265 Church Street
One Century Tower
New Haven, CT 06510
Tel: (203) 786-8300
Fax (203) 772-2037

CERTIFICATION

I hereby certify that a copy of the foregoing has been sent via email and United States mail, postage prepaid, this 10th of August, 2012 to the following:

Stephen M. Cowherd
Jeffers Cowherd
5 Walls Drive
Fairfield, CT 06824

Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.

EXHIBIT A

during medical care, correct?

DR. HOWES: Yes.

HEARING OFFICER YANDOW: Any other questions of Dr. Howes?

MS. MARTONE: No.

MR. LAZARUS: Thank you. I have a couple questions of Mr. Corvino. Good morning Mr. Corvino.

MR. CORVINO: Good morning.

MR. LAZARUS: On page 681 of the prefile, you state, that this program will reduce overall costs of angioplasty care in the Connecticut health system. What did you mean by that when you state that?

MR. CORVINO: In addition to what Dr. Howes has already said, you know, when we talk about transferring patients out there is a cost to that. And I think he articulated very well in that we've got to redo another admission and there's an ambulance charge to transfer the patient. So we calculate the value of that to be somewhere around $8,000. And if you multiply that by the number of cases we transfer out it's close to half a million dollars that could be saved. Without counting all of the subjective savings that would go into the patient's psyche for not having to be transferred.

MR. LAZARUS: What's the percentage of

patients that come in for cath. or some sort of a need, an elective that's considered to be emergency transport?

MR. CORVINO: I don't have that number. Does somebody else have a number?

MR. LAZARUS: I know you mentioned -- for example, in 53 cases, for example, you have based your testimony on, those 53 cases, what's the total number of cases that you put those 53 cases on?

MS. GROVES: Are you talking about the number that still need to be transferred anyway and wouldn't be able to stay?

MR. LAZARUS: Well, is that what you're referring to in your testimony, when you say emergency transport?

MR. CORVINO: Procedures that could not be done at Greenwich under the current regulations.

MS. GROVES: Under the current protocols.

MR. LAZARUS: Okay. Under the current protocols. But I'm saying, considering that this is an elective procedure, not every -- not every procedure that can be done at the hospital is considered an emergency transport, am I correct on that?

MR. CORVINO: Can Chris answer that? He's got more expertise.

MR. LAZARUS: Sure.

DR. HOWES: Again, when we use the term elective, it is a misnomer, I mean, no one elects to have a heart procedure, you know, this is serious stuff. And there are different things. Patients who come in with an acute coronary state syndrome and are sick, and you know, may end up hypotensive with a balloon pump, they're still being called elective angioplasties in this realm, in this discussion. So they're not all elective. Now, that said, some of them are much more stable and in fact are outpatients. I would say about half of the outpatients that we do a diagnostic cath. on in Greenwich, we end up transferring because we've already put, you know, entered arterial access, we have access to the arterial system, we transfer them and they'll end up getting the angioplasty the same day. The other half, we stopped, we regroup, and they go back up to New Haven or to New York Presbyterian some other day. So that's of the outpatient elective angioplasties, about half of them.

And then about half of those patients are actually inpatient, you know, not stable patients. So I'm making these numbers up, I don't have them off the top of my head, but my sense is of those, 53 number that's being reported, I would say about three quarters

of those patients go by ambulance or helicopter or something like that. Does that answer, what your asking?

MR. LAZARUS: That helps, yes. That gets it. Thank you. Mr. Corvino, are you -- let's just say those 53 cases you mentioned, you said there is about an $8,000 cost. $1,000 for the transport and about 7,000 for the admission and angioplasty. What's made up of the $7,000 cost that you're talking about?

MR. CORVINO: You know, that's the -- that's the charge, the average charge that goes along with that procedure.

MR. LAZARUS: Would that charge --

MR. CORVINO: And, you know, it may not be one-to-one with costs at the second facility we're talking about.

MR. LAZARUS: -- would there not be a charge at your facility if the service was here?

MR. CORVINO: But it would be much less because of the lack of transportation cost.

MR. LAZARUS: So it would be a savings of $1,000, not 8,000?

MR. CORVINO: Yeah, but you're also duplicating services at the other place.

MR. LAZARUS: Okay. So you're duplicating

services, I understand --

MR. CORVINO: Plus transportation.

MR. LAZARUS: -- but only the charge for the angioplasty, if it was approved, an elective angioplasty at Greenwich Hospital would be less than 7,000?

MR. CORVINO: I don't know that we have a charge code for that yet.

MR. LAZARUS: You also made a statement on the same page that, you know, we're committed to provide services that our community have come to rely on us and will need in the future. Was there a community needs assessment done for you to figure out what the community needs? Was there a study that the hospital had performed?

MR. CORVINO: Well, yes. I mean, we've done many community needs assessments throughout the years. Clearly, cardiology is a very important part of any institution's make up. And with the growing population and the incidence of heart attack in the U.S., you know, it's clear to us that we, you know, we have to improve and make sure that we've got all of the services that our community relies on on a regular basis. And we have saved many lives through the primary angioplasty

program from the communities we serve. And clearly, as Dr. Howes mentioned earlier, if we are able to do elective it'll make us better.

If you go back to when United Hospital closed in New York, about seven or eight years ago, we saw a huge increase in usage of our emergency room to the point where we went from 15 percent of our patients coming from Westchester to now 43 percent of our patients coming from Westchester County in New York, that made us a better institution. It made our emergency room better. It made our clinicians better. And we anticipate the same thing will happen here.

MS. MARTONE: Now, Mr. Corvino, to your knowledge the incidents of heart disease you just mentioned, is it higher in the Greenwich -- the Greenwich service area compared to other areas of the state?

MR. CORVINO: You know, I don't know the answer to that question. But what I can tell you is that when you look at heart disease and the potential for heart attack that's probably, number one, what frightens patients the most. And we've, you know, we've noticed that even through some of our fundraising efforts, even if people are affiliated with a New York hospital and they live in a local community they're are going to rely

on that local community to deal with their heart attack, if you will, in the middle of the night. They're not going to be traveling to another place. So having a strong heart program really bolsters your position in the community's eyes as a really good institution.

So regardless of whether the incidents is higher or lower, if you've got the illness you want to know that the very best is available in your community.

MR. LAZARUS: When was the last time, Mr. Corvino, a community needs assessment was done? Because you mentioned there were several done.

MR. CORVINO: I would say in the last three or four years.

MR. LAZARUS: And does it specifically discuss cardiac services?

MR. CORVINO: Yes.

MR. LAZARUS: Would you be able to provide OHCA a copy of that?

MR. CORVINO: Sure.

MR. LAZARUS: OCHA would like to accept that as --

HEARING OFFICER YANDOW: Okay. I'd like to order that to be produced. How much time do you need to produce that?

UKS
MERITAS LAW FIRMS WORLDWIDE

Jennifer L. Groves
(t) 203.786.8316
(f) 203.772.2037
jgroves@uks.com

August 10, 2012

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VIA ELECTRONIC MAIL & FEDERAL EXPRESS

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EXHIBIT A

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MR. LAZARUS: What's the percentage of

patients that come in for cath. or some sort of a need, an elective that's considered to be emergency transport?

MR. CORVINO: I don't have that number. Does somebody else have a number?

MR. LAZARUS: I know you mentioned -- for example, in 53 cases, for example, you have based your testimony on, those 53 cases, what's the total number of cases that you put those 53 cases on?

MS. GROVES: Are you talking about the number that still need to be transferred anyway and wouldn't be able to stay?

MR. LAZARUS: Well, is that what you're referring to in your testimony, when you say emergency transport?

MR. CORVINO: Procedures that could not be done at Greenwich under the current regulations.

MS. GROVES: Under the current protocols.

MR. LAZARUS: Okay. Under the current protocols. But I'm saying, considering that this is an elective procedure, not every -- not every procedure that can be done at the hospital is considered an emergency transport, am I correct on that?

MR. CORVINO: Can Chris answer that? He's got more expertise.

MR. LAZARUS: Sure.

DR. HOWES: Again, when we use the term elective, it is a misnomer, I mean, no one elects to have a heart procedure, you know, this is serious stuff. And there are different things. Patients who come in with an acute coronary state syndrome and are sick, and you know, may end up hypotensive with a balloon pump, they're still being called elective angioplasties in this realm, in this discussion. So they're not all elective. Now, that said, some of them are much more stable and in fact are outpatients. I would say about half of the outpatients that we do a diagnostic cath. on in Greenwich, we end up transferring because we've already put, you know, entered arterial access, we have access to the arterial system, we transfer them and they'll end up getting the angioplasty the same day. The other half, we stopped, we regroup, and they go back up to New Haven or to New York Presbyterian some other day. So that's of the outpatient elective angioplasties, about half of them.

And then about half of those patients are actually inpatient, you know, not stable patients. So I'm making these numbers up, I don't have them off the top of my head, but my sense is of those, 53 number that's being reported, I would say about three quarters

of those patients go by ambulance or helicopter or something like that. Does that answer, what your asking?

MR. LAZARUS: That helps, yes. That gets it. Thank you. Mr. Corvino, are you -- let's just say those 53 cases you mentioned, you said there is about an $8,000 cost. $1,000 for the transport and about 7,000 for the admission and angioplasty. What's made up of the $7,000 cost that you're talking about?

MR. CORVINO: You know, that's the -- that's the charge, the average charge that goes along with that procedure.

MR. LAZARUS: Would that charge --

MR. CORVINO: And, you know, it may not be one-to-one with costs at the second facility we're talking about.

MR. LAZARUS: -- would there not be a charge at your facility if the service was here?

MR. CORVINO: But it would be much less because of the lack of transportation cost.

MR. LAZARUS: So it would be a savings of $1,000, not 8,000?

MR. CORVINO: Yeah, but you're also duplicating services at the other place.

MR. LAZARUS: Okay. So you're duplicating

services, I understand --

MR. CORVINO: Plus transportation.

MR. LAZARUS: -- but only the charge for the angioplasty, if it was approved, an elective angioplasty at Greenwich Hospital would be less than 7,000?

MR. CORVINO: I don't know that we have a charge code for that yet.

MR. LAZARUS: You also made a statement on the same page that, you know, we're committed to provide services that our community have come to rely on us and will need in the future. Was there a community needs assessment done for you to figure out what the community needs? Was there a study that the hospital had performed?

MR. CORVINO: Well, yes. I mean, we've done many community needs assessments throughout the years. Clearly, cardiology is a very important part of any institution's make up. And with the growing population and the incidence of heart attack in the U.S., you know, it's clear to us that we, you know, we have to improve and make sure that we've got all of the services that our community relies on on a regular basis. And we have saved many lives through the primary angioplasty

program from the communities we serve. And clearly, as Dr. Howes mentioned earlier, if we are able to do elective it'll make us better.

If you go back to when United Hospital closed in New York, about seven or eight years ago, we saw a huge increase in usage of our emergency room to the point where we went from 15 percent of our patients coming from Westchester to now 43 percent of our patients coming from Westchester County in New York, that made us a better institution. It made our emergency room better. It made our clinicians better. And we anticipate the same thing will happen here.

MS. MARTONE: Now, Mr. Corvino, to your knowledge the incidents of heart disease you just mentioned, is it higher in the Greenwich -- the Greenwich service area compared to other areas of the state?

MR. CORVINO: You know, I don't know the answer to that question. But what I can tell you is that when you look at heart disease and the potential for heart attack that's probably, number one, what frightens patients the most. And we've, you know, we've noticed that even through some of our fundraising efforts, even if people are affiliated with a New York hospital and they live in a local community they're are going to rely

on that local community to deal with their heart attack, if you will, in the middle of the night. They're not going to be traveling to another place. So having a strong heart program really bolsters your position in the community's eyes as a really good institution.

So regardless of whether the incidents is higher or lower, if you've got the illness you want to know that the very best is available in your community.

MR. LAZARUS: When was the last time, Mr. Corvino, a community needs assessment was done? Because you mentioned there were several done.

MR. CORVINO: I would say in the last three or four years.

MR. LAZARUS: And does it specifically discuss cardiac services?

MR. CORVINO: Yes.

MR. LAZARUS: Would you be able to provide OHCA a copy of that?

MR. CORVINO: Sure.

MR. LAZARUS: OCHA would like to accept that as --

HEARING OFFICER YANDOW: Okay. I'd like to order that to be produced. How much time do you need to produce that?

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

August 23, 2012 VIA FAX ONLY

Stephen M. Cowherd
Attorney
Jeffers Cowherd, P.C.
55 Walls drive
Fairfield, CT 06824

RE: Certificate of Need Application Docket Number 12-31748-CON
Greenwich Hospital and Yale-New Haven Hospital
Proposal to Establish Elective Angioplasty Program at Greenwich Hospital

Dear Attorney Cowherd:

Enclosed is the ruling by the Department Public Health's Office of Health Care Access on the Objection to and Motion to Strike Greenwich Hospital and Yale-New Haven Hospital's Late File Submission by The Stamford Hospital filed with OHCA on August 3, 2012.

If you have any questions concerning this matter, please contact me at (860) 418-7001.

Sincerely,

Steven W. Lazarus
Associate Health Care Analyst

Copy: Jean Ahn, Yale-New Haven Hospital
Jennifer L. Groves, Updike, Kelly & Spellacy

IN THE MATTER OF:

A Certificate of Need Application by
Greenwich Hospital and Yale-New Haven Hospital
To Establish And Operate an Elective Angioplasty
Program at Greenwich Hospital

Docket Number: 12-31748-CON
August 23, 2012

RULING ON THE STAMFORD HOSPITAL'S OBJECTION TO AND MOTION TO STRIKE APPLICANT'S LATE-FILE SUBMISSION

On August 3, 2012, The Stamford Hospital ("Intervenor") filed Objection to and Motion to Strike Applicants' Late File Submission filed by Greenwich Hospital and Yale-New Haven Hospital ("Applicant"). On August 10, 2012, Applicant filed a reply to the Intervener's Objection to and Motion to Strike the Applicant's Late-File Submission.

The Intervenor's Objection is overruled and the Motion to Strike Applicant's Late File Submission is denied.

8/23/12
Date

Joanne V. Yandow
Hearing Officer

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*** TX REPORT ***
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OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: STEPHEN M. COWHERD

FAX: (203) 259-1070

AGENCY: JEFFERS COWHERD P.C.

FROM: STEVEN LAZARUS

DATE: 8/23/12 **TIME:**

NUMBER OF PAGES: 3
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Comments: Docket 12-31748-CON

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STATE OF CONNECTICUT
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OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: JEAN AHN, ESQ.

FAX: (203) 688-5013

AGENCY: YALE NEW HAVEN HOSPITAL

FROM: STEVEN LAZARUS

DATE: 8/23/12 **TIME:**

NUMBER OF PAGES: 3
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Comments: Docket 12-31748-CON

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FAX SHEET

TO: JENNIFER GROVES, ESQ.

FAX: (203) 772-2037

AGENCY: UPDIKE, KELLY & SPELLACY

FROM: STEVEN LAZARUS

DATE: 8/23/12 **TIME:**

NUMBER OF PAGES: 3
(including transmittal sheet

Comments: Docket 12-31748-CON

PLEASE PHONE IF THERE ARE ANY TRANSMISSION PROBLEMS.

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

September 6, 2012

VIA FACSIMILE ONLY

Stephen M. Cowherd
Attorney
Jeffers Cowherd, P.C.
55 Walls drive
Fairfield, CT 06824

Jennifer L. Groves,
Attorney
Updike, Kelly & Spellacy, P.C.
265 Church Street
Once Century Tower
New Haven, CT 06510

RE: Certificate of Need Application Docket Number 12-31748-CON
Greenwich Hospital and Yale-New Haven Hospital
Proposal to Establish Elective Angioplasty Program at Greenwich Hospital
Rulings and Closure of the Public Hearing

Dear Attorneys Cowherd and Groves:

With then enclosed rulings, dated September 6, 2012, by the Office of Health Care Access ("OHCA"), the hearing on the above application is hereby closed.

If you have any questions regarding this matter, please feel free to contact Steven W. Lazarus at (860) 418-7012.

Sincerely,

Joanne V. Yandow, Esq.
Hearing Officer

JAY:swl

IN THE MATTER OF:

A Certificate of Need Application by
Greenwich Hospital and Yale-New Haven Hospital
To Establish And Operate an Elective Angioplasty
Program at Greenwich Hospital

Docket Number: 12-31748-CON
September 6, 2012

RULING ON GREENWICH HOSPITAL AND YALE-NEW HAVE HOSPITAL'S MOTION TO STRIKE TESTIMONY

On July 16, 2012, Greenwich Hospital and Yale-New Haven Hospital ("Applicants") filed an Objection to The Stamford Hospital's Petition for Intervenor Status & Motion to Strike Testimony. The Applicant's objection to the petition for intervenor status was overruled and The Stamford Hospital was granted limited intervenor status.

The Applicant's motion to strike testimony is denied. Evidence will be reviewed and given its due weight. No weight will be given to irrelevant or immaterial evidence.

9/6/12
Date

Joanne V. Yandow
Hearing Officer

IN THE MATTER OF:

A Certificate of Need Application by
Greenwich Hospital and Yale-New Haven Hospital
To Establish And Operate an Elective Angioplasty
Program at Greenwich Hospital

Docket Number: 12-31748-CON
September 6, 2012

RULING ON THE STAMFORD HOSPITAL'S OBJECTION TO AND MOTION TO STRIKE A PORTION OF REBUTTAL TESTIMONY OF MARNA BORGSTROM AND CHRISTOPHER HOWES, M.D.

On July 17, 2012, The Stamford Hospital ("Intervenor") filed an objection to and motion to strike a portion of rebuttal testimony of Marna Borgstrom and Christopher Howes, M.D.

The intervenor's objection is overruled and the motion is denied. Evidence will be reviewed and given its due weight. No weight will be given to irrelevant or immaterial evidence.

9/6/12
Date

Joanne V. Yandow
Hearing Officer

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*** TX REPORT ***
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STATE OF CONNECTICUT
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OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: **STEPHEN M. COWHERD**

FAX: **(203) 259-1070**

AGENCY: **JEFFERS COWHERD P.C.**

FROM: **STEVEN LAZARUS**

DATE: **9/6/12** **TIME:**

NUMBER OF PAGES: **4**
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Comments: Docket 12-31748-CON Rulings and Closure of Public Hearing

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DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: JENNIFER GROVES, ESQ.

FAX: (203) 772-2037

AGENCY: UPDIKE, KELLY & SPELLACY

FROM: STEVEN LAZARUS

DATE: 9/6/12 **TIME:**

NUMBER OF PAGES: 4
(including transmittal sheet

Comments: Docket 12-31748-CON Rulings and Closure of the Public Hearing

PLEASE PHONE IF THERE ARE ANY TRANSMISSION PROBLEMS.

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

November 20, 2012

Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.
265 Chruch Street
Once Century Towner,
New Haven, CT 06510

RE: Certificate of Need Application; Docket Number: 12-31748-CON
Greenwich Hospital and Yale-New Haven Hospital
Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup
at Greenwich Hospital

Dear Attorney Groves:

Enclosed please find a copy of the Proposed Final Decision rendered by Hearing Officer Joanne V. Yandow, Esq. in the above-referenced case.

Pursuant to Connecticut General Statutes § 4-179, Greenwich Hospital and Yale-New Haven Hospital, the parties in this matter, may request the opportunity to file exceptions or a brief or a request to present an oral argument, in writing, with the Deputy Commissioner, OHCA of the Department within twenty-one (21) days from the mailing of the decision, or by December 11, 2012. If no such request is received by this date, the Deputy Commissioner will take those rights to be waived and will render a Final Decision in this matter.

If you wish to expedite the process and avoid the necessity that the Deputy Commissioner await the expiration of the aforementioned fourteen days, you may submit a written statement to the Deputy Commissioner affirmatively waiving those rights.

Sincerely,

Kimberly R. Martone
Director of Operations

Copy: Stephen M. Cowherd, Jeffers and Cowherd, PC.

Office of Health Care Access
Certificate of Need Application

Proposed Final Decision

Applicant:	**Greenwich Hospital and Yale-New Haven Hospital**
Docket Number:	**12-31748-CON**
Project Title:	**Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital**

Project Description: Greenwich Hospital and Yale-New Haven Hospital propose to establish and operate an elective angioplasty program without onsite surgical backup at Greenwich Hospital, with no associated capital expenditure.

Nature of Proceedings: On June 20, 2012, the Office of Health Care Access ("OHCA") received the Certificate of Need ("CON") application from Greenwich Hospital and Yale-New Haven Hospital to establish an elective angioplasty program without onsite backup at Greenwich Hospital, with no associated capital expenditure. The Applicants are health care facilities or institutions as defined by Section 19a-630 of the Connecticut General Statutes ("General Statutes").

Pursuant to General Statutes § 19a-638, a public hearing regarding the CON application was held on July 17, 2012. On July 2, 2012, the Applicant was notified of the date, time, and place of the hearing. On July 3, 2012, a notice to the public announcing the hearing was published in *The Greenwich Times*. Attorney Joanne V. Yandow served as Hearing Officer. The hearing was conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the General Statutes) and General Statutes § 19a-638.

By petition dated July 12, 2012, The Stamford Hospital requested Party or, in the alternative, Intervenor status with full rights of cross-examination regarding the Applicants' CON application. The Hearing Officer denied the request of The Stamford Hospital for Party status and designated The Stamford Hospital as an Intervenor with limited rights of participation.

The Hearing Officer heard testimony from the Applicants' witnesses and the Intervenor's witnesses and, in rendering this decision, considered the entire record of the proceeding. The public hearing record was closed on September 6, 2012.

OHCA's authority to review and approve, modify, or deny the CON application is established by General Statutes § 19a-638. The provisions of this section, as well as the principles and guidelines set forth in General Statutes § 19a-639, were fully considered by OHCA in its review.

Findings of Fact

1. Greenwich Hospital is a not-for-profit 174-bed acute care hospital located at 5 Perryridge Road in Greenwich, Connecticut. Exhibit A, p. 573 (CON Application).

2. Yale-New Haven Hospital is a not-for-profit, acute care hospital located at 20 York Street, New Haven, Connecticut. Exhibit A, p. 575 (CON Application).

3. The Yale-New Haven Heart and Vascular Center provides elective and emergency ("primary") angioplasty at Yale-New Haven Hospital and has established satellite primary angioplasty programs at Greenwich Hospital and Lawrence & Memorial Hospital in New London, Connecticut. Exhibit H, pp. 629&632 (prefiled testimony of Marna Borgstrom, President and CEO of Yale-New Haven Health System and CEO of Yale New Haven Hospital); OHCA CON Final Decision, DN: 03-30148.

4. Angioplasty is historically a procedure in which a balloon tipped catheter is advanced to an artery narrowed from the buildup of cholesterol-laden plaque, but has been expanded to include other devices that serve as adjuncts to the balloon catheter, such as stents. Percutaneous coronary intervention ("PCI") also refers to this broader group of technologies. PCI for patients that present on an emergency basis with ST-segment elevation MI or new onset left bundle branch block is referred to as a "primary" PCI. Other PCI procedures are referred to as "elective" PCI. *See*, OHCA CON Final Decision, DN: 08-31210.

5. As part of Yale-New Haven Heart and Vascular Center, Greenwich Hospital currently provides diagnostic cardiac services including echocardiography, nuclear cardiac imaging, stress testing, cardiac CT angiography, and diagnostic cardiac catheterization. Greenwich Hospital also provides PCI angioplasty services for patients that present on an emergency basis with artery blockage in the heart. Exhibit A, pp. 22-23 (CON Application).

6. The primary angioplasty program at Greenwich Hospital received permanent status approval from OHCA on July 25, 2008, after completion of a 3-year demonstration project. Exhibit A, p. 22 (CON Application); OHCA CON Final Decision, DN: 03-30148.

7. Elective angioplasty is the same procedure as primary angioplasty but is typically a scheduled procedure (within 72 hours) and is not an emergency. *See*, OHCA CON Final Decision, DN: 08-31210.

8. The Applicants are proposing to establish an elective angioplasty program at Greenwich Hospital without an on-site open heart surgery program. Exhibit A, p. 14 (CON Application).

9. The Applicants define the population to be served through this proposal as the residents of the towns that comprise 85% of Greenwich Hospital's inpatient volume. The Applicants claim that the proposed service area ("PSA") is as follows:

Table I: Greenwich Hospital's PSA for Elective PCI

State	Towns
Connecticut	Darien, Greenwich, New Canaan, Norwalk, Stamford, Weston, Westport and Wilton
New York	Armonk, Bedford, Bedford Hills, Harrison, Hartsdale, Katonah, Larchmont, Mamaroneek, Mount Kisco, Mount Vernon, New Rochelle, Port Chester, Pound Ridge, Purchase, Rye Scarsdale, South Salem, West Harrison and White Plains

Exhibit A, p. 24 (CON Application).

10. The Stamford Hospital ("Stamford Hospital"), the Intervenor in this matter, performs cardiovascular services, including primary and elective PCIs. *See*, OHCA CON Final Decision, DN: 04-30374.

11. The Applicants claim that based on the 2011 inpatient cardiovascular discharge volume by patients' towns of origin for Stamford Hospital and Greenwich Hospital, cardiovascular patients at Greenwich Hospital are the low volume communities for Stamford Hospital. Specifically, the communities of Greenwich, Port Chester and Rye comprise 80% of Greenwich Hospital's cardiovascular patient population but only 4.6% of Stamford Hospital's cardiovascular patient population. Additionally, patients who live in the city of Stamford and the town of Darien comprise 88% of Stamford Hospital's cardiovascular patient volume but only comprise 7% of Greenwich Hospital's cardiovascular patients. Exhibit H, pp. 668-669 (prefiled testimony of Christopher Howes, MD, Chief of Cardiology and Medical Director of the primary angioplasty program at Greenwich Hospital).

12. In 2010, OHCA issued a decision denying Greenwich Hospital's first proposal to establish and operate elective angioplasty program without on-site open heart surgery. The proposal was denied because the projected volume included New York patients, there was insufficient evidence to support the projected volumes, and there was an existing provider of elective PCI and full service cardiac program in the service area (Stamford Hospital). CON Final Decision 08-31210-CON.

13. In or about January 2012, White Plains Hospital in White Plains, New York began offering elective angioplasty service. . Exhibit I, p. 49-50 (Intervenor's prefiled documents, letter from Susan Fox, Executive Vice President, White Plains Hospital).

14. Stamford Hospital and White Plains Hospital are currently providing elective angioplasty procedures in Greenwich Hospital's claimed PSA. Exhibit A, p. 28 (CON Application).

15. White Plains Hospital states it services most of the Westchester County towns identified by the Applicants as towns in Greenwich Hospital's PSA. Exhibit I, page, 49 (Intervenor's prefiled documents, letter from Susan Fox, Executive Vice President, White Plains Hospital).

16. The Applicants assert that Greenwich Hospital is already performing angioplasty on more acutely ill patients through its primary angioplasty program and the staff and physicians are well prepared to perform elective angioplasty for less acute patients. Exhibit A, p. 14 (CON Application).

17. The Medical Director of the cardiac services program at Greenwich Hospital is appointed by Yale University School of Medicine, Department of Cardiology and is a member of the Yale School of Medicine's interventional cardiology faculty. Exhibit A, p. 14 (CON Application).

18. The Applicants claim that the previous OHCA approval for the primary PCI demonstrated clear public need for emergency angioplasty services at Greenwich Hospital and that the current proposal expands upon that approval to demonstrate that the same population, from which Greenwich Hospital's primary angioplasty patients originate, also have a clear need for access to their provider of choice for high quality elective angioplasty services. Exhibit A, p. 15 (CON Application).

19. The Applicants claim that the clear public need for this proposal is supported by the following three key factors:

    a. Local access to elective angioplasty care at Greenwich Hospital is needed and appropriate;
    b. Greenwich Hospital must address the cost-effectiveness of angioplasty services; and
    c. The proposed program will improve the quality of elective angioplasty services provided to Greenwich Hospital's PSA patients.

    Exhibit A, p. 15 (CON Application).

20. The Applicants assert that significant stress and strain are placed on Greenwich Hospital patients and their families when they receive either a diagnostic catheterization or an emergency angioplasty and then must undergo an elective angioplasty at another facility. Exhibit H, p. 671 (prefiled testimony of Christopher Howes, MD, Chief of Cardiology and Medical Director of the primary angioplasty program at Greenwich Hospital).

21. In November 2011, the American College of Cardiology/American Heart Association/The Society for Cardiovascular Angiography and Interventions ("ACC/AHA/SCAI") updated their guidelines regarding PCI without on-site surgical backup. These guidelines are intended to assist healthcare providers in clinical decision making by describing a range of generally acceptable approaches to the diagnosis, management, and prevention of specific diseases or condition. Exhibit A, pp. 139-239 (CON Application).

22. The Applicants claim that an elective PCI program at Greenwich Hospital would fall within the ACC/AHA/SCAI updated guidelines. Exhibit H, pp. 635-636 (prefiled testimonoy of Henry Cabin, MD, Clinical Chief of Cardiology at Yale School of Medicine and Medical Director of Yale-New Haven Heart and Vascular Center).

23. The ACC/AHA/SCAI updated guidelines recommend, in part, that:
> elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection.

Exhibit A, p. 164 (CON Application).

24. The ACC/AHA/SCAI guidelines also recommend, in part, that:
> [i]t is only appropriate to consider initiation of a PCI program without on-site backup if the program will clearly fill a void in the healthcare needs of the community. Competition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interests of the community.

Exhibit A, p. 164 (CON Application).

25. It is found that although OHCA is not bound to the ACC/AHA/SCAI guidelines, these guidelines are instructive. *See*, CON Final Decision 08-31210-CON.

26. The Applicants claim that angioplasty has become a fairly routine procedure, often performed in an outpatient setting at much lower risk than used to exist. Exhibit H, p. 632. (prefiled testimony of Marna Borgstrom, President and CEO of Yale New Haven Health System and CEO of Yale-New Haven Hospital).

27. The Applicants claim that this proposal eliminates the need for two invasive procedures, diagnostic cardiac catheterization and elective angioplasty, which adds hospital costs, clinical risk and expensive medical transportation costs. Exhibit H, pp.

632 and 671 (prefiled testimonies of Marna Borgstrom, President and CEO of Yale New Haven Health System and CEO of Yale New Haven Hospital, and Christopher Howes, MD, Chief of Cardiology and Medical Director of the angioplasty program at Greenwich Hospital).

28. The Applicants assert that Yale School of Medicine cardiovascular physicians have been actively involved in the primary angioplasty program at Greenwich Hospital since its inception and will continue to provide clinical oversight, direct patient care, and staff and physician education at the proposed program. Exhibit H, p. 632 (prefiled testimony of Marna Borgstrom, President and CEO of Yale New Haven Health System and CEO of Yale New Haven Hospital).

29. The Applicants state that Greenwich Hospital participates in the National Cardiovascular Data Registry NCDR-CathPCI Registry. Exhibit A, p. 36 (CON Application).

30. According to the Applicants, since Fiscal Year ("FY") 2008, 272 patients presented at Greenwich Hospital for elective angioplasty service. A total of 246 of the 272 patients were transferred to other providers for elective PCI. The following table illustrates the total of transfers by provider:

Table II: Historical Greenwich Hospital Elective PCI Transfers

FY	Yale	Westchester Medical Center	Cornell	Columbia	Stamford	West Haven VA	Total Transfers
2008	44	1	0	0	0	0	45
2009	71	0	1	1	1	0	74
2010	51	0	2	0	1	0	54
2011	53	0	2	1	0	1	57
2012*	16	0	0	0	0	0	16
Totals	**235**	**1**	**5**	**2**	**2**	**1**	**246**

*Number of transfers between 10/1/11 and 12/31/11

Note: The remaining 26 patients were discharged and referred for elective angioplasty at a future time. Exhibit A, p. 19 (CON Application).

31. The Applicants identified the following historical primary angioplasty volumes for Greenwich Hospital for FYs 2008-2011:

Table III: Greenwich Hospital Historical Primary PCI

	FY 2008	FY 2009	FY 2010	FY 2011
Greenwich Hospital	40	40	32	38

Exhibit A, p. 30 (CON Application).

32. Greenwich Hospital's angioplasty volume projections:

Table IV: Greenwich Hospital Projected Primary and Elective PCI

	FY 2012	FY 2013	FY 2014
Primary Angioplasty	38	38	38
Elective Angioplasty	**53**	**53**	**53**
New Referred Elective PCI	105	126	151
Total	196	217	242

Exhibit A, p. 31 (CON Application).

33. The Applicants based the projected primary angioplasty volumes on historical volumes, which have remained fairly steady for the past few years. The projected elective angioplasty volumes have been based on the historical elective angioplasty patients transferred to other facilities. Exhibit A, pp. 32-34 (CON Application).

34. The Applicants claim that half of the outpatients that have a diagnostic catheterization performed at Greenwich Hospital are transferred to other facilities for elective PCI. Exhibit H, p. 669-671 (prefiled testimony of Christopher Howes, Chief of Cardiology of Angioplasty Program at Greenwich Hospital).

35. The Applicants state that an increase in the PCI patient volume will result from the addition of New York interventional cardiologists who currently do not practice at Greenwich Hospital but have referral relationships with Greenwich Hospital medical staff and would utilize and refer elective angioplasty to Greenwich Hospital. Exhibit H, pp. 670-671, 675-676 (prefiled testimony of Christopher Howes, Chief of Cardiology of Angioplasty Program at Greenwich Hospital).

36. Although the Applicants provided letters of support from the two (2) physicians from the State of New York who state they would offer elective PCI at Greenwich Hospital if that were an option, the projected new PCI volumes are speculative and appear to be a shifting of the elective PCI patients from an area provider to Greenwich Hospital. *See*, Exhibit H, page 671 &675-679 (prefiled testimony of Christopher Howes, M.D Chief of Cardiology of Angioplasty Program at Greenwich Hospital).

37. Stamford Hospital claims that elective angioplasty volumes are flat to declining in the State, with no volume growth in the Applicants' proposed service area, and therefore, there is no clear public need for the establishment of elective angioplasty program without onsite surgical back up at Greenwich Hospital. Exhibit K, p. 1 (Intervenor's prefiled testimony of Sharon Kiely, M.D., Senior Vice President of Medical Affairs and Chief Medical Officer for Stamford Hospital).

38. The following table illustrates the historical overall statewide PCI (primary and elective combined) discharges by provider between Federal Fiscal Years ("FFY") 2002-2011:

Table V: PCI discharges by provider, FFYs 2002-2011

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	FFY 05-07 (3-yr)* % Change	FFY 09-11 (3-yr) % Change	FFY 10-11 (1-yr) % Change
Bridgeport	1,191	1,249	1,288	1,052	692	560	580	428	379	298	-47%	-30%	-21%
CT Children's								2	0		n/a	-100%	n/a
Danbury	0	0	0	0	453	409	330	326	277	292	n/a	-10%	5%
Dempsey	452	464	453	519	401	353	376	334	368	253	-32%	-24%	-31%
Greenwich	0	0	0	20	38	32	40	40	32	37	60%	-8%	16%
Hartford	1,312	1,483	1,321	1,282	1,246	1,206	1,093	1,031	1,122	1,195	-6%	16%	7%
Hospital of Central CT	0	0	0	26	61	70	60	74	69	97	169%	31%	41%
Lawrence & Memorial	0	0	0	0	41	-	29	74	74	70	n/a	-5%	-5%
New Milford	0	0	0	0	0	6	11	11	0		n/a	-100%	n/a
Norwalk								14	57	65	n/a	364%	14%
St. Francis	1,192	1,253	1,349	1,223	1,170	1,188	1,171	1,232	1,030	938	-3%	-24%	-9%
St. Mary's	0	0	0	59	297	246	251	255	291	314	317%	23%	8%
St. Raphael	715	970	924	708	680	632	595	534	523	444	-11%	-17%	-15%
St. Vincent's	1,063	1,035	1,085	1,150	1,181	1,101	1,124	958	925	509	-4%	-47%	-45%
Stamford	0	0	0	9	39	34	45	159	151	135	278%	-15%	-11%
Waterbury	0	0	0	61	347	373	325	361	361	379	511%	5%	5%
Yale	1,635	1,715	1,460	1,297	1,218	1,131	1,186	1,352	1,469	1,324	-13%	-2%	-10%
Total	**7,560**	**8,169**	**7,880**	**7,406**	**7,864**	**7,341**	**7,216**	**7,185**	**7,128**	**6,350**	**-1%**	**-12%**	**-11%**

***Source**: CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database.*

ICD-9-CM Procedure Codes: .66, 36.01, 36.02, 36.05, 36.06 and 36.07
Please note: unduplicated counts utilizing all procedure codes
*This column in OHCA's Exhibit 1, Table 2A, was mislabeled. No data from this column was relied upon to support the findings in this decision.

39. The statewide inpatient PCI volumes demonstrate the following: a five year historical decline of 1% between FY 2007-2011; a 12% overall decline between FY 2009 and 2011; and an 11% decline in statewide PCI volume between FY 2010-2011. *See,* Table V, above.

40. Stamford Hospital's PCI discharges have declined 15% between FY 2009-2011 and, therefore, Stamford Hospital has capacity to serve the needs of the community. *See*, Table V, above.

41. The Intervenor claims that discharges of residents from Greenwich Hospital's service area from Connecticut and New York hospitals show that from FY 2009 through 2011, inpatient ("I/P") cardiac catheterization and PCI volumes have decreased in the service area:

Table VI: FY 2009-2011, I/P PCI Volume in proposed Service Area

State	FY 2009	FY 2010	FY 2011
CT Service Area	598	610	429
NY Service Area	844	775	772
Total	**1,442**	**1,385**	**1,201**

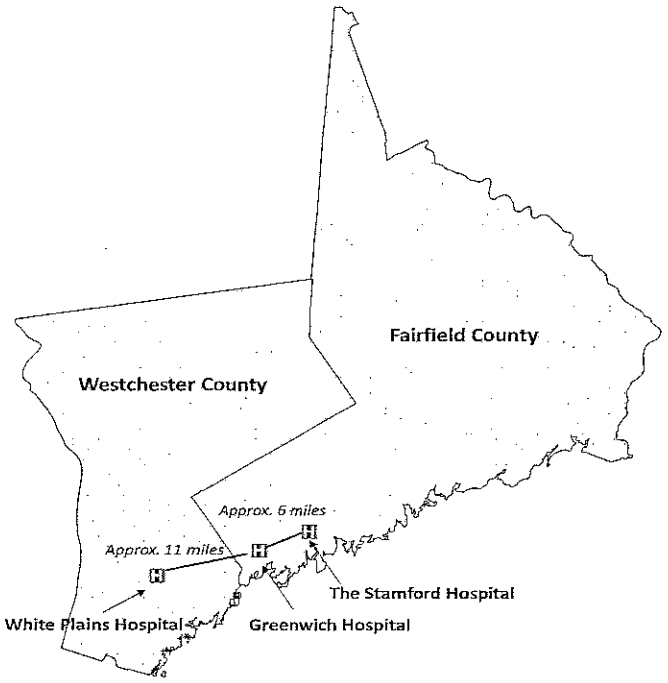
Exhibit K, p. 8 (Intervenor's prefiled testimony of Sharon Kiely, M.D., Senior Vice President of Medical Affairs and Chief Medical Officer for Stamford Hospital).

42. In light of the historical elective PCI transfers from Greenwich Hospital to existing providers and the declining statewide PCI volumes, OHCA finds that the Applicants have not provided sufficient evidence to support its projected PCI utilizations.

43. A letter from White Plains Hospital states that its elective PCI program presently has capacity to serve the needs of the community and they are not aware of any backlog of cases in their service area that would indicate patients are not receiving timely care. Exhibit I, pp. 49-50 (Intervenor's prefiled documents, letter from Susan Fox, Executive Vice President, White Plains Hospital).

44. White Plains Hospital is located approximately ten (10) miles west of Greenwich Hospital. If this application is approved, three (3) elective angioplasty programs will operate within sixteen (16) miles of each other. Exhibit K, p. 10 (Intervenor's prefiled testimony of Sharon Kiely, M.D., Senior Vice President of Medical Affairs and Chief Medical Officer for Stamford Hospital).

45. The map illustrates the location of Greenwich Hospital and the existing providers such as Stamford Hospital and White Plains Hospital, in Greenwich Hospital's proposed service area and their approximate distance to Greenwich Hospital:



46. There is no capital expenditure associated with this proposal. Exhibit A, p. 21(CON Application).

47. The Applicants assert that they estimate the unnecessary costs that now result and impact payers and patients total approximately $425,000 each year. This amount is based on an average of 53 elective angioplasty cases currently transferred that could be cared for by a Greenwich Hospital's elective angioplasty program multiplied by $8,000 ($7,000 for the average cost of an angioplasty admission at Yale New Haven Hospital plus $1,000 for emergency transportation). Exhibit H, p. 79 (prefiled testimony of Frank Corvino, President and CEO of Greenwich Hospital).

48. Greenwich Hospital's projected incremental revenue from operations, total operating expense and gain from operations associated with the CON proposal are as follows:

Table VII: Financial Projections Incremental to the Project

Description	FY 2013	FY 2014	FY 2015
Incremental Revenue from Operations	$2,935	$3,413	$3,976
Incremental Total Operating Expense	$2,353	$2,744	$3,222
Incremental Gain from Operations	**$582**	**$669**	**$756**

Note: figures are in thousands.
Exhibit A, p. 577 (CON Application).

49. The current and three-year projected payer mix for Greenwich Hospital is as follows:

Table VIII: Current & Three-Year Projected Payer Mix

Description	Current	Year 1	Year 2	Year 3
Medicare*	40.5%	40.5%	40.5%	40.5%
Medicaid*	5.4%	5.4%	5.4%	5.4%
CHAMPUS and TriCare				
Total Government	**45.9%**	**45.9%**	**45.9%**	**45.9%**
Commercial Insurers*	48.7%	48.7%	48.7%	48.7%
Self Pay	5.4%	5.4%	5.4%	5.4%
Workers Compensation	0%	0%	0%	0%
Total Non-Government	**54.1%**	**54.1%**	**54.1%**	**54.1%**
Total Payer Mix	**100%**	**100%**	**100%**	**100%**

* Includes managed care activity.
Exhibit A, p. 40 (CON Application).

50. The Applicants assert that Greenwich Hospital's primary angioplasty services are costing Greenwich Hospital approximately $1.78 million per year, as Greenwich Hospital has to pay Yale School of Medicine to provide 24/7 physician staffing for its existing program. The primary angioplasty program results in significant staffing costs to cover approximately 40 primary angioplasty cases treated at Greenwich Hospital each year. Utilizing the same physicians to perform elective angioplasty would be a cost-effective and efficient approach and would reduce the costs per case from the arrangement. Exhibit A, p. 20 (CON Application).

51. The Applicants claim that the proposed elective angioplasty program is cost effective as it maximizes use of the existing high-cost infrastructure of the primary angioplasty program and permits existing and available highly qualified expert physicians and staff to perform both primary and elective angioplasties for which they have been trained and are qualified to perform. In addition, as noted in the application, System-wide integration, coordination of care practices and standardization, more cost effectiveness and evidence-based care will be provided. Exhibit A, pp. 40-41 (CON Application).

52. OHCA is currently in the process of establishing its policies and standards as regulations. Therefore, OHCA has not made any findings as to this proposal's relationship to any regulations adopted by OHCA. (General Statutes § 19a-639(a)(1)).

53. OHCA is currently in the process of establishing the statewide facilities and services plan ("the plan"). The plan was not a published document at the time of this proposal was filed; however, even if the plan is published by the time this final decision is issued, it has no bearing on the outcome of this matter, as the Applicants have not sufficiently demonstrated a clear public need for this proposal. (General Statutes § 19a-639(a)(2)).

54. There is insufficient evidence to establish that there is a clear public need for the Applicants' proposal. (General Statutes § 19a-639(a)(3)).

55. The Applicants have not satisfactorily demonstrated how this proposal will impact the financial strength of the health care system in this state. (General Statutes § 19a-639(a)(4)).

56. The Applicants have failed to satisfactorily demonstrate that their proposal would improve the accessibility of health care delivery in the region but they have satisfactorily demonstrated a potential improvement in quality and cost effectiveness. (General Statutes § 19a-639(a)(5)).

57. The Applicants have shown that there would be no change to the provision of health care services to the relevant populations and payer mix. (General Statutes § 19a-639(a)(6)).

58. The Applicants have satisfactorily identified the population to be served by their proposal but have failed to satisfactorily demonstrate that this population has a need as proposed. (General Statutes § 19a-639(a)(7)).

59. The historical elective PCI discharges in the service area do not support this proposal. (General Statutes § 19a-639(a)(8)).

60. The Applicants have failed to satisfactorily demonstrate that their proposal would not result in an unnecessary duplication of existing elective PCI services in the area. (General Statutes § 19a-639(a)(9)).

Discussion

CON applications are decided on a case by case basis and do not lend themselves to general applicability due to the uniqueness of the facts in each case. In rendering its decision, OHCA considers the factors set forth in General Statutes § 19a-639(a) and the Applicant bears the burden of proof in this matter by a preponderance of the evidence. *Goldstar Medical Services, Inc., et al. v. Department of Social Services,* 288 Conn. 790 (2008); *Steadman v. SEC*, 450 U.S. 91, 101 S.Ct. 999, *reh'g den.*, 451 U.S. 933 (1981); *Bender v. Clark*, 744 F.2d 1424 (10th Cir. 1984); *Sea Island Broadcasting Corp. v. FCC*, 627 F.2d 240, 243 (D.C. Cir. 1980).

Greenwich Hospital is a 174-bed acute care hospital located at 5 Perryridge Road in Greenwich and Yale-New Haven Hospital is an acute care hospital located at 20 York Street in New Haven. Greenwich Hospital and Yale New Haven Hospital (collectively known as "Applicants") are proposing to establish and operate an elective angioplasty program without onsite surgical backup located at Greenwich Hospital. FFs 1, 2, 8.

Currently, Greenwich Hospital, as a satellite of Yale New Haven Hospital's Yale-New Haven Heart and Vascular Center, provides cardiac catheterization and primary (emergency) angioplasty services. Greenwich Hospital does not have an on-site open heart surgery program. FF 4-6.

The Applicants argue that there is a clear public need for elective angioplasty ("elective PCI") at Greenwich Hospital and that such a program would fall within the ACCF/AHA/SCAI updated guidelines regarding elective PCI without on-site surgical backup. FFs 18, 19, 21, 22. The ACCF/AHA/SCAI guidelines now state that elective PCI might be considered in hospitals without on-site cardiac, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection. FF 23.

The Applicants claim there is clear public need based on three key factors: local access, cost-effectiveness and improved quality. FF 19. Greenwich Hospital has transferred approximately 57 patients annually (between FYs 2008-2011) that required elective angioplasties to other providers over the each of the past three fiscal years. FF 30. Additionally, the Applicants claim that two new physicians (currently practicing in Westchester County, NY) will refer new angioplasty patients to Greenwich Hospital, if approved. FF 35.

Although the Applicants claim that there is need for elective PCI in the proposed service area, there are currently two providers of elective angioplasty service within its proposed service area, Stamford Hospital and White Plains Hospital. FFs 14, 44, 45. Each of the existing providers of elective angioplasty is approximately 6 and 11 miles away from Greenwich Hospital. FFs 44, 45. A letter from White Plains Hospital in Westchester County, NY, stated that its elective angioplasty program presently has capacity to serve the needs of the community and they are not aware of any backlog of cases in their service area. FF 43. Additionally, historical PCI discharge data shows that Stamford Hospital also has capacity to serve the needs of the community. FFs 37-40. Furthermore, based on OHCA's statewide hospital discharges, it's clear that since FY 2009,

the cardiac catheterization volume has declined 10% and the combined (emergent and elective) angioplasty volumes declined 12% at Connecticut providers. FFs 38-40.

The ACCF/AHA/SCAI updated guidelines state:

> It is only appropriate to consider initiation of a PCI program without on-site cardiac surgical backup if this program will clearly fill a void in the healthcare needs of the community. Competition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interests of the community.

FF 24. Regarding the proposal at hand, there is insufficient evidence to establish a void in the needs of the community for elective PCI services and that the Applicants' proposal is in the best interests of the community.

Based on the statewide decline at all Connecticut providers of cardiac catheterization and angioplasty programs, the speculative projected new cases, and the fact that there are two (2) existing providers currently providing elective PCI in Greenwich Hospital's proposed service area and that these providers have capacity to fulfill the needs of the community, OHCA finds there is access to elective angioplasty service for the residents within Greenwich Hospital's proposed service area and, further, that the Applicants failed to demonstrate and provide evidence of a clear public need for this proposal. Based upon the lack of sufficient evidence demonstrating that the Applicants' proposed project fulfills a clear public need for elective PCI, OHCA is unable to conclude that the Applicants' financial projections and volumes upon which they are based are reasonable and achievable, or that the project is financially feasible.

Based upon the foregoing Findings of Fact and Discussion, I respectfully recommend that the Certificate of Need application of Greenwich Hospital and Yale-New Haven Hospital for the establishment of an elective angioplasty program without onsite surgical backup at Greenwich Hospital, with no associated capital expenditure, be **DENIED**.

Respectfully submitted,

11/20/12
Date

Joanne V. Yandow
Hearing Officer

JVY:swl

****
*** TX REPORT ***
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TX/RX NO	3162
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FAX SHEET

TO: Jennifer Groves, Esq. ✔

FAX: (203) 772-2037

AGENCY:

FROM: Joanne V. Yanda

DATE: 11/20/12 TIME: ~~1:30 pm~~ ≈ 1pm

NUMBER OF PAGES:
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Re: DN: 12-31748- con Enclosed

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TO: Stephen M. Cowhard

FAX: (203) 259-1070

AGENCY:

FROM: Joanne V. Yandow

DATE: 11/20/12 TIME: ~~[illegible]~~ ≈ 1pm

NUMBER OF PAGES: 16
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TO: AMY RICHARDS

FAX: (203) 688-5013

AGENCY: YALE NEW HAVEN HOSPITAL

FROM: LESLIE GREER

DATE: 11/21/12 **TIME:**

NUMBER OF PAGES: 16
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5 Perryridge Road
Greenwich, CT 06830-4697
203-863-3900
Fax 203-863-3921

GREENWICH HOSPITAL
YALE NEW HAVEN HEALTH

FAX

Date: December 11, 2012

To: Lisa Davis, Deputy Commissioner

Fax: 860-418-7053

From: Marna Borgstrom, CEO Yale New Haven Hospital
Frank Corvino, President & CEO Greenwich Hospital

Subject: Greenwich Hospital
Establish & Operate an Elective Angioplasty program without Onsite Surgical Backup at Greenwich Hospital
Docket No. 12-31748-CON

DEC 11 2012

Number of pages including cover sheet: 2

Please call Diana O'Marra at 203-863-3900 to confirm receipt of this fax.

Thank you.

Office of the President

YALE NEW HAVEN HEALTH

December 11, 2012

VIA ELECTRONIC & FIRST CLASS MAIL

Lisa Davis, R.N., B.S.N., M.B.A.
Deputy Commissioner
State of Connecticut
Department of Public Health
Office of Health Care Access Division
410 Capitol Avenue
Post Office Box 340308
Hartford, CT 06134-0308

DEC 11 2012
OFFICE OF HEALTH CARE ACCESS

Re: Greenwich Hospital
Establish & Operate an Elective Angioplasty program Without Onsite Surgical Backup at Greenwich Hospital
Docket No. 12-31748-CON

Dear Deputy Commissioner Davis:

Pursuant to Section 4-179(a) of the Connecticut General Statutes, Greenwich Hospital ("Greenwich") and Yale-New Haven Hospital ("YNHH") (collectively "Applicants"), parties in the above-referenced CON proceeding, request the opportunity to file exceptions and briefs and present oral argument to the Department of Public Health regarding the Proposed Final Decision, dated November 20, 2012. Both Greenwich and YNHH are adversely affected by the Proposed Final Decision, which denies Applicants the right to establish and operate an elective angioplasty program at Greenwich Hospital. Per our discussions with OHCA staff, upon receipt of this letter a date will be assigned for the filing of exceptions and briefs, and oral argument will be scheduled sometime thereafter.

Thank you for your consideration of this request.

Very truly yours,

Frank Corvino
President and CEO
Greenwich Hospital

Marna P. Borgstrom
Chief Executive Officer
Yale-New Haven Hospital

cc: Jennifer L. Groves, Esq.
Stephen M. Cowherd, Esq.

644036

789 Howard Avenue
New Haven, CT 06519-1300
203.688.2608
Fax 203.688.3257

Office of the President

YALE NEW HAVEN HEALTH

December 11, 2012

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Lisa Davis, R.N., B.S.N., M.B.A.
Deputy Commissioner
State of Connecticut
Department of Public Health
Office of Health Care Access Division
410 Capitol Avenue
Post Office Box 340308
Hartford, CT 06134-0308

Re: Greenwich Hospital
Establish & Operate an Elective Angioplasty program Without Onsite Surgical Backup at Greenwich Hospital
Docket No. 12-31748-CON

Dear Deputy Commissioner Davis:

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Thank you for your consideration of this request.

Very truly yours,

Frank Corvino
President and CEO
Greenwich Hospital

Marna P. Borgstrom
Chief Executive Officer
Yale-New Haven Hospital

cc: Jennifer L. Groves, Esq.
Stephen M. Cowherd, Esq.

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DEPARTMENT OF PUBLIC HEALTH

Jewel Mullen, M.D., M.P.H., M.P.A.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

January 3, 2013

Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.
265 Church Street
One Century Tower
New Haven, CT 06510

Certified Mail: 7005 0390 0001 3506 9464

Stephen M. Cowherd, Esq.
Jeffers Cowherd, P.C.
55 Walls Drive
Fairfield, CT 06824

Certified Mail: 7005 0390 0001 3506 9457

In RE: Certificate of Need Application, Docket Number 12-31748-CON
Greenwich Hospital and Yale-New Haven Hospital
Proposal to Establish Elective Angioplasty Program at Greenwich Hospital

NOTICE OF ORAL ARGUMENT

Greenwich Hospital and Yale-New Haven Hospital have requested oral argument regarding the recommendation of Hearing Officer Joanne V. Yandow, Esq. Pursuant to Section 4-179 C.G.S., Oral Argument for the above cited case has been scheduled as follows:

January 16, 2013 at 2:00 p.m.
Department of Public Health
3rd Floor, DPH Commissioner's Hearing Room
410 Capitol Avenue, Hartford, Connecticut

On January 16, 2013, you will have fifteen minutes to make your argument. If you wish to file briefs, you must do so by January 11, 2013. Please call Barbara Olejarz at (860) 418-7005 if you have any questions.

Lisa Davis

Lisa Davis, MBA, BSN, RN
Deputy Commissioner

1/3/2013
Date

C: Jewel Mullen, M.D., M.P.H., M.P.A., Commissioner

Connecticut Department of Public Health

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TO: **STEPHEN M. COWHERD**

FAX: **203 259-1070**

AGENCY: **JEFFERS COWHERD, P.C..**

FROM: **OHCA**

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TO: JENNIFER GROVES

FAX: 203 772-2037

AGENCY: UPDIKE, KELLY & SPELLACY, P.C.

FROM: OHCA

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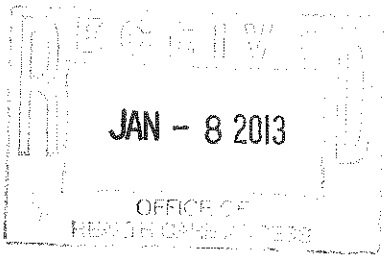

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Sender's Direct Fax Number:
(203) 772-2037

Date: January 8, 2013 **FAX#:** 860-418-7053

To: Lisa Davis c/o Barbara Olejarz **Company:** Office of Healthcare Access

From: Jennifer L. Groves, Esq. **Number of Pages** 3
(Including Cover Sheet)

Subject: Docket No. 12-31748-CON

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jgroves@uks.com

January 8, 2013

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Lisa Davis, MBA, BSN, RN
Deputy Commissioner
State of Connecticut
Department of Public Health
410 Capitol Avenue, P.O. Box 34038
MS #13HCA
Hartford, CT 06134-0308

Re: Proposal to Establish Elective Angioplasty Program at Greenwich Hospital
Docket No. 12-31748-CON

Dear Deputy Commissioner Davis,

This office represents Greenwich Hospital ("Greenwich") and Yale-New Haven Hospital ("YNHH") (collectively "Applicants") in connection with the above-referenced CON Application to establish an elective angioplasty program in Greenwich. We are in receipt of your letter scheduling oral argument on the Proposed Final Decision for January 16, 2013. We appreciate this opportunity to be heard and will submit our exceptions and brief to you by January 11, 2013, as requested.

The purpose of this letter is to confirm that the right to submit exceptions and a brief and to present oral argument on the Proposed Final Decision is limited to the ***parties*** in this matter only. Specifically, we are requesting confirmation that The Stamford Hospital ("TSH"), which was designated as an intervenor with limited rights for purposes of the July 16, 2012 public hearing, will not be allowed to make a written submission and/or to argue before the Deputy Commissioner on January 16th.

Section 4-179 of the Connecticut General Statutes provides, in pertinent part, as follows:

> When in an agency proceeding, a majority of the members of the agency who are to render the final decision have not heard the matter or read the record, the decision if adverse to a party, shall not be rendered until a proposed final decision is served upon the parties, and an opportunity is afforded ***for each party adversely affected*** to file exceptions and present briefs and oral argument to the members of the agency who are to render the final decision (emphasis added).

In addition, Section 19a-9-29(h) of the Regulations of Connecticut State Agencies (Department of Public Health Rules of Practice) states:

> ***Any party*** who wishes to challenge a proposed final decision under section 4-179 of the Connecticut General Statutes shall file exceptions or a brief or request oral argument within twenty-one (21) days of the mailing of the decision. ***Any party*** who wishes to present a brief or requests oral argument in support of a proposed final decision shall do so within thirty-five (35) days of the mailing of the decision (emphasis added).

Moreover, the November 20, 2012 letter from Office of Health Care Access ("OHCA") Director of Operations Kimberly Martone enclosing the Proposed Final Decision states that "Greenwich and Yale-New Haven Hospital, ***the parties in this matter***, may request the opportunity to file exceptions or a brief or to request to present an oral argument (emphasis added)."

Based upon the statutes and regulations pursuant to which oral argument on a Proposed Final Decision is authorized, it is clear that only parties – in this case Greenwich and YNHH – have a right to participate at this stage in an OHCA administrative proceeding. Applicants seek confirmation that TSH will not be allowed to participate on January 16th (either through written submission or oral presentation) so that we can properly prepare for the argument.

Thank you in advance for your consideration of this request.

Very truly yours,

Jennifer L. Groves

cc: Marna P. Borgstrom
Frank A. Corvino
Stephen M. Cowherd, Esq.

Martone, Kim

From: Jennifer Groves <JGroves@uks.com>
Sent: Thursday, January 10, 2013 9:37 AM
To: Martone, Kim

Thanks for the voicemail!

Jennifer L. Groves, Esq.
Principal
Updike, Kelly & Spellacy, P.C.
One Century Tower
265 Church Street
New Haven, CT 06510
Office (203) 786.8316
Cell (203) 927.8122
Fax (203) 772.2037
www.uks.com



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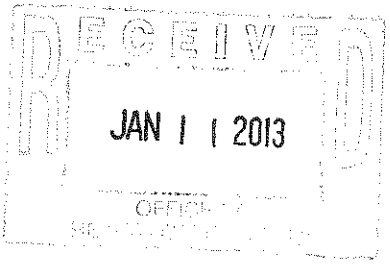
UKS

MERITAS LAW FIRMS WORLDWIDE

Jennifer L. Groves
(t) 203.786.8316
(f) 203.772.2037
jgroves@uks.com

January 11, 2013

Lisa Davis, MBA, BSN, RN
Deputy Commissioner
State of Connecticut
Department of Public Health
410 Capitol Avenue, P.O. Box 34038
MS #13HCA
Hartford, CT 06134-0308



Re: Proposal to Establish Elective Angioplasty Program at Greenwich Hospital
Docket No. 12-31748-CON

Dear Deputy Commissioner Davis,

This office represents Greenwich Hospital ("Greenwich") and Yale-New Haven Hospital ("YNHH") (collectively "Applicants") in connection with the above-referenced CON Application to establish an elective angioplasty program in Greenwich. Enclosed please find an original and two (2) copies of Applicants' Exceptions to Proposed Final Decision. Marna Borgstrom, CEO of YNHH and President and CEO of the Yale-New Haven Health System, and Frank Corvino, President and CEO of Greenwich Hospital, will accompany me to argue these exceptions on January 16, 2013.

Please feel free to contact me with any questions. We look forward to meeting with you.

Very truly yours,

Jennifer L. Groves

cc: Marna P. Borgstrom
Frank A. Corvino
Stephen M. Cowherd, Esq.

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

GREENWICH HOSPITAL AND YALE-NEW HAVEN HOSPITAL'S PROPOSAL TO ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM WITHOUT ON-SITE SURGICAL BACKUP AT GREENWICH HOSPITAL	)	DOCKET NO. 12-31748-CON
	)	JANUARY 11, 2013

EXCEPTIONS TO PROPOSED FINAL DECISION

Greenwich Hospital ("Greenwich") and Yale-New Haven Hospital ("YNHH"), Applicants in the above-referenced Certificate of Need ("CON") proceeding, submit the following Exceptions to the Proposed Final Decision rendered by the Office of Health Care Access ("OHCA"), through Hearing Officer Joanne V. Yandow, on November 20, 2012 (the "Proposed Final Decision"). Applicants intend to appear before Deputy Commissioner Lisa Davis on January 16, 2013, and present oral argument on these Exceptions.

I. Introduction

Greenwich and YNHH seek approval from OHCA to establish and operate an elective angioplasty program at Greenwich Hospital (the "Elective Angioplasty Program"). Greenwich is a short-term acute care hospital and an affiliate of the Yale-New Haven Health System ("YNHHS") (CON Application, p. 14). Greenwich offers a broad array of cardiac services in conjunction with the Yale-New Haven Heart and Vascular Center ("YNHHVC"), including a satellite primary angioplasty program (the "Primary Angioplasty Program"), which was

approved by OHCA on a permanent basis in July of 2008, after completion of a three-year demonstration project (Docket No. 03/08-30148; CON Application, pp. 14-15).

Greenwich has all of the infrastructure and staff in place to perform primary or "emergency" angioplasty procedures and has been performing these procedures on critically ill patients since 2005. Primary angioplasty patients are typically more difficult to care for and present greater risks than elective angioplasty patients given the emergent nature of their conditions. Greenwich Hospital has provided these patients with superior care for almost eight years, even without the availability of onsite cardiac surgical backup. Applicants now request permission to provide these same types of procedures (utilizing the staff and equipment already in place) on an elective basis, in more routine less emergent cases (Proposed Final Decision, FF 16; CON Application, pp. 14-15 & 40; Completeness Question Responses, p. 599; Testimony of Christopher Howes, M.D., p. 671; July 16, 2012 Public Hearing Transcript, pp. 19, 59, 70, 84 & 88).

Despite the fact that Greenwich does not have an Elective Angioplasty Program, patients continue to present at the Hospital in need of these critical healthcare services (CON Application, pp. 19 & 32; Completeness Question Responses, p. 589). The patients who present to Greenwich Hospital and require elective angioplasty are for the most part transferred to YNHH, where they received these services from the exact same physicians who would have performed the procedures at Greenwich if elective angioplasty was authorized. Greenwich service area resident have the right to receive cardiac care from the provider of their choosing, and they consistently choose Greenwich Hospital and the YNHHVC. This proposal would simply allow them to obtain this care within their community.

Applicants first applied for a full-service cardiac program at Greenwich Hospital, including elective angioplasty, in 2000 (Docket No. 00-520) (Public Hearing Transcript, pp. 91 & 138). The 2000 CON request was denied, largely based on a lack of "clear public need" for the proposal (Final Decision, Docket No. 00-520; Public Hearing Transcript, p. 91). However in the ensuing years, OHCA approved full-service cardiac programs, including elective angioplasty, at numerous hospitals throughout western Connecticut.[1] This included approval of a full-service cardiac program at The Stamford Hospital ("TSH") in 2006, located just six miles from Greenwich Hospital and within the service area where OHCA found there to be no need for these exact services (Rebuttal Testimony of Marna Borgstrom, p. 720; Public Hearing Transcript, p. 139). TSH was granted a CON at a time when angioplasty volumes were in decline – the primary reason why the Hearing Officer proposes to deny the current CON Application for an Elective Angioplasty Program at Greenwich (Proposed Final Decision, FF 37; Borgstrom Rebuttal Testimony, pp. 699-701). Now the existence of TSH's program (as well as a White Plains Hospital program established in 2010) is being used to support OHCA's position that there is no need for this proposal and that it will result in the unnecessary duplication of services, just as it was in 2010 when Applicants' second request to establish an Elective Angioplasty Program at Greenwich was denied (Docket No. 08-31210-CON) (Proposed Final Decision, FF 10, 13, 14, 15, 37, 40, 43, 44, 45, 53, 54, 58 & 60).

The Hearing Officer proposes to deny Applicants' most recent request for a CON primarily on the grounds that there is no "clear public need" for an Elective Angioplasty Program at Greenwich (Proposed Final Decision, FF 53, 54 & 58). We respectfully disagree

[1] Danbury Hospital, Docket No. 03-30143; Waterbury Hospital, St. Mary's Hospital & John Dempsey Hospital, Docket No. 03-30167; The Stamford Hospital, Docket No. 04-30374.

with the Hearing Officer's analysis of "clear public need," which overlooks such crucial factors as existing patient preference and physician referral patterns; credible evidence that area physicians will bring additional volume to Greenwich; the lack of overlap in the cardiac service areas of Greenwich and other elective angioplasty providers; and the clinical need for elective angioplasty services in Greenwich to ensure the quality of cardiac care and the safety of patients in the region, all of which is documented throughout Applicants' CON submissions and hearing testimony.

In addition, the Hearing Officer relies too heavily on the "clear public need" criteria set forth in Section 19a-639(a)(3) of the Connecticut General Statutes, to the exclusion of the other, equally relevant CON guidelines and principles that must be considered by the agency. Applicants respectfully disagree with a number of findings made by the Hearing Officer with respect to the remaining Section 19a-639(a) decision criteria (Proposed Final Decision, FF 53, 55, 56, 59 & 60). All of the Section 19a-639(a) criteria were thoroughly satisfied and the totality of the evidence supports approval of this CON Application. Applicants have shown not only that there is a clear public need for an Elective Angioplasty Program at Greenwich, but that such a program would improve the quality, accessibility and cost-effectiveness of healthcare in the region. It honors a patient's right to choose and it will not adversely impact existing providers of elective angioplasty services. Moreover, this program will help to strengthen Greenwich Hospital financially, making it good public policy and consistent with OHCA's statutory mission to ensure, among other things, the financial strength of the healthcare system statewide. For these reasons, Applicants' proposal should be approved.

II. Exceptions

Applicants take exception with numerous Findings of Fact contained within the Proposed Final Decision. These Findings of Fact center mostly around the Section 19a-639(a) decision criteria and are set forth below. Arguments in support of these exceptions are presented in Section III of this brief.

FF 12: *In 2010, OHCA issued a decision denying Greenwich Hospital's first proposal to establish and operate elective angioplasty program without on-site open heart surgery. The proposal was denied because the projected volume included New York patients, there was insufficient evidence to support the projected volumes, and there was an existing provider of elective PCI and full service cardiac program in the service area (Stamford Hospital).*

FF 14: *Stamford Hospital and White Plains Hospital are currently providing elective angioplasty procedures in Greenwich Hospital's claimed PSA.*

FF 36: *Although Applicants provided letters of support from the two (2) physicians from the state of New York who state they would offer elective PCI at Greenwich Hospital if that were an option, the projected new PCI volumes are speculative and appear to be a shifting of the elective PCI patients from an area provider to Greenwich Hospital.*

FF 40: *Stamford Hospital's PCI discharges have declined 15% between FY 2009-2011 and, therefore, Stamford Hospital has capacity to serve the needs of the community.*

FF 42: *In light of the historical elective PCI transfers from Greenwich Hospital to existing providers and the declining statewide PCI volumes, OHCA finds that the Applicants have not provided sufficient evidence to support its projected PCI utilizations.*

FF 43: *A letter from White Plains Hospital states that its elective PCI program presently has capacity to service the needs of the community and they are not aware of any backlog of cases in their service area that would indicate patients are not receiving timely care.*

FF 44: *White Plains Hospital is located approximately ten (10) miles west of Greenwich Hospital. If this application is approved, three (3) elective angioplasty programs will operate within sixteen (16) miles of each other.*

FF 45: *The map illustrates the location of Greenwich Hospital and the existing providers such as Stamford Hospital and White Plains Hospital, in Greenwich Hospital's proposed service area and their approximate distance to Greenwich Hospital.*

FF 53: *OHCA is currently in the process of establishing the statewide facilities and services plan ("the plan"). The plan was not a published document at the time of this*

proposal was filed; however, even if the plan is published by the time this final decision is issued, it has no bearing on the outcome of this matter, as the Applicants have not sufficient demonstrated a clear public need for this proposal.

FF 54: *There is insufficient evidence to establish that there is a clear public need for the Applicants' proposal.*

FF 55: *The Applicants have not satisfactorily demonstrated how this proposal will impact the financial strength of the health care system in this state.*

FF 56: *The Applicants have failed to satisfactorily demonstrate that their proposal would improve the accessibility of health care delivery in the region but they have satisfactorily demonstrated a potential improvement in quality and cost effectiveness.*

FF 58: *The Applicants have satisfactorily identified the population to be served by their proposal but have failed to satisfactorily demonstrate that this population has a need as proposed.*

FF 59: *The historical elective PCI discharges in the service area do not support this proposal.*

FF 60: *The Applicants have failed to satisfactorily demonstrate that their proposal would not result in any unnecessary duplication of existing elective PCI services in the area.*

Applicants also take exception with how these Findings of Fact are interpreted in the Discussion section of the Proposed Final Decision.

In addition, there are certain Findings of Fact that Applicants believe support their proposal and were not given due weight by the Hearing Officer. These Findings of Fact are discussed in the Argument section below.

III. Argument

A. Consideration of the Section 19a-639(a) Guidelines & Principles

Sections 19a-639(a)(1) through 19a-639(a)(9) of the Connecticut General Statutes set forth the guidelines and principles that must be used by OHCA in evaluating CON proposals. Section 19a-639(a) states that "[i]n any deliberations involving a certificate of need application filed pursuant to section 19a-638, the office shall take into consideration and make written

findings concerning" the guidelines and principles contained within the statute.[2] These guidelines and principles are more commonly known as the "statutory decision criteria" for CON applications. Although OHCA is required to consider and make written findings concerning each of the guidelines and principles set forth in Section 19a-639(a), the statute does not contain an express requirement that an applicant demonstrate a specific level of compliance with every stated criteria. Nor does the statute authorize OHCA to give substantial weight to one of the criteria to the exclusion of all others or to fail to make findings with respect to one of the criteria because another has not been met to the agency's satisfaction. If OHCA makes findings on the statutory decision criteria consistent with the evidence in the record, and considers all of these findings together, the CON Application should be approved.

[2] Conn. Gen. Stat. § 19a-639(a) provides in its entirety: In any deliberations involving a certificate of need application filed pursuant to section 19a-638, the office shall take into consideration and make written findings concerning each of the following guidelines and principles: (1) Whether the proposed project is consistent with any applicable policies and standards adopted in regulations by the office; (2) The relationship of the proposed project to the state-wide health care facilities and services plan; (3) Whether there is a clear public need for the health care facility or services proposed by the applicant; (4) Whether the applicant has satisfactorily demonstrated how the proposal will impact the financial strength of the health care system in the state; (5) Whether the applicant has satisfactorily demonstrated how the proposal will improve quality, accessibility and cost effectiveness of health care delivery in the region; (6) The applicant's past and proposed provision of health care services to relevant patient populations and payer mix; (7) Whether the applicant has satisfactorily identified the population to be served by the proposed project and satisfactorily demonstrated that the identified population has a need for the proposed services; (8) The utilization of existing health care facilities and health care services in the service area of the applicant; and (9) Whether the applicant has satisfactorily demonstrated that the proposed project shall not result in an unnecessary duplication of existing or approved health care services or facilities.

i. Applicants' Demonstrated a Clear Public Need For This Proposal

In this case, the Hearing Officer made a number of factual findings in support of her conclusion that there is no clear public need for Applicants' proposal (Conn. Gen. Stat. §19a-639(a)(3)) (Proposed Final Decision, FF 42, 53, 54 & 58). Applicants take exception with these findings as set forth below:

- Applicants' Projections Are Supported By Evidence.

  In Finding of Fact 35, the Hearing Officer acknowledges that a percentage of the projected elective angioplasty volume at Greenwich Hospital will result from the addition of New York interventional cardiologists who do not practice at Greenwich currently, but have referral relationships with the medical staff and will utilize the Hospital for elective angioplasty if a program is approved (Howes Testimony, pp. 670-671 & 675-676). Although Applicants provided letters of support from two of these New York physicians, OHCA found that their projected PCI volumes were speculative and appear to represent a shift of elective PCI patients from one area provider to Greenwich (Proposed Final Decision, FF 36).

  As a threshold matter, projections by their very nature are speculative. Applicants provided letters of support from named physicians, which included firm commitments to perform an identifiable number of elective angioplasties at Greenwich Hospital each year (Howes Testimony, pp. 675-676). OHCA has historically allowed providers to establish projected volume through letters from physicians indicating that they will refer/perform a certain number of procedures if a CON is approved. For example, this is common in CON applications for the acquisition of major imaging equipment or the addition of owners to an

ambulatory surgery center. In fact, OHCA will often accept projected volume attributable to anonymous physicians because in this competitive healthcare environment, many physicians are hesitant to publically support one provider when they work with many. Moreover, Applicants explained to the Hearing Officer that physicians typically will not make formal commitments (beyond a letter of support) unless and until a CON for a new service is approved (Public Hearing Transcript, p. 117).

In addition, while the Hearing Officer calls Applicants' letter evidence "speculative," a letter offered by Susan Fox, Executive Vice President of White Plains Hospital ("White Plains"), is taken as entirely true and accurate (Proposed Final Decision, FF 13-15, 36 & 43; Testimony of Sharon Kiely, M.D., pp. 49-50).[3] This letter caused the Hearing Officer to conclude that White Plains has the "capacity to serve the needs of the community," without any critical analysis of the unsubstantiated claims made by Ms. Fox (Proposed Final Decision, FF 43).

Moreover, the evidence in the record does not support the Hearing Officer's conclusion that the projected volume from New York interventional cardiologists "appears to be a shifting of the elective PCI patients from an area provider to Greenwich Hospital (emphasis added)" (Proposed Final Decision, FF 36). Neither TSH nor White Plains (via TSH) introduced any evidence that the cases promised by Drs. Newman and Hjemdahi-Monsen in their letters of support for this proposal were cases that would otherwise be performed at their facilities

[3] This letter was offered through Intervenor TSH. White Plains did not petition for status and Ms. Fox did not attend the hearing and testify.

(Howes Testimony, pp. 675-676). In fact, these are cases that we know to be performed for the most part at large New York City hospitals, including New York Presbyterian (Completeness Question Responses, p. 591; Public Hearing Transcript, pp. 57-58, 64-65). Moreover, the letters from Drs. Newman and Hjemdahi-Monsen state specifically that they would bring procedures to Greenwich that they currently treat at hospitals outside of Connecticut (Howes Testimony, pp. 675-676). Accordingly, there is no proof that this proposal will result in a shift of volume from a smaller Connecticut provider such as TSH or that it would impact TSH (or White Plains) in any way.

- Excess Capacity At Existing Providers Is Unsubstantiated and Irrelevant.

We respectfully disagree with the Hearing Officer's conclusion that TSH and White Plains have capacity to serve the elective angioplasty needs of the community (Proposed Final Decision, FF 40 & 43). These conclusions were drawn based upon a recent decline in TSH's inpatient PCI volume and the above-referenced letter from Susan Fox attesting to White Plains' capacity. No further analysis has been done regarding if and how these providers could and would meet the elective angioplasty needs of the Greenwich community. It is worth nothing that this decline in TSH's inpatient PCI volume may be attributable to the migration of more PCI cases to an outpatient setting.

The reality is there is minimal overlap between the service areas of TSH and Greenwich for cardiac services. The Hearing Officer acknowledges this in Finding of Fact 11, wherein she found that 80% of Greenwich's cardiovascular patients come from Greenwich, Port Chester and Rye, while only 4.6% of TSH's

cardiovascular patients originate from these towns. Conversely, 88% of TSH's cardiovascular patients come from Stamford and Darien, while only 7% of Greenwich's cardiovascular patients originate from these towns (Proposed Final Decision, FF 11; Howes Testimony, pp. 669-670).

OHCA cannot force a change in patient preference and physician referral patterns for cardiac services (Howes Rebuttal Testimony, pp. 668-671). The TSH and White Plains programs have been operational for years and yet patients continue to present at Greenwich Hospital in need of elective angioplasty services (CON Application, pp. 19 & 32; Completeness Question Responses, p. 589; Howes Rebuttal Testimony, pp. 762-763). Thus, even if there is excess capacity at TSH and/or White Plains, which has not been established as fact, this should not be considered in evaluating the needs of patients who choose Greenwich over either of these hospitals and who, if no program is available in Greenwich, will travel as far as New York City for their cardiac care (Howes Testimony, pp. 657-676; Public Hearing Transcript, pp. 57-58 & 64-65).

- Existence of Multiple Providers In Area Does Not Mean There Is No Need.

The Hearing Officer's determination that there is no clear public need for this proposal is based, in part, on the fact that if Greenwich Hospital offered elective angioplasty there would be three elective angioplasty providers within 16 miles of each other (Proposed Final Decision, FF 44 & 45). However, there are other areas in the state where three or more elective angioplasty providers operate within a similar radius. OHCA has approved full-service cardiac programs at John Dempsey Hospital, Hartford Hospital and St. Francis Hospital and Medical

Center, which are located less than 10 miles from each other (see Exhibit A attached). In addition, OHCA has approved full-service cardiac programs at YNHH (and the former Hospital for St. Raphael – now YNHH), Bridgeport Hospital and St. Vincent's Medical Center. The distance between the farthest of these locations is just over 20 miles (see Exhibit B attached). Note also that in these areas of the state, travel within a 10 to 20 mile radius is considerably easier and faster than traveling within the 16 mile radius between Stamford and White Plains, which experiences significant traffic and delays at various times throughout the day. Thus, the fact that approval of Applicants' proposal would result in three elective angioplasty providers being located within a 16 mile radius (one of which is a New York provider whose revenues do not support the financial strength of the Connecticut healthcare system) should not be determinative of a lack of clear public need.

- Flat PCI Volumes Do Not Mean There Is No Clear Public Need For Program.

The Hearing Officer found that the flat to declining elective angioplasty volumes in the state and proposed service area do not support establishment of an additional elective angioplasty program (Proposed Final Decision, FF 59). This was an argument raised by TSH in opposition to Applicants' proposal. However, the Hearing Officer has overlooked the equally important fact that when TSH sought and received approval for its full-service cardiac program, which includes elective angioplasty, PCI volumes were also declining statewide and in the service area (Borgstrom Rebuttal Testimony, pp. 699-701). If this factor were determinative of need, then TSH's CON application should have been denied.

But it was not denied, rather that CON was approved based on factors such as improved accessibility, continuity of care and improved quality of cardiac services (Borgstrom Rebuttal Testimony, pp. 701 & 732-733). These are the same factors that were raised by Applicants in support of a program at Greenwich. They speak less of a numerical demand for services and more to a clinical demand for care. That demand exists in terms of a patient's right to receive critical cardiac healthcare services at the provider of his/her choice (Howes Rebuttal Testimony, pp. 668-671); in the physical and mental stress that results for patients and families when they are transferred out of Greenwich Hospital for elective angioplasty (Proposed Final Decision, FF 20; CON Application, pp. 19-20; Completeness Question Responses, pp. 589 & 599); and in the physical risks and excess costs associated with having duplicate cardiac procedures, all of which were documented throughout Applicants CON submissions and hearing testimony (Proposed Final Decision, FF 27 & 47; CON Application, p. 40; Public Hearing Transcript, pp. 30-31, 66-67 & 76). Applicants therefore request that in the interest of fairness and consistency in decision making, OHCA reconsider its findings in this regard.

Based on the foregoing and all of the evidence in the record, Applicants have established a clear public need for the proposed Elective Angioplasty Program at Greenwich Hospital. Applicants respectfully request that Findings of Fact 12, 14, 36, 40, 42-45, 53, 54 58 and 59, and any discussion arising from those Findings of Fact, be revised accordingly.

ii. Applicants Met The Remaining Applicable Statutory Decision Criteria

Applicants also take exception with a number of the Findings of Fact relative to the remaining Section 19a-639(a) decision criteria, as set forth below.

a. Financial Strength of the Healthcare System

The Hearing Officer found that Applicants failed to satisfactorily demonstrate how the proposal will impact the financial strength of the healthcare system in this state (Conn. Gen. Stat. §19a-639(a)(4)) (Proposed Final Decision, FF 55). However, Applicants have introduced sufficient evidence to demonstrate that the proposed elective angioplasty program will have a positive financial impact on Greenwich Hospital and, as such, on the healthcare system as a whole.

As a threshold matter, this statutory guideline is relatively new. It was introduced in 2010, when CON laws were completely overhauled by the legislature. In 2012, OHCA attempted to revise this guideline out of Section 19a-639(a). The rationale given by OHCA staff was that the agency "does not have the data to properly evaluate the financial impact of the CON proposal on the state's healthcare system" and "CON applicants struggle to produce evidence demonstrating the impact of the proposal on the state's health care system" (Public Health Committee Testimony, dated March 7, 2012, attached as Exhibit C). Historically, OHCA has allowed providers to demonstrate compliance with this guideline by introducing evidence regarding the positive financial impact of a proposal on a healthcare facility as a result of cost-savings, increased revenue and the like (see i.e. Docket Nos. 11-31736-CON & 12-31750-CON). Anything that improves a hospital or healthcare facility's financial position and/or streamlines

care appears to impact favorable on the financial strength of the institution and the healthcare system as a whole.[4]

Applicants offered evidence to support a finding that the proposed Elective Angioplasty Program will benefit both Greenwich Hospital and its patients financially and, therefore, impact favorably on the financial strength of the healthcare system. This includes evidence, referenced by OHCA in the Proposed Final Decision, that the existence of elective angioplasty at Greenwich would reduce the need for patient transfers and duplicate procedures, which in turn reduces healthcare costs (Proposed Final Decision, FF 47; CON Application, p. 40; Frank Corvino's Testimony, p. 681-682; Public Hearing Transcript, pp. 30-31, 67 & 76, 79-80). In addition, Applicants submitted evidence that the inclusion of elective angioplasty cases would reduce some of the financial burden attributable to the maintenance of staff and infrastructure for primary angioplasty cases (Proposed Final Decision, FF 50 & 51; CON Application pp. 20 & 40-41; Completeness Question Responses, pp. 598-599). Given the broad manner in which this statutory provision has been interpreted by OHCA, a finding should have been made in favor of Applicants. Applicants respectfully request that Finding of Fact 55, and any discussion arising from that Finding of Fact, be revised accordingly.

[4] Note also that there are a number of 2012 CON approvals that make no mention of this particular decision criteria, therefore, failure to meet it should not, in and of itself, be used as a basis for denial (i.e. Docket Nos. 12-1759-CON; 11-31734-CON; and 11-31730-CON).

b. Accessibility, Quality and Cost-Effectiveness of Healthcare

The Hearing Officer correctly found that Applicants demonstrated a potential improvement in quality and cost-effectiveness with the proposed Elective Angioplasty Program, but erred in finding no evidence that the proposal would improve the accessibility of healthcare delivery in the region (Proposed Final Decision, FF 56). Applicants take exception with this finding for several reasons.

First, any time a hospital adds a healthcare service it enhances access to care. Elective angioplasty is not available at Greenwich Hospital despite the fact that many patients attempt to access this service at the Hospital each year. These patients are denied access and as result, experience considerable stress and incur additional costs associated with the receipt elective angioplasty services elsewhere (CON Application, pp. 19-20, 32; Completeness Question Responses, pp. 589 & 599; Public Hearing Transcript, pp. 19, 66-67, 86, 119-120). Drs. Newman and Hjemdahi-Monsen indicated in their letters of support for this proposal that their patients desire local access to elective angioplasty services, access that is not currently available (Howes Testimony, pp. 675-676). If Greenwich had an elective angioplasty program, these individuals would have access to this critical healthcare service at the hospital of their choosing in their community, where care can be provided appropriately and safely – in this case, a hospital affiliated one of the nation's leading cardiac providers (Public Hearing Transcript, pp. 24, 92). This is improved accessibility of healthcare.

Moreover, while there are no current regulations that define "accessibility" for CON purposes, the former OHCA regulations define this term to include

"accessibility to medically underserved individuals who often experience the greatest difficult in obtaining equitable access to health services" (Regulations of Connecticut State Agencies, §19a-643-71). Increasing access to a hospital-based service inevitably increases access for the underserved, including uninsured individuals, as well as Medicare and Medicaid patients. As the payer mix projections in Applicants' CON submissions show, the Elective Angioplasty Program would be comprised of 45.9% Medicare/Medicaid patients and 5.4% uninsured patients (CON Application, p. 40).

c. Decline in Elective PCI Is Not Basis For Denial of CON

Section 19a-639(a)(8) of the General Statutes requires OHCA to consider and make findings regarding the "utilization of existing health care facilities and health care services" in the service area. In this regard, the Hearing Officer made findings with respect to the historic utilization of PCI services, which are set forth in Findings of Fact 38 through 42 and 55. Ultimately, the Hearing Officer found that Applicants had not provided sufficient evidence to support their projected PCI utilization and that historical elective PCI discharges in the service area do not support this proposal (Proposed Final Decision, FF 42 & 59). Applicants take exception with these findings.

Specifically, Applicants take exception with the Hearing Officer's conclusion that declining PCI volumes indicate that there is no clear public need for an Elective Angioplasty Program at Greenwich. As previously mentioned, Applicants have projected volume that is supported by evidence in the record. Applicants' volume projections are based on historical primary angioplasty

volume and elective angioplasty transfers, as well as an informal survey of referring physicians and letters from New York physicians indicating that they would perform cases at Greenwich if this CON is approved. These letters should be afforded the same weight, and considered equally as credible, as the letter from Susan Fox of White Plains, which the Hearing Officer cites throughout her decision (Proposed Final Decision, FF 13, 15 & 43).

Moreover, although PCI volume is declining, it was also declining leading up to 2006, when TSH was given permission to establish a full-service cardiac program including elective angioplasty (Borgstrom Rebuttal Testimony, pp. 699-701). Even with declining PCI volume and an elective angioplasty program at TSH, patients continue to present at Greenwich Hospital in consistent numbers each year in need of these services (CON Application, p. 19-22 & 32; Completeness Question Responses, p. 589; Public Hearing Transcript, p. 27). There is clearly a need for elective angioplasty in the Greenwich area among this patient population, which is not being met by area providers. In evaluating this proposal, OHCA should consider not only this need, but those same factors it considered in evaluating TSH's application – namely, whether the program would improve accessibility, quality and continuity of care (Borgstrom Rebuttal Testimony, pp. 701 & 732-733).

In addition, as mentioned above, the Hearing Officer's finding that TSH has the capacity to meet all community need for elective angioplasty is not supported by evidence in the record (Proposed Final Decision, FF 40). For these reasons, Applicants ask OHCA to find that utilization of elective PCI services – in

particular, the continued attempts by area residents to access these services at Greenwich Hospital – supports approval of this CON request. Finding of Fact 59, and any discussion related thereto, should be revised accordingly.

d. This Proposal Will Not Result in an Unnecessary Duplication of Services

OHCA is required by Section 19a-639(a)(9) to make findings with respect to whether a proposal results in the unnecessary duplication of existing healthcare services. Applicants take exception with the Hearing Officer's finding that they failed to show that unnecessary duplication of services will not result from the addition of elective angioplasty at Greenwich Hospital (Proposed Final Decision, FF 60). As previously mentioned, the Hearing Officer concedes in Finding of Fact 11 that there is virtually no overlap for cardiovascular services between Greenwich and TSH. The disparity in patient towns of origin is significant (Howes Testimony, pp. 668-671; Howes Rebuttal Testimony, pp. 762-763). If Greenwich and TSH are not providing cardiac services to the same patient populations, then the addition of an Elective Angioplasty Program at Greenwich will not result in the unnecessary duplication of services. Moreover, there is no evidence in the record that definitively establishes a service area for elective angioplasty at White Plains, therefore the Hearing Officer cannot conclude that a Greenwich program would duplicate services available at this New York hospital. As previously noted, the geographic proximity of programs is not sufficient evidence that services are duplicative and unnecessary at any given location. Connecticut has thriving cardiac programs at many hospitals in close proximity to each other (i.e. John Dempsey Hospital/Hartford Hospital/St. Francis Hospital &

Medical Center; Yale-New Haven Hospital/Bridgeport Hospital/St. Vincent's Medical Center).

In addition, there is evidence in the record that this proposal would in fact avoid the unnecessary duplication of services. As OHCA acknowledged in the Proposed Final Decision, payers and patients incur unnecessary costs of approximately $425,000 per year as a result of the need to be transferred from Greenwich Hospital to another provider for elective angioplasty (Proposed Final Decision, FF 47; CON Application, p. 40; Corvino Testimony, pp. 681-682; Public Hearing Transcript, pp. 30-31, 66-67 & 76). If Greenwich was authorized to provide this service, these duplicate procedures and costs would be avoided. For these reasons, OHCA should find that Applicants have adduced evidence that this proposal will not result in the unnecessary duplication of services. Finding of Fact 60, and any discussion related thereto, should be revised accordingly.

iii. OHCA's Decision Relied Too Heavily On The Clear Public Need Criteria

The Hearing Officer based her decision to deny Applicants' request for permission to establish an Elective Angioplasty Program at Greenwich almost entirely on her conclusion that there is no clear public need for the proposal. Even assuming this is the case, which Applicants dispute, the Hearing Officer should not have relied on one of the Section 19a-639(a) criteria to the exclusion of all others. As previously mentioned, Section 19a-639(a) requires OHCA to make written finding on each of the guidelines and principles set forth in the statute, but it does not require a specific level of compliance with every one of these criteria. Nor does it allow the agency to make decisions based on one of the criteria only or to fail to make findings on certain criteria. OHCA is obligated to review CON proposals based upon all of the factors that the

legislature deemed relevant and to base its decisions on the totality of evidence. Applicants have shown that there is a clear public need for an Elective Angioplasty Program at Greenwich and there is ample additional evidence in the record to support approval of this proposal. To deny Applicants' CON request would be clearly erroneous in view of the reliable, probative and substantial evidence on the whole record.

The Hearing Officer acknowledges that this proposal will potentially improve the quality and cost-effectiveness of cardiac care in the Greenwich area (Proposed Final Decision, FF 56). Enhanced quality of care is probably the most significant benefit of this CON proposal. The Greenwich Hospital cardiac program is part of the YNHHVC – an integrated model whereby the interventional cardiologists who perform angioplasty at Greenwich also perform cases at YNHH, the highest volume angioplasty provider with the most advanced cardiac program in the state (Proposed Final Decision, FF 3, 5 & 28; Borgstrom Testimony, p.. 672). The Hearing Officer does not give adequate weight to these key facts in recommending that the CON for an Elective Angioplasty Program at Greenwich be denied. Yet the practical effect of denial is to deprive Greenwich area residents in need of elective angioplasty of local access to the resources and professional expertise of the YNHHVC.

Moreover, both the quality and cost-effectiveness of care are enhanced by having an Elective Angioplasty Program at Greenwich, which avoids the need for patient transfers and duplicate procedures (Proposed Final Decision, FF 56). As Dr. Henry Cabin, Clinical Chief of Cardiology at the Yale University School of Medicine and Medical Director of the YNHHVC, testified at the public hearing on this matter, elective angioplasty would be performed at Greenwich Hospital by the exact same physicians who perform the procedure at YNHH, and it can be done as safely at Greenwich as at YNHH (Public Hearing Transcript, p. 60). It therefore

makes little sense, either from a cost or patient safety perspective, to deny patients local access to these services (Public Hearing Transcript, p. 60).[5]

As discussed above, the evidence demonstrates that the Elective Angioplasty Program will also improve the accessibility of cardiac care in the region. Increased patient access is inextricably linked with issues of quality and cost-effectiveness of care. Providing patients with local access to care is not just a convenience issue. It will truly enhance the quality of care for those patients who will continue to present at Greenwich in need of elective angioplasty, and who will insist that these services be provided by the highly qualified and experienced physicians and staff of the YNHHVC. As noted above, it makes little sense to allow the Greenwich-based YNHHVC physicians to perform elective angioplasty on Greenwich patients in New Haven, but not in their own community.

Increased access will also have a positive impact on the costs associated with obtaining and providing angioplasty services. OHCA cannot ignore the fact that when patients need to be transferred from Greenwich to another facility for elective angioplasty, which could safely and competently be performed at Greenwich, this costs patients, payers and the system as a whole more money. In addition, the Primary Angioplasty Program at Greenwich is a necessary but extremely costly program to operate on a continuous basis. The addition of an Elective Angioplasty Program at Greenwich, with more procedure volume over which to spread these fixed costs, will make the provision of angioplasty services more cost-effective for the Hospital. All of this will in turn have a positive financial impact on Greenwich Hospital and the state's healthcare system.

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[5] The Hearing Officer does not appear to be concerned, from a quality perspective, with the lack of onsite surgical backup at Greenwich. In fact, she suggests that White Plains, which has an elective angioplasty program without onsite surgery, is an appropriate alternative provider to meet the demand for these services in the Greenwich area.

Moreover, the Elective Angioplasty Program at Greenwich will not result in the unnecessary duplication of services because, as the evidence in the record clearly shows, there is minimal overlap in the cardiovascular patient populations at Greenwich and TSH. While it is true that PCI volume is in moderate decline, the present situation is no different that the situation that existed in 2006, when OHCA approved TSH's request for a CON to establish a full-service cardiac program. OHCA approved that application based upon factors including improved accessibility, quality and continuity of care – these are the same factors that support approval of Applicants' request. Applicants ask OHCA to reconsider and acknowledge the substantial benefits to patients, payers and the healthcare system that will result from a Final Decision approving this proposal.

B. Approval of This CON Is Sound Public Policy & Consistent With OHCA's Mission

Approving Applicants' request to establish an Elective Angioplasty Program at Greenwich Hospital is consistent with OHCA's statutory mission to promote the availability of cost-effective care and to ensure the financial strength of the healthcare delivery system in this state (Conn. Gen. Stat, Section 19a-637). The Hearing Officer's suggestion that White Plain has capacity to handle patients (presumably including Connecticut residents) in need of elective angioplasty is contrary to OHCA's mission in that it encourages the outmigration to New York of healthcare services and revenues. This is particularly troubling at a time when Connecticut hospitals are experiencing rising costs and declining revenue, all while trying to maintain their ability to provide core hospital services to their communities.

In addition, denial of this CON Application limits patient choice for critical health care services. Greenwich area residents have spoken and their preference is to obtain cardiac services through Greenwich Hospital and the YNHHVC. Given the nature of the services involved,

patients should not be forced to obtain care at an alternate provider. Moreover, patients should not be placed in a situation where they are expected to travel unreasonably long distances to obtain elective angioplasty services at the provider of their choosing.

IV. Requested Relief

In light of the foregoing, Applicants respectfully request the following relief:

- That OHCA revise the various Findings of Fact listed in the Exceptions section above, and any language within the Discussion section of the Proposed Final Decision based on the erroneous factual findings.

- That OHCA determine, specifically, that there is a clear public need for this proposal, that it will enhance the accessibility, quality and cost-effectiveness of healthcare and improve the financial strength of the healthcare delivery system, and that it will not result in the unnecessary duplication of services.

- That OHCA issue a Final Decision approving Applicants' request for a CON to establish an Elective Angioplasty Program at Greenwich Hospital.

In the alternative, Applicants ask that OHCA consider granting provisional approval of the proposed Elective Angioplasty Program under whatever terms the agency and Applicants agree are necessary to measure the need for this program and its impact on the healthcare delivery system. Any provisional approval might be similar to the approval given for the Primary Angioplasty Program at Greenwich (see Docket No. 03/08-30148), via Agreed Settlement, which included initial approval for a period of three years in order to validate that Applicants' projections (and minimum ACC/AHA/SCAI Guidelines volumes) had been

achieved. Applicants would agree to submit volume data to OHCA so that a similar analysis can be undertaken regarding the Elective Angioplasty Program. OHCA could also collect and analyze outcome and other relevant data to determine whether the proposal has met the programmatic requirements of the ACC/AHA/SCAI Guidelines. The submission of data would allow the agency to evaluate the proposed Elective Angioplasty Program at Greenwich Hospital and determine whether it should be given permanent status. Applicants are confident that all projections will be met and all measure will be achieved, proving that the proposal is necessary and fulfills the guidelines and principles set forth in Section 19a-639(a).

V. Conclusion

For all of the foregoing reasons, Applicants urges the Deputy Commissioner to revise the Findings of Fact and issue a Final Decision approving the proposed Elective Angioplasty Program at Greenwich Hospital. In the alternative, Applicants welcome a conversation with OHCA staff regarding the possibility of a provisional approval that will allow the agency to validate the need for the proposal and its impact on the accessibility, quality and cost-effectiveness of healthcare – cardiovascular services in particular – in the Greenwich Area. This program is critical to Greenwich Hospital patients and the time has come for it to be approved.

Respectfully Submitted,

GREENWICH HOSPITAL
YALE-NEW HAVEN HOSPITAL

By: _____

JENNIFER L. GROVES, ESQ.
Updike, Kelly & Spellacy, P.C.
265 Church Street
One Century Tower
New Haven, CT 06510
Tel: (203) 786-8300
Fax (203) 772-2037

CERTIFICATION

I hereby certify that a copy of the foregoing has been sent via first class mail, postage prepaid, this 11th of January, 2013 to the following:

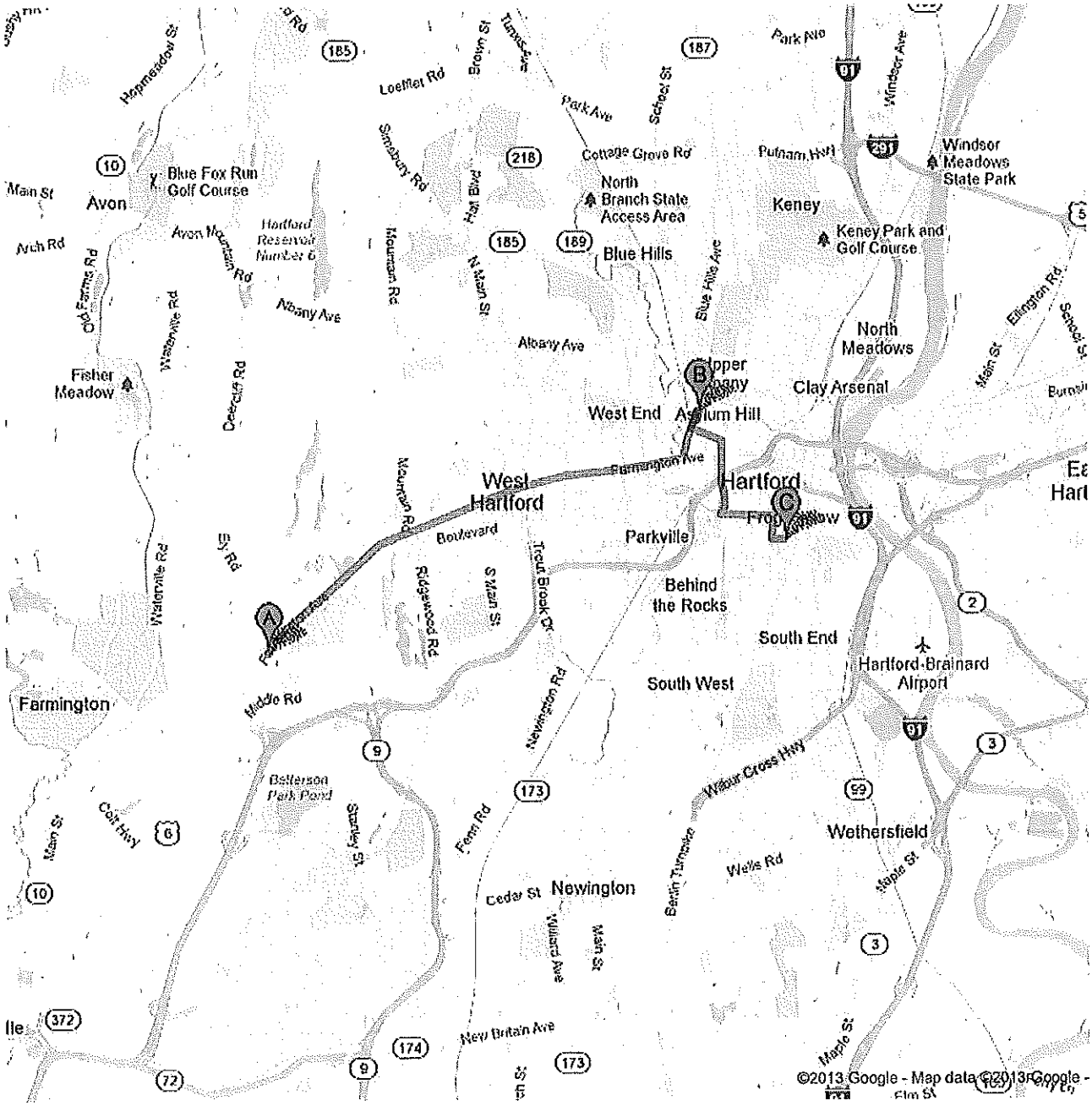
Stephen M. Cowherd
Jeffers Cowherd
5 Walls Drive
Fairfield, CT 06824

Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.

EXHIBIT A

Google

Directions to Hartford Hospital
80 Seymour Street, Hartford, Connecticut 06102
8.4 mi – about **23 mins**



John Dempsey Hospital
263 Farmington Avenue, Farmington, CT 06032

	1. Head **northeast** on **CT-4 E/Farmington Ave** toward **Main Rd** Continue to follow Farmington Ave About 13 mins	go 5.4 mi total 5.4 mi
↰	2. Turn left onto **Woodland St** About 2 mins	go 0.6 mi total 6.0 mi
		Total: **6.0 mi** – about **15 mins**

Saint Francis Behavioral Health
114 Woodland St, Hartford, CT 06105

total 0.0 mi

	3. Head **south** on **Woodland St** toward **Collins St**	go 0.2 mi total 0.2 mi
↰	4. Take the 2nd left onto **Asylum Ave** About 1 min	go 0.4 mi total 0.6 mi
↱	5. Turn right onto **Sigourney St** About 2 mins	go 0.7 mi total 1.3 mi
	6. Continue onto **Park Terrace**	go 0.2 mi total 1.4 mi
↰	7. Turn left onto **Park St** About 2 mins	go 0.6 mi total 2.0 mi
↱	8. Turn right onto **Washington St** About 58 secs	go 0.3 mi total 2.3 mi
↰	9. Turn left onto **Zwieback St** Destination will be on the left	go 0.1 mi total 2.4 mi
		Total: **2.4 mi** – about **8 mins**

Hartford Hospital
80 Seymour Street, Hartford, Connecticut 06102

These directions are for planning purposes only. You may find that construction projects, traffic, weather, or other events may cause conditions to differ from the map results, and you should plan your route accordingly. You must obey all signs or notices regarding your route.

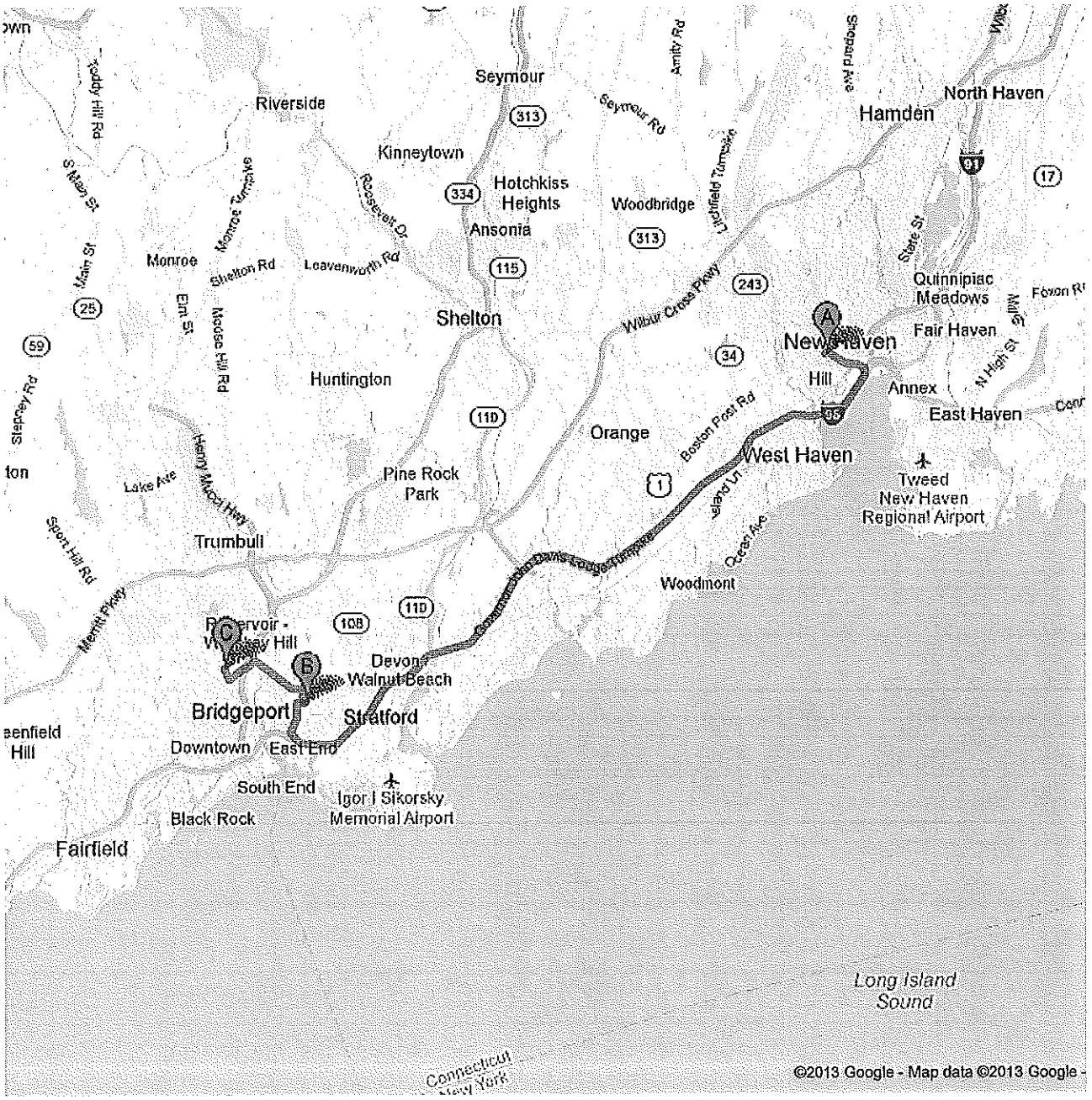
Map data ©2013 Google

Directions weren't right? Please find your route on maps.google.com and click "Report a problem" at the bottom left.

EXHIBIT B

Google

Directions to St. Vincent's Medical Center
2800 Main St, Bridgeport, CT 06606
22.1 mi – about **35 mins**



Yale-New Haven Hospital
20 York Street, New Haven, CT 06510

	1. Head **northeast** toward **York St**	go 148 ft total 148 ft
	2. Turn left onto **York St**	go 249 ft total 397 ft
	3. Take the 1st right onto **S Frontage Rd**	go 341 ft total 0.1 mi
	4. Slight left onto **Oak St Connector** About 1 min	go 0.7 mi total 0.9 mi
	5. Keep right at the fork, follow signs for **Interstate 95 S/N.Y. City** and merge onto **I-95 S** About 18 mins	go 17.2 mi total 18.1 mi
	6. Take exit **29** for **Seaview Avenue** toward **Connecticut 130/Stratford Avenue**	go 0.3 mi total 18.4 mi
	7. Turn right onto **Seaview Ave** About 2 mins	go 0.7 mi total 19.1 mi
	8. Turn right onto **Grant St** Destination will be on the left About 1 min	go 0.2 mi total 19.3 mi

Total: **19.3 mi** – about **24 mins**

Bridgeport Hospital
267 Grant Street, Bridgeport, CT 06610

total 0.0 mi

	9. Head **west** on **Grant St** toward **Central Ave**	go 266 ft total 266 ft
	10. Turn right onto **Central Ave** About 2 mins	go 0.3 mi total 0.4 mi
	11. Turn left onto **Boston Ave** About 4 mins	go 1.3 mi total 1.7 mi
	12. Turn left onto **North Ave** About 2 mins	go 0.2 mi total 1.9 mi
	13. Turn right onto **Capitol Ave** About 2 mins	go 0.5 mi total 2.5 mi
	14. Turn right onto **Main St** Destination will be on the right About 1 min	go 0.3 mi total 2.8 mi

Total: **2.8 mi** – about **11 mins**

St. Vincent's Medical Center
2800 Main St, Bridgeport, CT 06606

These directions are for planning purposes only. You may find that construction projects, traffic, weather, or other events may cause conditions to differ from the map results, and you should plan your route accordingly. You must obey all signs or notices regarding your route.

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EXHIBIT C

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

TESTIMONY PRESENTED BEFORE THE COMMITTEE ON PUBLIC HEALTH
March 7, 2012

Kimberly Martone, Director of Operations, Office of Health Care Access, 860-418-7029

House Bill – Bill 5321 - An Act Concerning the Office of Health Care Access and the Certificate of Need Process

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The Department of Public Health would like to provide the following information in favor of House Bill 5321. We thank the Committee for choosing to take up the Department's proposal. Below is information on the provisions contained in the bill.

Section 1

The Department's Office of Health Care Access (OHCA) is proposing to replace the phrase "how the proposal will impact the financial strength of the health care system in the state" within §19a-639(a)(4) of the General Statutes with "that the proposal is financially feasible for the applicant." In evaluating Certificate of Need (CON) applications, OHCA can verify and measure the effect a CON proposal has on the applicant by reviewing the financial status of the applicant; however, OHCA does not have the data to properly evaluate the financial impact of the CON proposal on the state's health care system. Moreover, CON applicants struggle to produce evidence demonstrating the impact of the proposal on the state's health care system. It is also worth noting that the majority of the CON proposals received and reviewed by OHCA over the past year involve the acquisition of imaging equipment, the establishment of substance abuse/mental health services, and transfer of ownership of a health care facility. Such proposals do not lend themselves to an easy demonstration of their impact on the financial strength of the health care system statewide.

Prior to the changes implemented under Public Act 10-179, OHCA evaluated the financial feasibility of the proposal rather than looking at the impact on the entire state. This financial feasibility evaluation is a more realistic guideline and most applicants are able to produce financial documents and analysis demonstrating that a particular proposal is financially feasible.

Section 2

OHCA proposes to amend the proposed language in this section by deleting "after the date the office closes the public hearing" in line 49 and substituting "following the close of the hearing record." This is to clarify the closing of the hearing record as opposed to the actual public hearing. At the public hearing, OHCA often orders additional evidence be provided after the public hearing has ended. Once the information is received by OHCA, it then *closes* the hearing record through a letter. Therefore, the proposed language clarifies when the hearing record is legally closed as well as the day on which the 60 day review period for OHCA to render a decision begins.

Phone: (860) 509-7269, Fax: (860) 509-7100
Telephone Device for the Deaf (860) 509-7191
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P.O. Box 340308 Hartford, CT 06134
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STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

January 31, 2013

IN THE MATTER OF:

An Application for a Certificate of Need filed pursuant to General Statutes § 19a-638 (a) (1) by:	Notice of Final Decision Office of Health Care Access Docket Number: 12-31748-CON
Greenwich Hospital and Yale-New Haven Hospital	**Establish and Operate an Elective Angioplasty Program Without Onsite Surgical Backup at Greenwich Hospital**

To: Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.
265 Church Street
One Century Tower
New Haven, CT 06510

Dear Attorney Groves:

In accordance with the Connecticut General Statutes Section 4-179, the Proposed Final Decision dated November 20, 2012, by Hearing Officer Joanne Yandow, Esq., is hereby adopted as the final decision of the Deputy Commissioner of Department of Public Health in this matter. A copy of the Proposed Final Decision is attached hereto and incorporated herein.

Sincerely,

Kimberly R. Martone,
Director of Operations

KRM: swl
cc: Marianne Horn, Esq., Hearing Officer, DPH

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Jewel Mullen, M.D., M.P.H., M.P.A.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

In Re: **Greenwich Hospital and Yale-New Haven Hospital**
Docket Number: 12-31748-CON

FINAL DECISION

On November 20, 2012, a Proposed Final Decision was issued in the above matter pursuant to Section 4-179 of the Connecticut General Statutes.

In accordance with Connecticut General Statutes Section 4-179, the attached Proposed Final Decision dated November 20, 2012 by Hearing Officer Joanne Yandow, Esq., is hereby adopted as the final decision of the Deputy Commissioner of the Department of Public Health in this matter. A copy of the Proposed Final Decision is attached hereto and incorporated herein.

WHEREFORE, it is the final decision of the Deputy Commissioner that the application of Greenwich Hospital and Yale-New Haven Hospital, to establish and operate an elective angioplasty program without onsite surgical backup at Greenwich Hospital, is hereby denied.

1/31/13
Date

Lisa A. Davis, MBA, BSN, RN
Deputy Commissioner

Connecticut Department of Public Health

Phone: (860) 509-8000 • Fax: (860) 509-7184 • VP: (860) 899-1611
410 Capitol Avenue, P.O. Box 340308
Hartford, Connecticut 06134-0308
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Office of Health Care Access
Certificate of Need Application

Proposed Final Decision

Applicant:	**Greenwich Hospital and Yale-New Haven Hospital**
Docket Number:	**12-31748-CON**
Project Title:	**Establish and Operate an Elective Angioplasty Program without Onsite Surgical Backup at Greenwich Hospital**

Project Description: Greenwich Hospital and Yale-New Haven Hospital propose to establish and operate an elective angioplasty program without onsite surgical backup at Greenwich Hospital, with no associated capital expenditure.

Nature of Proceedings: On June 20, 2012, the Office of Health Care Access ("OHCA") received the Certificate of Need ("CON") application from Greenwich Hospital and Yale-New Haven Hospital to establish an elective angioplasty program without onsite backup at Greenwich Hospital, with no associated capital expenditure. The Applicants are health care facilities or institutions as defined by Section 19a-630 of the Connecticut General Statutes ("General Statutes").

Pursuant to General Statutes § 19a-638, a public hearing regarding the CON application was held on July 17, 2012. On July 2, 2012, the Applicant was notified of the date, time, and place of the hearing. On July 3, 2012, a notice to the public announcing the hearing was published in *The Greenwich Times*. Attorney Joanne V. Yandow served as Hearing Officer. The hearing was conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the General Statutes) and General Statutes § 19a-638.

By petition dated July 12, 2012, The Stamford Hospital requested Party or, in the alternative, Intervenor status with full rights of cross-examination regarding the Applicants' CON application. The Hearing Officer denied the request of The Stamford Hospital for Party status and designated The Stamford Hospital as an Intervenor with limited rights of participation.

The Hearing Officer heard testimony from the Applicants' witnesses and the Intervenor's witnesses and, in rendering this decision, considered the entire record of the proceeding. The public hearing record was closed on September 6, 2012.

OHCA's authority to review and approve, modify, or deny the CON application is established by General Statutes § 19a-638. The provisions of this section, as well as the principles and guidelines set forth in General Statutes § 19a-639, were fully considered by OHCA in its review.

Findings of Fact

1. Greenwich Hospital is a not-for-profit 174-bed acute care hospital located at 5 Perryridge Road in Greenwich, Connecticut. Exhibit A, p. 573 (CON Application).

2. Yale-New Haven Hospital is a not-for-profit, acute care hospital located at 20 York Street, New Haven, Connecticut. Exhibit A, p. 575 (CON Application).

3. The Yale-New Haven Heart and Vascular Center provides elective and emergency ("primary") angioplasty at Yale-New Haven Hospital and has established satellite primary angioplasty programs at Greenwich Hospital and Lawrence & Memorial Hospital in New London, Connecticut. Exhibit H, pp. 629&632 (prefiled testimony of Marna Borgstrom, President and CEO of Yale-New Haven Health System and CEO of Yale New Haven Hospital); OHCA CON Final Decision, DN: 03-30148.

4. Angioplasty is historically a procedure in which a balloon tipped catheter is advanced to an artery narrowed from the buildup of cholesterol-laden plaque, but has been expanded to include other devices that serve as adjuncts to the balloon catheter, such as stents. Percutaneous coronary intervention ("PCI") also refers to this broader group of technologies. PCI for patients that present on an emergency basis with ST-segment elevation MI or new onset left bundle branch block is referred to as a "primary" PCI. Other PCI procedures are referred to as "elective" PCI. *See*, OHCA CON Final Decision, DN: 08-31210.

5. As part of Yale-New Haven Heart and Vascular Center, Greenwich Hospital currently provides diagnostic cardiac services including echocardiography, nuclear cardiac imaging, stress testing, cardiac CT angiography, and diagnostic cardiac catheterization. Greenwich Hospital also provides PCI angioplasty services for patients that present on an emergency basis with artery blockage in the heart. Exhibit A, pp. 22-23 (CON Application).

6. The primary angioplasty program at Greenwich Hospital received permanent status approval from OHCA on July 25, 2008, after completion of a 3-year demonstration project. Exhibit A, p. 22 (CON Application); OHCA CON Final Decision, DN: 03-30148.

7. Elective angioplasty is the same procedure as primary angioplasty but is typically a scheduled procedure (within 72 hours) and is not an emergency. *See*, OHCA CON Final Decision, DN: 08-31210.

8. The Applicants are proposing to establish an elective angioplasty program at Greenwich Hospital without an on-site open heart surgery program. Exhibit A, p. 14 (CON Application).

9. The Applicants define the population to be served through this proposal as the residents of the towns that comprise 85% of Greenwich Hospital's inpatient volume. The Applicants claim that the proposed service area ("PSA") is as follows:

Table I: Greenwich Hospital's PSA for Elective PCI

State	Towns
Connecticut	Darien, Greenwich, New Canaan, Norwalk, Stamford, Weston, Westport and Wilton
New York	Armonk, Bedford, Bedford Hills, Harrison, Hartsdale, Katonah, Larchmont, Mamaroneek, Mount Kisco, Mount Vernon, New Rochelle, Port Chester, Pound Ridge, Purchase, Rye Scarsdale, South Salem, West Harrison and White Plains

Exhibit A, p. 24 (CON Application).

10. The Stamford Hospital ("Stamford Hospital"), the Intervenor in this matter, performs cardiovascular services, including primary and elective PCIs. *See*, OHCA CON Final Decision, DN: 04-30374.

11. The Applicants claim that based on the 2011 inpatient cardiovascular discharge volume by patients' towns of origin for Stamford Hospital and Greenwich Hospital, cardiovascular patients at Greenwich Hospital are the low volume communities for Stamford Hospital. Specifically, the communities of Greenwich, Port Chester and Rye comprise 80% of Greenwich Hospital's cardiovascular patient population but only 4.6% of Stamford Hospital's cardiovascular patient population. Additionally, patients who live in the city of Stamford and the town of Darien comprise 88% of Stamford Hospital's cardiovascular patient volume but only comprise 7% of Greenwich Hospital's cardiovascular patients. Exhibit H, pp. 668-669 (prefiled testimony of Christopher Howes, MD, Chief of Cardiology and Medical Director of the primary angioplasty program at Greenwich Hospital).

12. In 2010, OHCA issued a decision denying Greenwich Hospital's first proposal to establish and operate elective angioplasty program without on-site open heart surgery. The proposal was denied because the projected volume included New York patients, there was insufficient evidence to support the projected volumes, and there was an existing provider of elective PCI and full service cardiac program in the service area (Stamford Hospital). CON Final Decision 08-31210-CON.

13. In or about January 2012, White Plains Hospital in White Plains, New York began offering elective angioplasty service. . Exhibit I, p. 49-50 (Intervenor's prefiled documents, letter from Susan Fox, Executive Vice President, White Plains Hospital).

14. Stamford Hospital and White Plains Hospital are currently providing elective angioplasty procedures in Greenwich Hospital's claimed PSA. Exhibit A, p. 28 (CON Application).

15. White Plains Hospital states it services most of the Westchester County towns identified by the Applicants as towns in Greenwich Hospital's PSA. Exhibit I, page, 49 (Intervenor's prefiled documents, letter from Susan Fox, Executive Vice President, White Plains Hospital).

16. The Applicants assert that Greenwich Hospital is already performing angioplasty on more acutely ill patients through its primary angioplasty program and the staff and physicians are well prepared to perform elective angioplasty for less acute patients. Exhibit A, p. 14 (CON Application).

17. The Medical Director of the cardiac services program at Greenwich Hospital is appointed by Yale University School of Medicine, Department of Cardiology and is a member of the Yale School of Medicine's interventional cardiology faculty. Exhibit A, p. 14 (CON Application).

18. The Applicants claim that the previous OHCA approval for the primary PCI demonstrated clear public need for emergency angioplasty services at Greenwich Hospital and that the current proposal expands upon that approval to demonstrate that the same population, from which Greenwich Hospital's primary angioplasty patients originate, also have a clear need for access to their provider of choice for high quality elective angioplasty services. Exhibit A, p. 15 (CON Application).

19. The Applicants claim that the clear public need for this proposal is supported by the following three key factors:

    a. Local access to elective angioplasty care at Greenwich Hospital is needed and appropriate;
    b. Greenwich Hospital must address the cost-effectiveness of angioplasty services; and
    c. The proposed program will improve the quality of elective angioplasty services provided to Greenwich Hospital's PSA patients.

    Exhibit A, p. 15 (CON Application).

20. The Applicants assert that significant stress and strain are placed on Greenwich Hospital patients and their families when they receive either a diagnostic catheterization or an emergency angioplasty and then must undergo an elective angioplasty at another facility. Exhibit H, p. 671 (prefiled testimony of Christopher Howes, MD, Chief of Cardiology and Medical Director of the primary angioplasty program at Greenwich Hospital).

21. In November 2011, the American College of Cardiology/American Heart Association/The Society for Cardiovascular Angiography and Interventions ("ACC/AHA/SCAI") updated their guidelines regarding PCI without on-site surgical backup. These guidelines are intended to assist healthcare providers in clinical decision making by describing a range of generally acceptable approaches to the diagnosis, management, and prevention of specific diseases or condition. Exhibit A, pp. 139-239 (CON Application).

22. The Applicants claim that an elective PCI program at Greenwich Hospital would fall within the ACC/AHA/SCAI updated guidelines. Exhibit H, pp. 635-636 (prefiled testimonoy of Henry Cabin, MD, Clinical Chief of Cardiology at Yale School of Medicine and Medical Director of Yale-New Haven Heart and Vascular Center).

23. The ACC/AHA/SCAI updated guidelines recommend, in part, that:
> elective PCI might be considered in hospitals without on-site cardiac surgery, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection.

Exhibit A, p. 164 (CON Application).

24. The ACC/AHA/SCAI guidelines also recommend, in part, that:
> [i]t is only appropriate to consider initiation of a PCI program without on-site backup if the program will clearly fill a void in the healthcare needs of the community. Competition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interests of the community.

Exhibit A, p. 164 (CON Application).

25. It is found that although OHCA is not bound to the ACC/AHA/SCAI guidelines, these guidelines are instructive. *See*, CON Final Decision 08-31210-CON.

26. The Applicants claim that angioplasty has become a fairly routine procedure, often performed in an outpatient setting at much lower risk than used to exist. Exhibit H, p. 632. (prefiled testimony of Marna Borgstrom, President and CEO of Yale New Haven Health System and CEO of Yale-New Haven Hospital).

27. The Applicants claim that this proposal eliminates the need for two invasive procedures, diagnostic cardiac catheterization and elective angioplasty, which adds hospital costs, clinical risk and expensive medical transportation costs. Exhibit H, pp.

632 and 671 (prefiled testimonies of Marna Borgstrom, President and CEO of Yale New Haven Health System and CEO of Yale New Haven Hospital, and Christopher Howes, MD, Chief of Cardiology and Medical Director of the angioplasty program at Greenwich Hospital).

28. The Applicants assert that Yale School of Medicine cardiovascular physicians have been actively involved in the primary angioplasty program at Greenwich Hospital since its inception and will continue to provide clinical oversight, direct patient care, and staff and physician education at the proposed program. Exhibit H, p. 632 (prefiled testimony of Marna Borgstrom, President and CEO of Yale New Haven Health System and CEO of Yale New Haven Hospital).

29. The Applicants state that Greenwich Hospital participates in the National Cardiovascular Data Registry NCDR-CathPCI Registry. Exhibit A, p. 36 (CON Application).

30. According to the Applicants, since Fiscal Year ("FY") 2008, 272 patients presented at Greenwich Hospital for elective angioplasty service. A total of 246 of the 272 patients were transferred to other providers for elective PCI. The following table illustrates the total of transfers by provider:

Table II: Historical Greenwich Hospital Elective PCI Transfers

FY	Yale	Westchester Medical Center	Cornell	Columbia	Stamford	West Haven VA	Total Transfers
2008	44	1	0	0	0	0	45
2009	71	0	1	1	1	0	74
2010	51	0	2	0	1	0	54
2011	53	0	2	1	0	1	57
2012*	16	0	0	0	0	0	16
Totals	**235**	**1**	**5**	**2**	**2**	**1**	**246**

*Number of transfers between 10/1/11 and 12/31/11

Note: The remaining 26 patients were discharged and referred for elective angioplasty at a future time. Exhibit A, p. 19 (CON Application).

31. The Applicants identified the following historical primary angioplasty volumes for Greenwich Hospital for FYs 2008-2011:

Table III: Greenwich Hospital Historical Primary PCI

	FY 2008	FY 2009	FY 2010	FY 2011
Greenwich Hospital	40	40	32	38

Exhibit A, p. 30 (CON Application).

32. Greenwich Hospital's angioplasty volume projections:

Table IV: Greenwich Hospital Projected Primary and Elective PCI

	FY 2012	FY 2013	FY 2014
Primary Angioplasty	38	38	38
Elective Angioplasty	**53**	**53**	**53**
New Referred Elective PCI	105	126	151
Total	196	217	242

Exhibit A, p. 31 (CON Application).

33. The Applicants based the projected primary angioplasty volumes on historical volumes, which have remained fairly steady for the past few years. The projected elective angioplasty volumes have been based on the historical elective angioplasty patients transferred to other facilities. Exhibit A, pp. 32-34 (CON Application).

34. The Applicants claim that half of the outpatients that have a diagnostic catheterization performed at Greenwich Hospital are transferred to other facilities for elective PCI. Exhibit H, p. 669-671 (prefiled testimony of Christopher Howes, Chief of Cardiology of Angioplasty Program at Greenwich Hospital).

35. The Applicants state that an increase in the PCI patient volume will result from the addition of New York interventional cardiologists who currently do not practice at Greenwich Hospital but have referral relationships with Greenwich Hospital medical staff and would utilize and refer elective angioplasty to Greenwich Hospital. Exhibit H, pp. 670-671, 675-676 (prefiled testimony of Christopher Howes, Chief of Cardiology of Angioplasty Program at Greenwich Hospital).

36. Although the Applicants provided letters of support from the two (2) physicians from the State of New York who state they would offer elective PCI at Greenwich Hospital if that were an option, the projected new PCI volumes are speculative and appear to be a shifting of the elective PCI patients from an area provider to Greenwich Hospital. *See*, Exhibit H, page 671 &675-679 (prefiled testimony of Christopher Howes, M.D Chief of Cardiology of Angioplasty Program at Greenwich Hospital).

37. Stamford Hospital claims that elective angioplasty volumes are flat to declining in the State, with no volume growth in the Applicants' proposed service area, and therefore, there is no clear public need for the establishment of elective angioplasty program without onsite surgical back up at Greenwich Hospital. Exhibit K, p. 1 (Intervenor's prefiled testimony of Sharon Kiely, M.D., Senior Vice President of Medical Affairs and Chief Medical Officer for Stamford Hospital).

38. The following table illustrates the historical overall statewide PCI (primary and elective combined) discharges by provider between Federal Fiscal Years ("FFY") 2002-2011:

Table V: PCI discharges by provider, FFYs 2002-2011

Hospital	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	FFY 05-07 (3-yr)* % Change	FFY 09-11 (3-yr) % Change	FFY 10-11 (1-yr) % Change
Bridgeport	1,191	1,249	1,288	1,052	692	560	580	428	379	298	-47%	-30%	-21%
CT Children's								2	0		n/a	-100%	n/a
Danbury	0	0	0	0	453	409	330	326	277	292	n/a	-10%	5%
Dempsey	452	464	453	519	401	353	376	334	368	253	-32%	-24%	-31%
Greenwich	0	0	0	20	38	32	40	40	32	37	60%	-8%	16%
Hartford	1,312	1,483	1,321	1,282	1,246	1,206	1,093	1,031	1,122	1,195	-6%	16%	7%
Hospital of Central CT	0	0	0	26	61	70	60	74	69	97	169%	31%	41%
Lawrence & Memorial	0	0	0	0	41	-	29	74	74	70	n/a	-5%	-5%
New Milford	0	0	0	0	0	6	11	11	0		n/a	-100%	n/a
Norwalk								14	57	65	n/a	364%	14%
St. Francis	1,192	1,253	1,349	1,223	1,170	1,188	1,171	1,232	1,030	938	-3%	-24%	-9%
St. Mary's	0	0	0	59	297	246	251	255	291	314	317%	23%	8%
St. Raphael	715	970	924	708	680	632	595	534	523	444	-11%	-17%	-15%
St. Vincent's	1,063	1,035	1,085	1,150	1,181	1,101	1,124	958	925	509	-4%	-47%	-45%
Stamford	0	0	0	9	39	34	45	159	151	135	278%	-15%	-11%
Waterbury	0	0	0	61	347	373	325	361	361	379	511%	5%	5%
Yale	1,635	1,715	1,460	1,297	1,218	1,131	1,186	1,352	1,469	1,324	-13%	-2%	-10%
Total	**7,560**	**8,169**	**7,880**	**7,406**	**7,864**	**7,341**	**7,216**	**7,185**	**7,128**	**6,350**	**-1%**	**-12%**	**-11%**

Source: *CT Department of Public Health Office of Health Care Access Inpatient Acute Care Hospital Database.*

ICD-9-CM Procedure Codes: .66, 36.01, 36.02, 36.05, 36.06 and 36.07
Please note: unduplicated counts utilizing all procedure codes
*This column in OHCA's Exhibit 1, Table 2A, was mislabeled. No data from this column was relied upon to support the findings in this decision.

39. The statewide inpatient PCI volumes demonstrate the following: a five year historical decline of 1% between FY 2007-2011; a 12% overall decline between FY 2009 and 2011; and an 11% decline in statewide PCI volume between FY 2010-2011. *See,* Table V, above.

40. Stamford Hospital's PCI discharges have declined 15% between FY 2009-2011 and, therefore, Stamford Hospital has capacity to serve the needs of the community. *See*, Table V, above.

41. The Intervenor claims that discharges of residents from Greenwich Hospital's service area from Connecticut and New York hospitals show that from FY 2009 through 2011, inpatient ("I/P") cardiac catheterization and PCI volumes have decreased in the service area:

Table VI: FY 2009-2011, I/P PCI Volume in proposed Service Area

State	FY 2009	FY 2010	FY 2011
CT Service Area	598	610	429
NY Service Area	844	775	772
Total	**1,442**	**1,385**	**1,201**

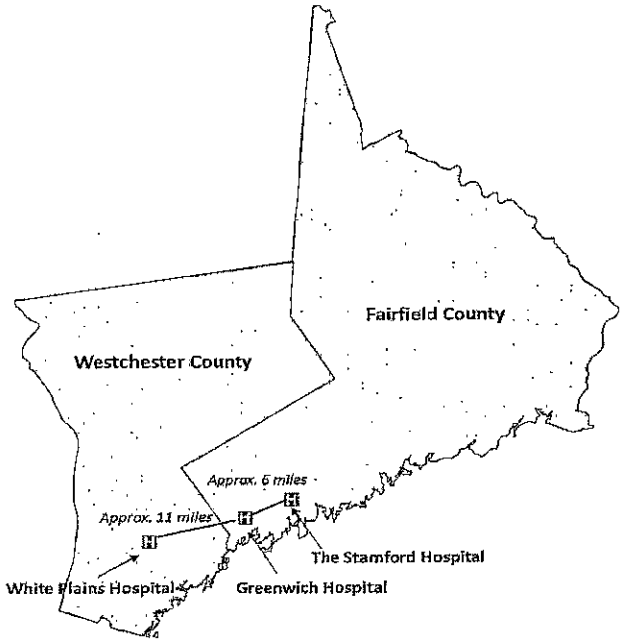
Exhibit K, p. 8 (Intervenor's prefiled testimony of Sharon Kiely, M.D., Senior Vice President of Medical Affairs and Chief Medical Officer for Stamford Hospital).

42. In light of the historical elective PCI transfers from Greenwich Hospital to existing providers and the declining statewide PCI volumes, OHCA finds that the Applicants have not provided sufficient evidence to support its projected PCI utilizations.

43. A letter from White Plains Hospital states that its elective PCI program presently has capacity to serve the needs of the community and they are not aware of any backlog of cases in their service area that would indicate patients are not receiving timely care. Exhibit I, pp. 49-50 (Intervenor's prefiled documents, letter from Susan Fox, Executive Vice President, White Plains Hospital).

44. White Plains Hospital is located approximately ten (10) miles west of Greenwich Hospital. If this application is approved, three (3) elective angioplasty programs will operate within sixteen (16) miles of each other. Exhibit K, p. 10 (Intervenor's prefiled testimony of Sharon Kiely, M.D., Senior Vice President of Medical Affairs and Chief Medical Officer for Stamford Hospital).

45. The map illustrates the location of Greenwich Hospital and the existing providers such as Stamford Hospital and White Plains Hospital, in Greenwich Hospital's proposed service area and their approximate distance to Greenwich Hospital:



46. There is no capital expenditure associated with this proposal. Exhibit A, p. 21(CON Application).

47. The Applicants assert that they estimate the unnecessary costs that now result and impact payers and patients total approximately $425,000 each year. This amount is based on an average of 53 elective angioplasty cases currently transferred that could be cared for by a Greenwich Hospital's elective angioplasty program multiplied by $8,000 ($7,000 for the average cost of an angioplasty admission at Yale New Haven Hospital plus $1,000 for emergency transportation). Exhibit H, p. 79 (prefiled testimony of Frank Corvino, President and CEO of Greenwich Hospital).

48. Greenwich Hospital's projected incremental revenue from operations, total operating expense and gain from operations associated with the CON proposal are as follows:

Table VII: Financial Projections Incremental to the Project

Description	FY 2013	FY 2014	FY 2015
Incremental Revenue from Operations	$2,935	$3,413	$3,976
Incremental Total Operating Expense	$2,353	$2,744	$3,222
Incremental Gain from Operations	**$582**	**$669**	**$756**

Note: figures are in thousands.
Exhibit A, p. 577 (CON Application).

49. The current and three-year projected payer mix for Greenwich Hospital is as follows:

Table VIII: Current & Three-Year Projected Payer Mix

Description	Current	Year 1	Year 2	Year 3
Medicare*	40.5%	40.5%	40.5%	40.5%
Medicaid* CHAMPUS and TriCare	5.4%	5.4%	5.4%	5.4%
Total Government	**45.9%**	**45.9%**	**45.9%**	**45.9%**
Commercial Insurers*	48.7%	48.7%	48.7%	48.7%
Self Pay	5.4%	5.4%	5.4%	5.4%
Workers Compensation	0%	0%	0%	0%
Total Non-Government	**54.1%**	**54.1%**	**54.1%**	**54.1%**
Total Payer Mix	**100%**	**100%**	**100%**	**100%**

* Includes managed care activity.
Exhibit A, p. 40 (CON Application).

50. The Applicants assert that Greenwich Hospital's primary angioplasty services are costing Greenwich Hospital approximately $1.78 million per year, as Greenwich Hospital has to pay Yale School of Medicine to provide 24/7 physician staffing for its existing program. The primary angioplasty program results in significant staffing costs to cover approximately 40 primary angioplasty cases treated at Greenwich Hospital each year. Utilizing the same physicians to perform elective angioplasty would be a cost-effective and efficient approach and would reduce the costs per case from the arrangement. Exhibit A, p. 20 (CON Application).

51. The Applicants claim that the proposed elective angioplasty program is cost effective as it maximizes use of the existing high-cost infrastructure of the primary angioplasty program and permits existing and available highly qualified expert physicians and staff to perform both primary and elective angioplasties for which they have been trained and are qualified to perform. In addition, as noted in the application, System-wide integration, coordination of care practices and standardization, more cost effectiveness and evidence-based care will be provided. Exhibit A, pp. 40-41 (CON Application).

52. OHCA is currently in the process of establishing its policies and standards as regulations. Therefore, OHCA has not made any findings as to this proposal's relationship to any regulations adopted by OHCA. (General Statutes § 19a-639(a)(1)).

53. OHCA is currently in the process of establishing the statewide facilities and services plan ("the plan"). The plan was not a published document at the time of this proposal was filed; however, even if the plan is published by the time this final decision is issued, it has no bearing on the outcome of this matter, as the Applicants have not sufficiently demonstrated a clear public need for this proposal. (General Statutes § 19a-639(a)(2)).

54. There is insufficient evidence to establish that there is a clear public need for the Applicants' proposal. (General Statutes § 19a-639(a)(3)).

55. The Applicants have not satisfactorily demonstrated how this proposal will impact the financial strength of the health care system in this state. (General Statutes § 19a-639(a)(4)).

56. The Applicants have failed to satisfactorily demonstrate that their proposal would improve the accessibility of health care delivery in the region but they have satisfactorily demonstrated a potential improvement in quality and cost effectiveness. (General Statutes § 19a-639(a)(5)).

57. The Applicants have shown that there would be no change to the provision of health care services to the relevant populations and payer mix. (General Statutes § 19a-639(a)(6)).

58. The Applicants have satisfactorily identified the population to be served by their proposal but have failed to satisfactorily demonstrate that this population has a need as proposed. (General Statutes § 19a-639(a)(7)).

59. The historical elective PCI discharges in the service area do not support this proposal. (General Statutes § 19a-639(a)(8)).

60. The Applicants have failed to satisfactorily demonstrate that their proposal would not result in an unnecessary duplication of existing elective PCI services in the area. (General Statutes § 19a-639(a)(9)).

Discussion

CON applications are decided on a case by case basis and do not lend themselves to general applicability due to the uniqueness of the facts in each case. In rendering its decision, OHCA considers the factors set forth in General Statutes § 19a-639(a) and the Applicant bears the burden of proof in this matter by a preponderance of the evidence. *Goldstar Medical Services, Inc., et al. v. Department of Social Services*, 288 Conn. 790 (2008); *Steadman v. SEC*, 450 U.S. 91, 101 S.Ct. 999, *reh'g den.*, 451 U.S. 933 (1981); *Bender v. Clark*, 744 F.2d 1424 (10th Cir. 1984); *Sea Island Broadcasting Corp. v. FCC*, 627 F.2d 240, 243 (D.C. Cir. 1980).

Greenwich Hospital is a 174-bed acute care hospital located at 5 Perryridge Road in Greenwich and Yale-New Haven Hospital is an acute care hospital located at 20 York Street in New Haven. Greenwich Hospital and Yale New Haven Hospital (collectively known as "Applicants") are proposing to establish and operate an elective angioplasty program without onsite surgical backup located at Greenwich Hospital. FFs 1, 2, 8.

Currently, Greenwich Hospital, as a satellite of Yale New Haven Hospital's Yale-New Haven Heart and Vascular Center, provides cardiac catheterization and primary (emergency) angioplasty services. Greenwich Hospital does not have an on-site open heart surgery program. FF 4-6.

The Applicants argue that there is a clear public need for elective angioplasty ("elective PCI") at Greenwich Hospital and that such a program would fall within the ACCF/AHA/SCAI updated guidelines regarding elective PCI without on-site surgical backup. FFs 18, 19, 21, 22. The ACCF/AHA/SCAI guidelines now state that elective PCI might be considered in hospitals without on-site cardiac, provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection. FF 23.

The Applicants claim there is clear public need based on three key factors: local access, cost-effectiveness and improved quality. FF 19. Greenwich Hospital has transferred approximately 57 patients annually (between FYs 2008-2011) that required elective angioplasties to other providers over the each of the past three fiscal years. FF 30. Additionally, the Applicants claim that two new physicians (currently practicing in Westchester County, NY) will refer new angioplasty patients to Greenwich Hospital, if approved. FF 35.

Although the Applicants claim that there is need for elective PCI in the proposed service area, there are currently two providers of elective angioplasty service within its proposed service area, Stamford Hospital and White Plains Hospital. FFs 14, 44, 45. Each of the existing providers of elective angioplasty is approximately 6 and 11 miles away from Greenwich Hospital. FFs 44, 45. A letter from White Plains Hospital in Westchester County, NY, stated that its elective angioplasty program presently has capacity to serve the needs of the community and they are not aware of any backlog of cases in their service area. FF 43. Additionally, historical PCI discharge data shows that Stamford Hospital also has capacity to serve the needs of the community. FFs 37-40. Furthermore, based on OHCA's statewide hospital discharges, it's clear that since FY 2009,

the cardiac catheterization volume has declined 10% and the combined (emergent and elective) angioplasty volumes declined 12% at Connecticut providers. FFs 38-40.

The ACCF/AHA/SCAI updated guidelines state:

> It is only appropriate to consider initiation of a PCI program without on-site cardiac surgical backup if this program will clearly fill a void in the healthcare needs of the community. Competition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interests of the community.

FF 24. Regarding the proposal at hand, there is insufficient evidence to establish a void in the needs of the community for elective PCI services and that the Applicants' proposal is in the best interests of the community.

Based on the statewide decline at all Connecticut providers of cardiac catheterization and angioplasty programs, the speculative projected new cases, and the fact that there are two (2) existing providers currently providing elective PCI in Greenwich Hospital's proposed service area and that these providers have capacity to fulfill the needs of the community, OHCA finds there is access to elective angioplasty service for the residents within Greenwich Hospital's proposed service area and, further, that the Applicants failed to demonstrate and provide evidence of a clear public need for this proposal. Based upon the lack of sufficient evidence demonstrating that the Applicants' proposed project fulfills a clear public need for elective PCI, OHCA is unable to conclude that the Applicants' financial projections and volumes upon which they are based are reasonable and achievable, or that the project is financially feasible.

Based upon the foregoing Findings of Fact and Discussion, I respectfully recommend that the Certificate of Need application of Greenwich Hospital and Yale-New Haven Hospital for the establishment of an elective angioplasty program without onsite surgical backup at Greenwich Hospital, with no associated capital expenditure, be **DENIED**.

Respectfully submitted,

11/20/12
Date

Joanne V. Yandow
Hearing Officer

JVY:swl

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*** TX REPORT ***
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STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: Stephen Cowhard, Esq.

FAX: (203) 259-1070

AGENCY:

FROM: Steven Lazarus

DATE: 1/31/13 TIME: 3:16 pm

NUMBER OF PAGES: 17
(including transmittal sheet

Comments:
Final Decision in the matter of DN. 12-31748-CON
Enclosed.

PLEASE PHONE IF THERE ARE ANY TRANSMISSION PROBLEMS.

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*** TX REPORT ***
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STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

FAX SHEET

TO: Jennifer Groves, Esq.

FAX: (203) 772-2037

AGENCY:

FROM: Steven Lazarus

DATE: 1/31/13 TIME: 3:15

NUMBER OF PAGES: 17
(including transmittal sheet

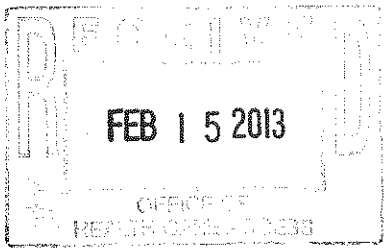
Comments:
Final Decision in the Matter of 12-31748-CON enclosed.

PLEASE PHONE IF THERE ARE ANY TRANSMISSION PROBLEMS.

MERITAS LAW FIRMS WORLDWIDE

Jennifer L. Groves
(t) 203.786.8316
(f) 203.772.2037
jgroves@uks.com

February 15, 2013



VIA HAND DELIVERY

Lisa Davis, MBA, BSN, RN
Deputy Commissioner
State of Connecticut
Department of Public Health
410 Capitol Avenue, P.O. Box 34038
MS #13HCA
Hartford, CT 06134-0308

Re: Proposal to Establish Elective Angioplasty Program at Greenwich Hospital
Docket No. 12-31748-CON

Dear Deputy Commissioner Davis,

This office represents Greenwich Hospital and Yale-New Haven Hospital (collectively "Applicants") in connection with the above-referenced CON Application to establish an elective angioplasty program in Greenwich. Enclosed please find an original and two (2) copies of Applicants' Petition for Reconsideration of the Final Decision issued by the Office of Health Care Access on January 31, 2013.

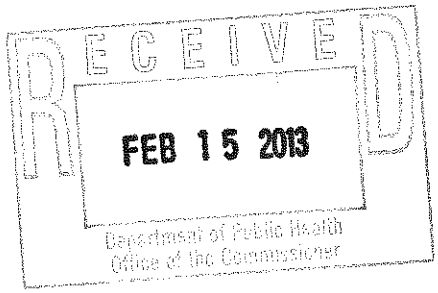
Thank you in advance for your consideration of this request.

Very truly yours,

Jennifer L. Groves

/jlg

cc: Marna P. Borgstrom
Frank A. Corvino



STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

GREENWICH HOSPITAL AND YALE-NEW HAVEN HOSPITAL'S PROPOSAL TO ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM WITHOUT ON-SITE SURGICAL BACKUP AT GREENWICH HOSPITAL	DOCKET NO. 12-31748-CON
	FEBRUARY 15, 2013

PETITION FOR RECONSIDERATION OF FINAL DECISION

In accordance with Section 4-181a(a)(1) of the Connecticut General Statutes, Greenwich Hospital ("Greenwich") and Yale-New Haven Hospital ("YNHH"), Applicants in the above-referenced Certificate of Need ("CON") proceeding, submit this Petition for Reconsideration of the Final Decision issued by the Office of Health Care Access ("OHCA") on January 31, 2013 ("Final Decision"). Applicants sought permission from OHCA to establish and operate an elective angioplasty program at Greenwich Hospital (the "Elective Angioplasty Program") in conjunction with the Yale-New Haven Heart and Vascular Center ("YNHHVC"). OHCA denied Applicants' CON request.

As discussed herein, the Final Decision contains errors of fact and law that should be corrected by the agency. These include erroneous findings with regard to whether Applicants submitted sufficient evidence to meet the criteria for issuance of a CON set forth in Section 19a-639(a) of the General Statutes. In addition, new evidence has been discovered, which materially affects the merits of this CON Application and which for good reason was not presented in the

agency proceeding. This includes the Agreed Settlement, entered into between OHCA and Lawrence & Memorial Hospital ("L&M") on February 4, 2013, authorizing the addition of an elective angioplasty program at L&M, also in conjunction with YNHH and the Yale School of Medicine ("YSM") (the "L&M Agreed Settlement").

I. Background

This is the third request to OHCA for permission to establish and operate an Elective Angioplasty Program at Greenwich Hospital. Greenwich is a short-term acute care hospital and an affiliate of the Yale-New Haven Health System ("YNHHS") (CON Application, p. 14). Greenwich offers a broad array of cardiac services in conjunction with the YNHHVC, including a primary angioplasty program (the "Primary Angioplasty Program"), which was approved by OHCA on a permanent basis in July of 2008 (Docket No. 03/08-30148; CON Application, pp. 14-15). L&M also operates a primary angioplasty program in conjunction with the YNHHVC (the "L&M Primary Angioplasty Program"), which is staffed, equipped and operated in the exact same manner, and according to the same policies, procedures and protocols, as the program at Greenwich (see Docket No. 04-30297-CON) (L&M Agreed Settlement, FF 5).

Greenwich has all of the infrastructure and staff in place to perform primary or "emergency" angioplasty procedures and has been performing these procedures on critically ill patients since 2005. Applicants now request permission to provide these same types of procedures (utilizing the staff and equipment already in place) on an elective basis, in more routine, less emergent cases (Final Decision, FF 16; CON Application, pp. 14-15 & 40; Completeness Question Responses, p. 599; Testimony of Christopher Howes, M.D., p. 671; July 16, 2012 Public Hearing Transcript, pp. 19, 59, 70, 84 & 88). Despite the fact that Greenwich does not have an Elective Angioplasty Program, patients continue to present at the Hospital in

need of these critical healthcare services (CON Application, pp. 19 & 32; Completeness Question Responses, p. 589). The patients who present to Greenwich Hospital and require elective angioplasty are for the most part transferred to YNHH, where they receive these services from the exact same physicians who would have performed the procedures at Greenwich if elective angioplasty was authorized.

Each request for permission to establish an Elective Angioplasty Program at Greenwich has been denied because according to OHCA, there is no "clear public need" for a program of this type in the Greenwich service area (see Final Decision, Docket No. 00-520; Final Decision, Docket No. 08-31210; Final Decision, Docket No. 12-31748-CON). Notwithstanding the foregoing, OHCA has approved a number of full-service cardiac programs in Connecticut (including a program at The Stamford Hospital ("TSH") just six miles from Greenwich) in the years since Greenwich's first request was denied. The Greenwich denials, which have been focused primarily on need, disregard the positive impact that an Elective Angioplasty Program at Greenwich Hospital would have on the accessibility, quality and cost-effectiveness of cardiac care in the region. It is these very factors that contributed to OHCA's recent approval of an elective angioplasty program at L&M, to be supported by the YNHHVC.

On November 20, 2012, the Hearing Officer in this matter issued a Proposed Final Decision recommending denial of Applicants' CON request (the "Proposed Final Decision"). On January 11, 2013, Applicants filed Exceptions to the Proposed Final Decision and a brief in support of their positions (copy attached as Exhibit A). Therein, Applicants argued that all of the Section 19a-639(a) CON decision criteria had been satisfied, and that based on the totality of the evidence record the CON should have been approved.

Applicants presented oral argument on the Exceptions on January 16, 2013. Two weeks later, OHCA issued a Final Decision denying the CON request. This Final Decision made no modifications to the Findings of Fact or conclusions of law in the Proposed Final Decision, as requested by Applicants. The L&M Agreed Settlement was signed four (4) days after the Final Decision was issued.

For the reasons set forth in the Exceptions, as well as in this Petition for Reconsideration, Applicants respectfully request that the agency reconsider its findings and issue a Reconsidered Final Decision approving the CON.

II. Legal Standard For Reconsideration

Section 4-181a of the General Statutes provides that a petition for reconsideration of an OHCA final decision may be filed within fifteen (15) days of the date of personal delivery or mailing of the decision. Grounds for reconsideration include that: (A) An error of fact or law should be corrected; (B) new evidence has been discovered, which materially affects the merits of the case and which for good reasons was not presented in the agency proceeding; or (C) other good cause for reconsideration has been shown. If a petition for reconsideration is filed, OHCA must decide within twenty-five (25) days whether it will reconsider the decision. The agency may also review a final decision *sua sponte* within forty (40) days of issuance.

If OHCA decides to reconsider a final decision, either at the request of a party or of its own accord, it must proceed in a reasonable time to conduct such additional proceedings as may be necessary to render a decision modifying, affirming or reversing the final decision. Any decision made after reconsideration must be issued no later than ninety (90) days following the date on which the agency decides to reconsider the final decision.

III. Argument

OHCA should reconsider the Final Decision and approve Applicants' CON request for several reasons. First, Applicants respectfully submit that OHCA erred in finding that the Section 19a-639(a) guidelines and principles were not satisfied in this case. The arguments in support of this claim are summarized below and are discussed at length in the Exceptions attached as Exhibit A. Second, new evidence has come to light since the record was closed in the Greenwich-YNHH CON, which materially affects this case and should be considered by OHCA. This evidence includes an Agreed Settlement between OHCA and L&M, dated February 4, 2013, approving an elective angioplasty program at that hospital (copy attached as Exhibit B). The L&M Agreed Settlement acknowledges the benefits – in terms of accessibility, quality and cost-effectiveness of care, in particular – of operating an elective angioplasty program at a community hospital in conjunction with the YNHHVC. These same arguments were raised by Applicants in support of their CON request and were not given due weight by OHCA. Applicants' Elective Angioplasty Program will bring the same benefits to the Greenwich community that the L&M program will bring to the New London community. These benefits justify approving the CON requests filed by both hospitals.

A. OHCA Erred In Concluding That the Section 19a-639(a) Criteria Have Not Been Met

Applicants continue to believe that OHCA erred in finding that certain of the Section 19a-639(a) CON decision criteria were not satisfied in this proceeding. As set forth in greater detail in the Exceptions attached as Exhibit A, Applicants maintain that they established a clear public need for the proposed Elective Angioplasty Program at Greenwich; that the proposal will impact favorably on the financial strength of the healthcare system; that the Elective Angioplasty Program will increase access to care; and that their proposal will not result in the unnecessary

duplication of services. Applicants also maintain that those CON guidelines and principles that have been firmly established – namely, that this proposal will improve the accessibility, quality and cost-effectiveness of cardiac care – when considered with other evidence in the record, support approval of this CON.

The arguments contained in the Exceptions are summarized briefly below:

i. Applicants Demonstrated a Clear Public Need for the Elective Angioplasty Program

- Applicants' angioplasty volume projections were supported by evidence. They were comprised of primary angioplasty cases, historical elective angioplasty transfers and incremental volume from New York interventional cardiologists with patients residing in the Greenwich area.
- There is no evidence in the record to support OHCA's conclusion that the projected elective angioplasty volume is a shifting of elective PCI patients from an area provider to Greenwich Hospital. This new volume will include cases currently performed at hospitals as far away as New York City.
- There is no evidence in the record to support OHCA's conclusion that TSH and White Plains Hospital have sufficient excess capacity to meet the elective angioplasty needs of the Greenwich community. OHCA erred in finding that a decline in TSH's inpatient angioplasty volume signals an excess of capacity (versus a simple shift of volume to an outpatient setting). Nor has OHCA given appropriate weight to the almost complete lack in overlap in the cardiovascular service areas of Greenwich Hospital and TSH.
- The existence of multiple providers in the region does not mean that there is no need for an Elective Angioplasty Program at Greenwich. There are other areas in the state where multiple providers are approved to operate full-service cardiac programs (i.e. Hartford and New Haven/Bridgeport).
- A decline in PCI volume in the Greenwich area does not mean that the proposed Elective Angioplasty Program is not needed. TSH's program was approved at a time when PCI volume was declining statewide. In addition, as discussed in more detail below, OHCA found that there is a clear public need for L&M's elective program despite a recent decline in elective transfers from that hospital.

ii. Applicants Established That the Proposal Will Impact Favorably on the Financial Strength of the Healthcare System

- Applicants offered evidence to support a finding that the proposed Elective Angioplasty Program will benefit patients any payers financially by reducing costs associated with patient transfers and duplicate procedures.
- Applicants offered evidence to support a finding that the proposed Elective Angioplasty Program will benefit and strengthen Greenwich Hospital financially by

providing additional revenue over which to spread the fixed costs associated with the Primary Angioplasty Program (including $1.78 million in professional fees).

iii. The Elective Angioplasty Program Will Improve the Accessibility, Quality and Cost-effectiveness of Cardiac Care in the Greenwich Service Area

- OHCA correctly concluded that the proposed Elective Angioplasty Program, which was to be operated in conjunction with the YNHHVC with its institutional and individual experience and expertise, would potentially improve the quality of cardiac care in the region.
- OHCA correctly concluded that the proposed Elective Angioplasty Program would potentially enhance the cost-effectiveness of care by reducing transfer and duplicate procedure costs and offsetting some of the fixed costs associated with the Primary Angioplasty Program at Greenwich.
- OHCA should have concluded that the proposed Elective Angioplasty Program would improve accessibility by making a critical healthcare service available at a community hospital where many individuals try to obtain this care every year. In addition, the establishment of an Elective Angioplasty Program at an acute-care hospital such as Greenwich increases access for Medicare and Medicaid patients.

iv. A Modest Decline in PCI Volume Is Not Determinative of Need for the Elective Angioplasty Program

- Applicants have projected volume based on historical utilization/transfers and confirmed additional volume from New York interventional cardiologists. These projections support need, regardless of whether PCI volume is declining.
- PCI volume was declining when TSH's CON for a full-service cardiac program was approved. Similarly, L&M's elective angioplasty transfers have declined in recent years, yet their elective program was just approved by OHCA.

v. The Elective Angioplasty Program Will Not Result In the Unnecessary Duplication of Services

- There is virtually no overlap in the cardiovascular service areas of Greenwich Hospital and TSH. Without overlap in patient populations, the proposed Elective Angioplasty Program cannot duplicate the program at TSH.
- The proposed Elective Angioplasty Program will eliminate the need for patient transfers and duplicate procedures, which may be considered the unnecessary duplication of services.

Applicants also argued that OHCA relied too heavily on the "clear public need" CON decision criteria to the exclusion of other, equally important guidelines and principles. OHCA must consider each of the Section 19a-639(a) CON criteria in reaching its decision. Here,

OHCA acknowledges that the proposal will potentially improve the quality of care and she is correct. The YNHHVC is an integrated model whereby interventional cardiologists perform procedures both at Greenwich and YNHH, which has one of the busiest and most advanced cardiac programs in the state. By denying this CON request, OHCA is denying Greenwich patients local access to the resources and professional expertise of the YNHHVC. OHCA also disregarded significant findings with respect to the cost-effectiveness of this proposal. As discussed below, OHCA acknowledges in the L&M Agreed Settlement that having an elective program at a community hospital reduces the costs (and risks) associated with transfers and duplicate procedures. It also allows a hospital to spread the fixed overhead costs associated with an emergency angioplasty program over greater case volume.

Respectfully, OHCA was incorrect in many of its findings relative to the Section 19a-639(a) guidelines and principles. The agency also erred in denying the CON Application based primarily on clear public need, while ignoring the significant enhancements to patient access and the quality and cost-effectiveness of care that would result from having an Elective Angioplasty Program in Greenwich. For these reasons, OHCA should reconsider the Final Decision, modify the Findings of Fact as necessary and issue a Reconsidered Final Decision approving Applicants' request.

B. The L&M Agreed Settlement Is New Evidence That Should Be Considered By OHCA

On August 31, 2012, several months after Applicants initiated this CON proceeding, L&M filed a CON Application requesting permission to establish an elective angioplasty program without onsite surgery, to be supported by YNHH and the YSM (the "L&M Elective Angioplasty Program") (L&M Agreed Settlement, FF 2 & 3). A public hearing was held in

December of 2012, and on February 4, 2013, OHCA and L&M entered into an Agreed Settlement authorizing the L&M Elective Angioplasty Program.

The L&M Elective Angioplasty Program is in essence the same program that Greenwich Hospital sought permission to establish. Both Greenwich and L&M are community hospitals that provide emergency angioplasty in conjunction with the YNHHVC (Final Decision, FF 3; L&M Agreed Settlement, FF 5); both hospitals seek to expand their angioplasty programs to include more routine, elective cases (Final Decision, FF 3, 6-8; L&M Agreed Settlement, FF 5); both elective programs would be fully supported by YNHH and the YSM (Final Decision, FF 17, 28; L&M Agreed Settlement, FF 5, 6); the interventional cardiologists from both community hospitals perform procedures at YNHH, gaining invaluable experience at one of the state's busiest and most advanced cardiac programs (Exceptions, p. 21; L&M Agreed Settlement, FF 17); both elective programs would employ the same YNHH/YSM interventional cardiologists and clinical staff that support their emergency programs (Final Decision, FF 28; L&M Agreed Settlement, FF 28); both hospitals argued that there is a need to expand their programs to include an elective component based in part on existing transfer volume and the need to more efficiently use resources (Final Decision, FF 32-33, 47, 50 & 51; L&M Agreed Settlement, FF 19-21, 33 & 34); both argued that expanding elective would improve access to, and the quality of, cardiac care for their patients (Exceptions, pp. 21-22; L&M Agreed Settlement, FF 29); both also argued that the expansion would be cost-effective and beneficial to patients, payers and the hospitals (Final Decision, FF 47, 50-51; L&M Agreed Settlement, FF 30, 33 & 34).

Applicants understand that OHCA reviews each CON request on its own merits and that CON Applications do not lend themselves to general applicability due to the unique facts of each case. That being said, it is difficult to understand how OHCA could reach the conclusions that it

reached with respect to the Section 19a-639(a) criteria in the Greenwich-YNHH elective angioplasty CON, and then reach such vastly different conclusions with respect to the identical program at L&M. Applicants respectfully request that OHCA reconsider its findings and conclusions in the Greenwich CON in light of the L&M Agreed Settlement. This new evidence affects the merits of this CON proceeding and could not have been presented in the contested case, given the fact that the L&M Agreed Settlement was issued after the Final Decision.

Applicants have set forth below findings from the L&M Agreed Settlement that are inconsistent with the Greenwich-YNHH Final Decision and which should be reconsidered by OHCA:

i. Quality of Care

OHCA found that the elective program at L&M will use the same YNHH/YSM interventional cardiologists and clinical staff that currently support the hospital's primary program (L&M Agreed Settlement, FF 28). OHCA also found that quality would be enhanced for patients who are transferred for elective angioplasty and are therefore at greater risk of infections, bleeding complications and other adverse events associated with multiple procedures at two facilities (L&M Agreed Settlement, FF 29). These findings were used to support the conclusion that the L&M Elective Angioplasty Program will improve the quality of healthcare in the region (L&M Agreed Settlement, FF 40). This ultimately contributed to the approval of L&M's proposal.

Applicants introduced the same evidence of involvement and support for the proposed Elective Angioplasty Program by YNHH/YSM physicians and staff, which OHCA acknowledged (Final Decision, FF 17, 28). Applicants also made the same arguments throughout their CON submissions regarding the enhancements to quality that come not only

from a YNHH/YSM-affiliated program, but from the ability to avoid unnecessary transfers and the risks and complications associated therewith. Notwithstanding the presentation of nearly identical evidence about a program supported by the same academic medical center as the L&M program, OHCA found only the "potential" that the Greenwich program would improve quality of care for patients. OHCA did not consider this "potential" improvement in the quality of care sufficient to support approval of the CON, contrary to its findings in the L&M proceeding. Finding of Fact 56 should be revised accordingly, and this revised finding should be considered as a basis for approving Applicants' proposal.

ii. Cost-Effectiveness of Care

OHCA found that the L&M Elective Angioplasty Program would reduce the cost per case for angioplasty while using the same YNHH physicians, thus reducing the burden on the hospital of the $1.45 million professional fee it pays in connection with coverage for the L&M Primary Angioplasty Program (L&M Agreed Settlement, FF 33). OHCA also found that eliminating transfers for elective PCI would reduce costs to the healthcare system from duplicate testing and other redundant costs (L&M Agreed Settlement, FF 30). OHCA further found that there were no additional capital or overhead costs associated with the L&M Elective Angioplasty Program, which improves the cost-effectiveness of PCI services in general (L&M Agreed Settlement, FF 34). These findings were used to support the conclusion that the L&M Elective Angioplasty Program will improve the cost-effectiveness of healthcare in the region (L&M Agreed Settlement, FF 40). This ultimately contributed to the approval of L&M's proposal.

Applicants introduced the same evidence regarding the cost-effectiveness of care with their proposal. Specifically, Applicants claimed that patient transfers for elective angioplasty resulted in approximately $425,000 in unnecessary costs each year, which would be avoided if elective

cases were allowed at Greenwich Hospital (Final Decision, FF 47). Applicants also claimed that utilizing the same physicians to perform elective angioplasty cases would help to offset overhead costs (including $1.78 million in professional fees) associated with the Primary Angioplasty Program (Final Decision, FF 50-51). Unlike the L&M Agreed Settlement, OHCA found only that "Applicants asserted" or "Applicants claimed" these facts to be true and that they could "potentially" improve the cost-effectiveness of healthcare. Given that Greenwich has produced the exact same evidence of program costs savings as L&M, the disparate treatment by OHCA is unwarranted. Finding of Fact 56 should be revised accordingly, and this revised finding should be considered as support for approval of this CON.

iii. Financial Strength & Financial Feasibility

OHCA found that there was no additional capital or overhead cost associated with the L&M Elective Angioplasty Program, which appears to support its conclusion that the project is financially feasible (L&M Agreed Settlement, FF 34 & 39). Greenwich introduced the same evidence regarding the lack of additional capital or overhead cost associated with its Elective Angioplasty Program (Final Decision, FF 46). However, OHCA did not conclude that the Greenwich proposal was financially feasible. Instead, OHCA found that Applicants did not satisfactorily demonstrate how the Elective Angioplasty Program would impact the financial strength of the state's healthcare system (Final Decision, FF 55). The CON law in effect at the time of the Greenwich Final Decision (and the L&M Agreed Settlement) states that Applicants must show either that their program improves the financial strength of the healthcare system or that it is financially feasible for the Applicants. Conn. Gen. Stat. 19a-639(a)(4). Applicants maintain that they demonstrated how their proposal would improve the financial strength of the healthcare system. And like L&M, they have also demonstrated that the project is financially

feasible in that it has no associated capital expenditure or costs. For these reasons, the conclusions drawn by OHCA in Finding of Fact 55 are incorrect and should be revised. A revised finding would further support approval of this CON.

iv. Clear Public Need

It is worth noting that certain factors used to establish a clear public need for the L&M Elective Angioplasty Program were considered differently by OHCA in evaluating the Greenwich-YNHH CON request. For example, Applicants' CON request was denied in part based on a modest decline in PCI volume in the service area (Final Decision, FF 38-39, 59). However, OHCA appears to have disregarded a thirty-one percent (31%) decline in elective angioplasty transfers at L&M between 2010 and 2011, and a projected fifteen percent (15%) decline between 2011 and 2012, in determining that there is a need for this service in New London (L&M Agreed Settlement, FF 19). Applicants assume that this is due to a host of other factors (including improved accessibility, quality and cost-effectiveness of care) that justified approving L&M's proposal.

In addition, OHCA found there to be a clear public need for the L&M Elective Angioplasty Program based in part on the fact that New London County has high heart-disease-related death and hospitalization rates and a growing population over the age of 65 (L&M Agreed Settlement, FF 15 & 16). Applicants provided identical evidence (in the form of Centers for Disease Control and Prevention maps), which shows that Fairfield County has equally high heart-disease-related death and hospitalization rates (CON Application, p. 26). In addition, Applicants provided evidence that its service area population over the age of 65 is expected to increase significantly between 2011 and 2016 (CON Application, p. 27). These factors, which were important to OHCA's assessment of need in the L&M CON, were seemingly overlooked by the agency in

evaluating the Greenwich-YNHH submissions. If they support need for an elective angioplasty program in New London County, they support need for such a program in Fairfield County as well.

IV. Conclusion

For all of the foregoing reasons, Applicants respectfully request that OHCA reconsider the Final Decision, revise its findings and issue a Reconsidered Final Decision approving the proposed Elective Angioplasty Program at Greenwich Hospital. Approval of Applicants' proposal is consistent with the Section 19a-639(a) guidelines and principles and the reasoning behind OHCA's approval of the L&M CON request – namely, that the addition of elective angioplasty services to a YNHHVC-supported program that is already authorized and equipped to provide emergency angioplasty services will increase patient access and significantly enhance the quality and cost-effectiveness of healthcare.

Respectfully Submitted,

GREENWICH HOSPITAL
YALE-NEW HAVEN HOSPITAL

By: _____

JENNIFER L. GROVES, ESQ.
Updike, Kelly & Spellacy, P.C.
265 Church Street
One Century Tower
New Haven, CT 06510
Tel: (203) 786-8300
Fax (203) 772-2037

EXHIBIT A

STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH CARE ACCESS

GREENWICH HOSPITAL AND YALE-NEW HAVEN HOSPITAL'S PROPOSAL TO ESTABLISH AND OPERATE AN ELECTIVE ANGIOPLASTY PROGRAM WITHOUT ON-SITE SURGICAL BACKUP AT GREENWICH HOSPITAL	)	DOCKET NO. 12-31748-CON
	)	JANUARY 11, 2013

EXCEPTIONS TO PROPOSED FINAL DECISION

Greenwich Hospital ("Greenwich") and Yale-New Haven Hospital ("YNHH"), Applicants in the above-referenced Certificate of Need ("CON") proceeding, submit the following Exceptions to the Proposed Final Decision rendered by the Office of Health Care Access ("OHCA"), through Hearing Officer Joanne V. Yandow, on November 20, 2012 (the "Proposed Final Decision"). Applicants intend to appear before Deputy Commissioner Lisa Davis on January 16, 2013, and present oral argument on these Exceptions.

I. Introduction

Greenwich and YNHH seek approval from OHCA to establish and operate an elective angioplasty program at Greenwich Hospital (the "Elective Angioplasty Program"). Greenwich is a short-term acute care hospital and an affiliate of the Yale-New Haven Health System ("YNHHS") (CON Application, p. 14). Greenwich offers a broad array of cardiac services in conjunction with the Yale-New Haven Heart and Vascular Center ("YNHHVC"), including a satellite primary angioplasty program (the "Primary Angioplasty Program"), which was

approved by OHCA on a permanent basis in July of 2008, after completion of a three-year demonstration project (Docket No. 03/08-30148; CON Application, pp. 14-15).

Greenwich has all of the infrastructure and staff in place to perform primary or "emergency" angioplasty procedures and has been performing these procedures on critically ill patients since 2005. Primary angioplasty patients are typically more difficult to care for and present greater risks than elective angioplasty patients given the emergent nature of their conditions. Greenwich Hospital has provided these patients with superior care for almost eight years, even without the availability of onsite cardiac surgical backup. Applicants now request permission to provide these same types of procedures (utilizing the staff and equipment already in place) on an elective basis, in more routine less emergent cases (Proposed Final Decision, FF 16; CON Application, pp. 14-15 & 40; Completeness Question Responses, p. 599; Testimony of Christopher Howes, M.D., p. 671; July 16, 2012 Public Hearing Transcript, pp. 19, 59, 70, 84 & 88).

Despite the fact that Greenwich does not have an Elective Angioplasty Program, patients continue to present at the Hospital in need of these critical healthcare services (CON Application, pp. 19 & 32; Completeness Question Responses, p. 589). The patients who present to Greenwich Hospital and require elective angioplasty are for the most part transferred to YNHH, where they received these services from the exact same physicians who would have performed the procedures at Greenwich if elective angioplasty was authorized. Greenwich service area resident have the right to receive cardiac care from the provider of their choosing, and they consistently choose Greenwich Hospital and the YNHHVC. This proposal would simply allow them to obtain this care within their community.

Applicants first applied for a full-service cardiac program at Greenwich Hospital, including elective angioplasty, in 2000 (Docket No. 00-520) (Public Hearing Transcript, pp. 91 & 138). The 2000 CON request was denied, largely based on a lack of "clear public need" for the proposal (Final Decision, Docket No. 00-520; Public Hearing Transcript, p. 91). However in the ensuing years, OHCA approved full-service cardiac programs, including elective angioplasty, at numerous hospitals throughout western Connecticut.[1] This included approval of a full-service cardiac program at The Stamford Hospital ("TSH") in 2006, located just six miles from Greenwich Hospital and within the service area where OHCA found there to be no need for these exact services (Rebuttal Testimony of Marna Borgstrom, p. 720; Public Hearing Transcript, p. 139). TSH was granted a CON at a time when angioplasty volumes were in decline – the primary reason why the Hearing Officer proposes to deny the current CON Application for an Elective Angioplasty Program at Greenwich (Proposed Final Decision, FF 37; Borgstrom Rebuttal Testimony, pp. 699-701). Now the existence of TSH's program (as well as a White Plains Hospital program established in 2010) is being used to support OHCA's position that there is no need for this proposal and that it will result in the unnecessary duplication of services, just as it was in 2010 when Applicants' second request to establish an Elective Angioplasty Program at Greenwich was denied (Docket No. 08-31210-CON) (Proposed Final Decision, FF 10, 13, 14, 15, 37, 40, 43, 44, 45, 53, 54, 58 & 60).

The Hearing Officer proposes to deny Applicants' most recent request for a CON primarily on the grounds that there is no "clear public need" for an Elective Angioplasty Program at Greenwich (Proposed Final Decision, FF 53, 54 & 58). We respectfully disagree

[1] Danbury Hospital, Docket No. 03-30143; Waterbury Hospital, St. Mary's Hospital & John Dempsey Hospital, Docket No. 03-30167; The Stamford Hospital, Docket No. 04-30374.

with the Hearing Officer's analysis of "clear public need," which overlooks such crucial factors as existing patient preference and physician referral patterns; credible evidence that area physicians will bring additional volume to Greenwich; the lack of overlap in the cardiac service areas of Greenwich and other elective angioplasty providers; and the clinical need for elective angioplasty services in Greenwich to ensure the quality of cardiac care and the safety of patients in the region, all of which is documented throughout Applicants' CON submissions and hearing testimony.

In addition, the Hearing Officer relies too heavily on the "clear public need" criteria set forth in Section 19a-639(a)(3) of the Connecticut General Statutes, to the exclusion of the other, equally relevant CON guidelines and principles that must be considered by the agency. Applicants respectfully disagree with a number of findings made by the Hearing Officer with respect to the remaining Section 19a-639(a) decision criteria (Proposed Final Decision, FF 53, 55, 56, 59 & 60). All of the Section 19a-639(a) criteria were thoroughly satisfied and the totality of the evidence supports approval of this CON Application. Applicants have shown not only that there is a clear public need for an Elective Angioplasty Program at Greenwich, but that such a program would improve the quality, accessibility and cost-effectiveness of healthcare in the region. It honors a patient's right to choose and it will not adversely impact existing providers of elective angioplasty services. Moreover, this program will help to strengthen Greenwich Hospital financially, making it good public policy and consistent with OHCA's statutory mission to ensure, among other things, the financial strength of the healthcare system statewide. For these reasons, Applicants' proposal should be approved.

II. Exceptions

Applicants take exception with numerous Findings of Fact contained within the Proposed Final Decision. These Findings of Fact center mostly around the Section 19a-639(a) decision criteria and are set forth below. Arguments in support of these exceptions are presented in Section III of this brief.

FF 12: *In 2010, OHCA issued a decision denying Greenwich Hospital's first proposal to establish and operate elective angioplasty program without on-site open heart surgery. The proposal was denied because the projected volume included New York patients, there was insufficient evidence to support the projected volumes, and there was an existing provider of elective PCI and full service cardiac program in the service area (Stamford Hospital).*

FF 14: *Stamford Hospital and White Plains Hospital are currently providing elective angioplasty procedures in Greenwich Hospital's claimed PSA.*

FF 36: *Although Applicants provided letters of support from the two (2) physicians from the state of New York who state they would offer elective PCI at Greenwich Hospital if that were an option, the projected new PCI volumes are speculative and appear to be a shifting of the elective PCI patients from an area provider to Greenwich Hospital.*

FF 40: *Stamford Hospital's PCI discharges have declined 15% between FY 2009-2011 and, therefore, Stamford Hospital has capacity to serve the needs of the community.*

FF 42: *In light of the historical elective PCI transfers from Greenwich Hospital to existing providers and the declining statewide PCI volumes, OHCA finds that the Applicants have not provided sufficient evidence to support its projected PCI utilizations.*

FF 43: *A letter from White Plains Hospital states that its elective PCI program presently has capacity to service the needs of the community and they are not aware of any backlog of cases in their service area that would indicate patients are not receiving timely care.*

FF 44: *White Plains Hospital is located approximately ten (10) miles west of Greenwich Hospital. If this application is approved, three (3) elective angioplasty programs will operate within sixteen (16) miles of each other.*

FF 45: *The map illustrates the location of Greenwich Hospital and the existing providers such as Stamford Hospital and White Plains Hospital, in Greenwich Hospital's proposed service area and their approximate distance to Greenwich Hospital.*

FF 53: *OHCA is currently in the process of establishing the statewide facilities and services plan ("the plan"). The plan was not a published document at the time of this*

proposal was filed; however, even if the plan is published by the time this final decision is issued, it has no bearing on the outcome of this matter, as the Applicants have not sufficient demonstrated a clear public need for this proposal.

FF 54: *There is insufficient evidence to establish that there is a clear public need for the Applicants' proposal.*

FF 55: *The Applicants have not satisfactorily demonstrated how this proposal will impact the financial strength of the health care system in this state.*

FF 56: *The Applicants have failed to satisfactorily demonstrate that their proposal would improve the accessibility of health care delivery in the region but they have satisfactorily demonstrated a potential improvement in quality and cost effectiveness.*

FF 58: *The Applicants have satisfactorily identified the population to be served by their proposal but have failed to satisfactorily demonstrate that this population has a need as proposed.*

FF 59: *The historical elective PCI discharges in the service area do not support this proposal.*

FF 60: *The Applicants have failed to satisfactorily demonstrate that their proposal would not result in any unnecessary duplication of existing elective PCI services in the area.*

Applicants also take exception with how these Findings of Fact are interpreted in the Discussion section of the Proposed Final Decision.

In addition, there are certain Findings of Fact that Applicants believe support their proposal and were not given due weight by the Hearing Officer. These Findings of Fact are discussed in the Argument section below.

III. Argument

A. Consideration of the Section 19a-639(a) Guidelines & Principles

Sections 19a-639(a)(1) through 19a-639(a)(9) of the Connecticut General Statutes set forth the guidelines and principles that must be used by OHCA in evaluating CON proposals. Section 19a-639(a) states that "[i]n any deliberations involving a certificate of need application filed pursuant to section 19a-638, the office shall take into consideration and make written

findings concerning" the guidelines and principles contained within the statute.[2] These guidelines and principles are more commonly known as the "statutory decision criteria" for CON applications. Although OHCA is required to consider and make written findings concerning each of the guidelines and principles set forth in Section 19a-639(a), the statute does not contain an express requirement that an applicant demonstrate a specific level of compliance with every stated criteria. Nor does the statute authorize OHCA to give substantial weight to one of the criteria to the exclusion of all others or to fail to make findings with respect to one of the criteria because another has not been met to the agency's satisfaction. If OHCA makes findings on the statutory decision criteria consistent with the evidence in the record, and considers all of these findings together, the CON Application should be approved.

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[2] Conn. Gen. Stat. § 19a-639(a) provides in its entirety: In any deliberations involving a certificate of need application filed pursuant to section 19a-638, the office shall take into consideration and make written findings concerning each of the following guidelines and principles: (1) Whether the proposed project is consistent with any applicable policies and standards adopted in regulations by the office; (2) The relationship of the proposed project to the state-wide health care facilities and services plan; (3) Whether there is a clear public need for the health care facility or services proposed by the applicant; (4) Whether the applicant has satisfactorily demonstrated how the proposal will impact the financial strength of the health care system in the state; (5) Whether the applicant has satisfactorily demonstrated how the proposal will improve quality, accessibility and cost effectiveness of health care delivery in the region; (6) The applicant's past and proposed provision of health care services to relevant patient populations and payer mix; (7) Whether the applicant has satisfactorily identified the population to be served by the proposed project and satisfactorily demonstrated that the identified population has a need for the proposed services; (8) The utilization of existing health care facilities and health care services in the service area of the applicant; and (9) Whether the applicant has satisfactorily demonstrated that the proposed project shall not result in an unnecessary duplication of existing or approved health care services or facilities.

i. Applicants' Demonstrated a Clear Public Need For This Proposal

In this case, the Hearing Officer made a number of factual findings in support of her conclusion that there is no clear public need for Applicants' proposal (Conn. Gen. Stat. §19a-639(a)(3)) (Proposed Final Decision, FF 42, 53, 54 & 58). Applicants take exception with these findings as set forth below:

- Applicants' Projections Are Supported By Evidence.

  In Finding of Fact 35, the Hearing Officer acknowledges that a percentage of the projected elective angioplasty volume at Greenwich Hospital will result from the addition of New York interventional cardiologists who do not practice at Greenwich currently, but have referral relationships with the medical staff and will utilize the Hospital for elective angioplasty if a program is approved (Howes Testimony, pp. 670-671 & 675-676). Although Applicants provided letters of support from two of these New York physicians, OHCA found that their projected PCI volumes were speculative and appear to represent a shift of elective PCI patients from one area provider to Greenwich (Proposed Final Decision, FF 36).

  As a threshold matter, projections by their very nature are speculative. Applicants provided letters of support from named physicians, which included firm commitments to perform an identifiable number of elective angioplasties at Greenwich Hospital each year (Howes Testimony, pp. 675-676). OHCA has historically allowed providers to establish projected volume through letters from physicians indicating that they will refer/perform a certain number of procedures if a CON is approved. For example, this is common in CON applications for the acquisition of major imaging equipment or the addition of owners to an

ambulatory surgery center. In fact, OHCA will often accept projected volume attributable to anonymous physicians because in this competitive healthcare environment, many physicians are hesitant to publically support one provider when they work with many. Moreover, Applicants explained to the Hearing Officer that physicians typically will not make formal commitments (beyond a letter of support) unless and until a CON for a new service is approved (Public Hearing Transcript, p. 117).

In addition, while the Hearing Officer calls Applicants' letter evidence "speculative," a letter offered by Susan Fox, Executive Vice President of White Plains Hospital ("White Plains"), is taken as entirely true and accurate (Proposed Final Decision, FF 13-15, 36 & 43; Testimony of Sharon Kiely, M.D., pp. 49-50).[3] This letter caused the Hearing Officer to conclude that White Plains has the "capacity to serve the needs of the community," without any critical analysis of the unsubstantiated claims made by Ms. Fox (Proposed Final Decision, FF 43).

Moreover, the evidence in the record does not support the Hearing Officer's conclusion that the projected volume from New York interventional cardiologists "appears to be a shifting of the elective PCI patients <u>from an area provider</u> to Greenwich Hospital (emphasis added)" (Proposed Final Decision, FF 36). Neither TSH nor White Plains (via TSH) introduced any evidence that the cases promised by Drs. Newman and Hjemdahi-Monsen in their letters of support for this proposal were cases that would otherwise be performed at their facilities

[3] This letter was offered through Intervenor TSH. White Plains did not petition for status and Ms. Fox did not attend the hearing and testify.

(Howes Testimony, pp. 675-676). In fact, these are cases that we know to be performed for the most part at large New York City hospitals, including New York Presbyterian (Completeness Question Responses, p. 591; Public Hearing Transcript, pp. 57-58, 64-65). Moreover, the letters from Drs. Newman and Hjemdahi-Monsen state specifically that they would bring procedures to Greenwich that they currently treat at hospitals outside of Connecticut (Howes Testimony, pp. 675-676). Accordingly, there is no proof that this proposal will result in a shift of volume from a smaller Connecticut provider such as TSH or that it would impact TSH (or White Plains) in any way.

- Excess Capacity At Existing Providers Is Unsubstantiated and Irrelevant.

We respectfully disagree with the Hearing Officer's conclusion that TSH and White Plains have capacity to serve the elective angioplasty needs of the community (Proposed Final Decision, FF 40 & 43). These conclusions were drawn based upon a recent decline in TSH's inpatient PCI volume and the above-referenced letter from Susan Fox attesting to White Plains' capacity. No further analysis has been done regarding if and how these providers could and would meet the elective angioplasty needs of the Greenwich community. It is worth nothing that this decline in TSH's inpatient PCI volume may be attributable to the migration of more PCI cases to an outpatient setting.

The reality is there is minimal overlap between the service areas of TSH and Greenwich for cardiac services. The Hearing Officer acknowledges this in Finding of Fact 11, wherein she found that 80% of Greenwich's cardiovascular patients come from Greenwich, Port Chester and Rye, while only 4.6% of TSH's

cardiovascular patients originate from these towns. Conversely, 88% of TSH's cardiovascular patients come from Stamford and Darien, while only 7% of Greenwich's cardiovascular patients originate from these towns (Proposed Final Decision, FF 11; Howes Testimony, pp. 669-670).

OHCA cannot force a change in patient preference and physician referral patterns for cardiac services (Howes Rebuttal Testimony, pp. 668-671). The TSH and White Plains programs have been operational for years and yet patients continue to present at Greenwich Hospital in need of elective angioplasty services (CON Application, pp. 19 & 32; Completeness Question Responses, p. 589; Howes Rebuttal Testimony, pp. 762-763). Thus, even if there is excess capacity at TSH and/or White Plains, which has not been established as fact, this should not be considered in evaluating the needs of patients who choose Greenwich over either of these hospitals and who, if no program is available in Greenwich, will travel as far as New York City for their cardiac care (Howes Testimony, pp. 657-676; Public Hearing Transcript, pp. 57-58 & 64-65).

- Existence of Multiple Providers In Area Does Not Mean There Is No Need.

The Hearing Officer's determination that there is no clear public need for this proposal is based, in part, on the fact that if Greenwich Hospital offered elective angioplasty there would be three elective angioplasty providers within 16 miles of each other (Proposed Final Decision, FF 44 & 45). However, there are other areas in the state where three or more elective angioplasty providers operate within a similar radius. OHCA has approved full-service cardiac programs at John Dempsey Hospital, Hartford Hospital and St. Francis Hospital and Medical

Center, which are located less than 10 miles from each other (see Exhibit A attached). In addition, OHCA has approved full-service cardiac programs at YNHH (and the former Hospital for St. Raphael – now YNHH), Bridgeport Hospital and St. Vincent's Medical Center. The distance between the farthest of these locations is just over 20 miles (see Exhibit B attached). Note also that in these areas of the state, travel within a 10 to 20 mile radius is considerably easier and faster than traveling within the 16 mile radius between Stamford and White Plains, which experiences significant traffic and delays at various times throughout the day. Thus, the fact that approval of Applicants' proposal would result in three elective angioplasty providers being located within a 16 mile radius (one of which is a New York provider whose revenues do not support the financial strength of the Connecticut healthcare system) should not be determinative of a lack of clear public need.

- Flat PCI Volumes Do Not Mean There Is No Clear Public Need For Program.

The Hearing Officer found that the flat to declining elective angioplasty volumes in the state and proposed service area do not support establishment of an additional elective angioplasty program (Proposed Final Decision, FF 59). This was an argument raised by TSH in opposition to Applicants' proposal. However, the Hearing Officer has overlooked the equally important fact that when TSH sought and received approval for its full-service cardiac program, which includes elective angioplasty, PCI volumes were also declining statewide and in the service area (Borgstrom Rebuttal Testimony, pp. 699-701). If this factor were determinative of need, then TSH's CON application should have been denied.

But it was not denied, rather that CON was approved based on factors such as improved accessibility, continuity of care and improved quality of cardiac services (Borgstrom Rebuttal Testimony, pp. 701 & 732-733). These are the same factors that were raised by Applicants in support of a program at Greenwich. They speak less of a numerical demand for services and more to a clinical demand for care. That demand exists in terms of a patient's right to receive critical cardiac healthcare services at the provider of his/her choice (Howes Rebuttal Testimony, pp. 668-671); in the physical and mental stress that results for patients and families when they are transferred out of Greenwich Hospital for elective angioplasty (Proposed Final Decision, FF 20; CON Application, pp. 19-20; Completeness Question Responses, pp. 589 & 599); and in the physical risks and excess costs associated with having duplicate cardiac procedures, all of which were documented throughout Applicants CON submissions and hearing testimony (Proposed Final Decision, FF 27 & 47; CON Application, p. 40; Public Hearing Transcript, pp. 30-31, 66-67 & 76). Applicants therefore request that in the interest of fairness and consistency in decision making, OHCA reconsider its findings in this regard.

Based on the foregoing and all of the evidence in the record, Applicants have established a clear public need for the proposed Elective Angioplasty Program at Greenwich Hospital. Applicants respectfully request that Findings of Fact 12, 14, 36, 40, 42-45, 53, 54 58 and 59, and any discussion arising from those Findings of Fact, be revised accordingly.

ii. Applicants Met The Remaining Applicable Statutory Decision Criteria

Applicants also take exception with a number of the Findings of Fact relative to the remaining Section 19a-639(a) decision criteria, as set forth below.

a. Financial Strength of the Healthcare System

The Hearing Officer found that Applicants failed to satisfactorily demonstrate how the proposal will impact the financial strength of the healthcare system in this state (Conn. Gen. Stat. §19a-639(a)(4)) (Proposed Final Decision, FF 55). However, Applicants have introduced sufficient evidence to demonstrate that the proposed elective angioplasty program will have a positive financial impact on Greenwich Hospital and, as such, on the healthcare system as a whole.

As a threshold matter, this statutory guideline is relatively new. It was introduced in 2010, when CON laws were completely overhauled by the legislature. In 2012, OHCA attempted to revise this guideline out of Section 19a-639(a). The rationale given by OHCA staff was that the agency "does not have the data to properly evaluate the financial impact of the CON proposal on the state's healthcare system" and "CON applicants struggle to produce evidence demonstrating the impact of the proposal on the state's health care system" (Public Health Committee Testimony, dated March 7, 2012, attached as Exhibit C). Historically, OHCA has allowed providers to demonstrate compliance with this guideline by introducing evidence regarding the positive financial impact of a proposal on a healthcare facility as a result of cost-savings, increased revenue and the like (see i.e. Docket Nos. 11-31736-CON & 12-31750-CON). Anything that improves a hospital or healthcare facility's financial position and/or streamlines

care appears to impact favorably on the financial strength of the institution and the healthcare system as a whole.[4]

Applicants offered evidence to support a finding that the proposed Elective Angioplasty Program will benefit both Greenwich Hospital and its patients financially and, therefore, impact favorably on the financial strength of the healthcare system. This includes evidence, referenced by OHCA in the Proposed Final Decision, that the existence of elective angioplasty at Greenwich would reduce the need for patient transfers and duplicate procedures, which in turn reduces healthcare costs (Proposed Final Decision, FF 47; CON Application, p. 40; Frank Corvino's Testimony, p. 681-682; Public Hearing Transcript, pp. 30-31, 67 & 76, 79-80). In addition, Applicants submitted evidence that the inclusion of elective angioplasty cases would reduce some of the financial burden attributable to the maintenance of staff and infrastructure for primary angioplasty cases (Proposed Final Decision, FF 50 & 51; CON Application pp. 20 & 40-41; Completeness Question Responses, pp. 598-599). Given the broad manner in which this statutory provision has been interpreted by OHCA, a finding should have been made in favor of Applicants. Applicants respectfully request that Finding of Fact 55, and any discussion arising from that Finding of Fact, be revised accordingly.

[4] Note also that there are a number of 2012 CON approvals that make no mention of this particular decision criteria, therefore, failure to meet it should not, in and of itself, be used as a basis for denial (i.e. Docket Nos. 12-1759-CON; 11-31734-CON; and 11-31730-CON).

b. Accessibility, Quality and Cost-Effectiveness of Healthcare

The Hearing Officer correctly found that Applicants demonstrated a potential improvement in quality and cost-effectiveness with the proposed Elective Angioplasty Program, but erred in finding no evidence that the proposal would improve the accessibility of healthcare delivery in the region (Proposed Final Decision, FF 56). Applicants take exception with this finding for several reasons.

First, any time a hospital adds a healthcare service it enhances access to care. Elective angioplasty is not available at Greenwich Hospital despite the fact that many patients attempt to access this service at the Hospital each year. These patients are denied access and as result, experience considerable stress and incur additional costs associated with the receipt elective angioplasty services elsewhere (CON Application, pp. 19-20, 32; Completeness Question Responses, pp. 589 & 599; Public Hearing Transcript, pp. 19, 66-67, 86, 119-120). Drs. Newman and Hjemdahi-Monsen indicated in their letters of support for this proposal that their patients desire local access to elective angioplasty services, access that is not currently available (Howes Testimony, pp. 675-676). If Greenwich had an elective angioplasty program, these individuals would have access to this critical healthcare service at the hospital of their choosing in their community, where care can be provided appropriately and safely – in this case, a hospital affiliated one of the nation's leading cardiac providers (Public Hearing Transcript, pp. 24, 92). This is improved accessibility of healthcare.

Moreover, while there are no current regulations that define "accessibility" for CON purposes, the former OHCA regulations define this term to include

"accessibility to medically underserved individuals who often experience the greatest difficult in obtaining equitable access to health services" (Regulations of Connecticut State Agencies, §19a-643-71). Increasing access to a hospital-based service inevitably increases access for the underserved, including uninsured individuals, as well as Medicare and Medicaid patients. As the payer mix projections in Applicants' CON submissions show, the Elective Angioplasty Program would be comprised of 45.9% Medicare/Medicaid patients and 5.4% uninsured patients (CON Application, p. 40).

c. Decline in Elective PCI Is Not Basis For Denial of CON

Section 19a-639(a)(8) of the General Statutes requires OHCA to consider and make findings regarding the "utilization of existing health care facilities and health care services" in the service area. In this regard, the Hearing Officer made findings with respect to the historic utilization of PCI services, which are set forth in Findings of Fact 38 through 42 and 55. Ultimately, the Hearing Officer found that Applicants had not provided sufficient evidence to support their projected PCI utilization and that historical elective PCI discharges in the service area do not support this proposal (Proposed Final Decision, FF 42 & 59). Applicants take exception with these findings.

Specifically, Applicants take exception with the Hearing Officer's conclusion that declining PCI volumes indicate that there is no clear public need for an Elective Angioplasty Program at Greenwich. As previously mentioned, Applicants have projected volume that is supported by evidence in the record. Applicants' volume projections are based on historical primary angioplasty

volume and elective angioplasty transfers, as well as an informal survey of referring physicians and letters from New York physicians indicating that they would perform cases at Greenwich if this CON is approved. These letters should be afforded the same weight, and considered equally as credible, as the letter from Susan Fox of White Plains, which the Hearing Officer cites throughout her decision (Proposed Final Decision, FF 13, 15 & 43).

Moreover, although PCI volume is declining, it was also declining leading up to 2006, when TSH was given permission to establish a full-service cardiac program including elective angioplasty (Borgstrom Rebuttal Testimony, pp. 699-701). Even with declining PCI volume and an elective angioplasty program at TSH, patients continue to present at Greenwich Hospital in consistent numbers each year in need of these services (CON Application, p. 19-22 & 32; Completeness Question Responses, p. 589; Public Hearing Transcript, p. 27). There is clearly a need for elective angioplasty in the Greenwich area among this patient population, which is not being met by area providers. In evaluating this proposal, OHCA should consider not only this need, but those same factors it considered in evaluating TSH's application – namely, whether the program would improve accessibility, quality and continuity of care (Borgstrom Rebuttal Testimony, pp. 701 & 732-733).

In addition, as mentioned above, the Hearing Officer's finding that TSH has the capacity to meet all community need for elective angioplasty is not supported by evidence in the record (Proposed Final Decision, FF 40). For these reasons, Applicants ask OHCA to find that utilization of elective PCI services – in

particular, the continued attempts by area residents to access these services at Greenwich Hospital – supports approval of this CON request. Finding of Fact 59, and any discussion related thereto, should be revised accordingly.

d. This Proposal Will Not Result in an Unnecessary Duplication of Services

OHCA is required by Section 19a-639(a)(9) to make findings with respect to whether a proposal results in the unnecessary duplication of existing healthcare services. Applicants take exception with the Hearing Officer's finding that they failed to show that unnecessary duplication of services will not result from the addition of elective angioplasty at Greenwich Hospital (Proposed Final Decision, FF 60). As previously mentioned, the Hearing Officer concedes in Finding of Fact 11 that there is virtually no overlap for cardiovascular services between Greenwich and TSH. The disparity in patient towns of origin is significant (Howes Testimony, pp. 668-671; Howes Rebuttal Testimony, pp. 762-763). If Greenwich and TSH are not providing cardiac services to the same patient populations, then the addition of an Elective Angioplasty Program at Greenwich will not result in the unnecessary duplication of services. Moreover, there is no evidence in the record that definitively establishes a service area for elective angioplasty at White Plains, therefore the Hearing Officer cannot conclude that a Greenwich program would duplicate services available at this New York hospital. As previously noted, the geographic proximity of programs is not sufficient evidence that services are duplicative and unnecessary at any given location. Connecticut has thriving cardiac programs at many hospitals in close proximity to each other (i.e. John Dempsey Hospital/Hartford Hospital/St. Francis Hospital &

Medical Center; Yale-New Haven Hospital/Bridgeport Hospital/St. Vincent's Medical Center).

In addition, there is evidence in the record that this proposal would in fact avoid the unnecessary duplication of services. As OHCA acknowledged in the Proposed Final Decision, payers and patients incur unnecessary costs of approximately $425,000 per year as a result of the need to be transferred from Greenwich Hospital to another provider for elective angioplasty (Proposed Final Decision, FF 47; CON Application, p. 40; Corvino Testimony, pp. 681-682; Public Hearing Transcript, pp. 30-31, 66-67 & 76). If Greenwich was authorized to provide this service, these duplicate procedures and costs would be avoided. For these reasons, OHCA should find that Applicants have adduced evidence that this proposal will not result in the unnecessary duplication of services. Finding of Fact 60, and any discussion related thereto, should be revised accordingly.

iii. OHCA's Decision Relied Too Heavily On The Clear Public Need Criteria

The Hearing Officer based her decision to deny Applicants' request for permission to establish an Elective Angioplasty Program at Greenwich almost entirely on her conclusion that there is no clear public need for the proposal. Even assuming this is the case, which Applicants dispute, the Hearing Officer should not have relied on one of the Section 19a-639(a) criteria to the exclusion of all others. As previously mentioned, Section 19a-639(a) requires OHCA to make written finding on each of the guidelines and principles set forth in the statute, but it does not require a specific level of compliance with every one of these criteria. Nor does it allow the agency to make decisions based on one of the criteria only or to fail to make findings on certain criteria. OHCA is obligated to review CON proposals based upon all of the factors that the

legislature deemed relevant and to base its decisions on the totality of evidence. Applicants have shown that there is a clear public need for an Elective Angioplasty Program at Greenwich and there is ample additional evidence in the record to support approval of this proposal. To deny Applicants' CON request would be clearly erroneous in view of the reliable, probative and substantial evidence on the whole record.

The Hearing Officer acknowledges that this proposal will potentially improve the quality and cost-effectiveness of cardiac care in the Greenwich area (Proposed Final Decision, FF 56). Enhanced quality of care is probably the most significant benefit of this CON proposal. The Greenwich Hospital cardiac program is part of the YNHHVC – an integrated model whereby the interventional cardiologists who perform angioplasty at Greenwich also perform cases at YNHH, the highest volume angioplasty provider with the most advanced cardiac program in the state (Proposed Final Decision, FF 3, 5 & 28; Borgstrom Testimony, p.. 672). The Hearing Officer does not give adequate weight to these key facts in recommending that the CON for an Elective Angioplasty Program at Greenwich be denied. Yet the practical effect of denial is to deprive Greenwich area residents in need of elective angioplasty of local access to the resources and professional expertise of the YNHHVC.

Moreover, both the quality and cost-effectiveness of care are enhanced by having an Elective Angioplasty Program at Greenwich, which avoids the need for patient transfers and duplicate procedures (Proposed Final Decision, FF 56). As Dr. Henry Cabin, Clinical Chief of Cardiology at the Yale University School of Medicine and Medical Director of the YNHHVC, testified at the public hearing on this matter, elective angioplasty would be performed at Greenwich Hospital by the exact same physicians who perform the procedure at YNHH, and it can be done as safely at Greenwich as at YNHH (Public Hearing Transcript, p. 60). It therefore

makes little sense, either from a cost or patient safety perspective, to deny patients local access to these services (Public Hearing Transcript, p. 60).[5]

As discussed above, the evidence demonstrates that the Elective Angioplasty Program will also improve the accessibility of cardiac care in the region. Increased patient access is inextricably linked with issues of quality and cost-effectiveness of care. Providing patients with local access to care is not just a convenience issue. It will truly enhance the quality of care for those patients who will continue to present at Greenwich in need of elective angioplasty, and who will insist that these services be provided by the highly qualified and experienced physicians and staff of the YNHHVC. As noted above, it makes little sense to allow the Greenwich-based YNHHVC physicians to perform elective angioplasty on Greenwich patients in New Haven, but not in their own community.

Increased access will also have a positive impact on the costs associated with obtaining and providing angioplasty services. OHCA cannot ignore the fact that when patients need to be transferred from Greenwich to another facility for elective angioplasty, which could safely and competently be performed at Greenwich, this costs patients, payers and the system as a whole more money. In addition, the Primary Angioplasty Program at Greenwich is a necessary but extremely costly program to operate on a continuous basis. The addition of an Elective Angioplasty Program at Greenwich, with more procedure volume over which to spread these fixed costs, will make the provision of angioplasty services more cost-effective for the Hospital. All of this will in turn have a positive financial impact on Greenwich Hospital and the state's healthcare system.

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[5] The Hearing Officer does not appear to be concerned, from a quality perspective, with the lack of onsite surgical backup at Greenwich. In fact, she suggests that White Plains, which has an elective angioplasty program without onsite surgery, is an appropriate alternative provider to meet the demand for these services in the Greenwich area.

Moreover, the Elective Angioplasty Program at Greenwich will not result in the unnecessary duplication of services because, as the evidence in the record clearly shows, there is minimal overlap in the cardiovascular patient populations at Greenwich and TSH. While it is true that PCI volume is in moderate decline, the present situation is no different that the situation that existed in 2006, when OHCA approved TSH's request for a CON to establish a full-service cardiac program. OHCA approved that application based upon factors including improved accessibility, quality and continuity of care – these are the same factors that support approval of Applicants' request. Applicants ask OHCA to reconsider and acknowledge the substantial benefits to patients, payers and the healthcare system that will result from a Final Decision approving this proposal.

B. Approval of This CON Is Sound Public Policy & Consistent With OHCA's Mission

Approving Applicants' request to establish an Elective Angioplasty Program at Greenwich Hospital is consistent with OHCA's statutory mission to promote the availability of cost-effective care and to ensure the financial strength of the healthcare delivery system in this state (Conn. Gen. Stat, Section 19a-637). The Hearing Officer's suggestion that White Plain has capacity to handle patients (presumably including Connecticut residents) in need of elective angioplasty is contrary to OHCA's mission in that it encourages the outmigration to New York of healthcare services and revenues. This is particularly troubling at a time when Connecticut hospitals are experiencing rising costs and declining revenue, all while trying to maintain their ability to provide core hospital services to their communities.

In addition, denial of this CON Application limits patient choice for critical health care services. Greenwich area residents have spoken and their preference is to obtain cardiac services through Greenwich Hospital and the YNHHVC. Given the nature of the services involved,

patients should not be forced to obtain care at an alternate provider. Moreover, patients should not be placed in a situation where they are expected to travel unreasonably long distances to obtain elective angioplasty services at the provider of their choosing.

IV. Requested Relief

In light of the foregoing, Applicants respectfully request the following relief:

- That OHCA revise the various Findings of Fact listed in the Exceptions section above, and any language within the Discussion section of the Proposed Final Decision based on the erroneous factual findings.

- That OHCA determine, specifically, that there is a clear public need for this proposal, that it will enhance the accessibility, quality and cost-effectiveness of healthcare and improve the financial strength of the healthcare delivery system, and that it will not result in the unnecessary duplication of services.

- That OHCA issue a Final Decision approving Applicants' request for a CON to establish an Elective Angioplasty Program at Greenwich Hospital.

In the alternative, Applicants ask that OHCA consider granting provisional approval of the proposed Elective Angioplasty Program under whatever terms the agency and Applicants agree are necessary to measure the need for this program and its impact on the healthcare delivery system. Any provisional approval might be similar to the approval given for the Primary Angioplasty Program at Greenwich (see Docket No. 03/08-30148), via Agreed Settlement, which included initial approval for a period of three years in order to validate that Applicants' projections (and minimum ACC/AHA/SCAI Guidelines volumes) had been

achieved. Applicants would agree to submit volume data to OHCA so that a similar analysis can be undertaken regarding the Elective Angioplasty Program. OHCA could also collect and analyze outcome and other relevant data to determine whether the proposal has met the programmatic requirements of the ACC/AHA/SCAI Guidelines. The submission of data would allow the agency to evaluate the proposed Elective Angioplasty Program at Greenwich Hospital and determine whether it should be given permanent status. Applicants are confident that all projections will be met and all measure will be achieved, proving that the proposal is necessary and fulfills the guidelines and principles set forth in Section 19a-639(a).

V. Conclusion

For all of the foregoing reasons, Applicants urges the Deputy Commissioner to revise the Findings of Fact and issue a Final Decision approving the proposed Elective Angioplasty Program at Greenwich Hospital. In the alternative, Applicants welcome a conversation with OHCA staff regarding the possibility of a provisional approval that will allow the agency to validate the need for the proposal and its impact on the accessibility, quality and cost-effectiveness of healthcare – cardiovascular services in particular – in the Greenwich Area. This program is critical to Greenwich Hospital patients and the time has come for it to be approved.

Respectfully Submitted,

GREENWICH HOSPITAL
YALE-NEW HAVEN HOSPITAL

By: _____

JENNIFER L. GROVES, ESQ.
Updike, Kelly & Spellacy, P.C.
265 Church Street
One Century Tower
New Haven, CT 06510
Tel: (203) 786-8300
Fax (203) 772-2037

CERTIFICATION

I hereby certify that a copy of the foregoing has been sent via first class mail, postage prepaid, this 11th of January, 2013 to the following:

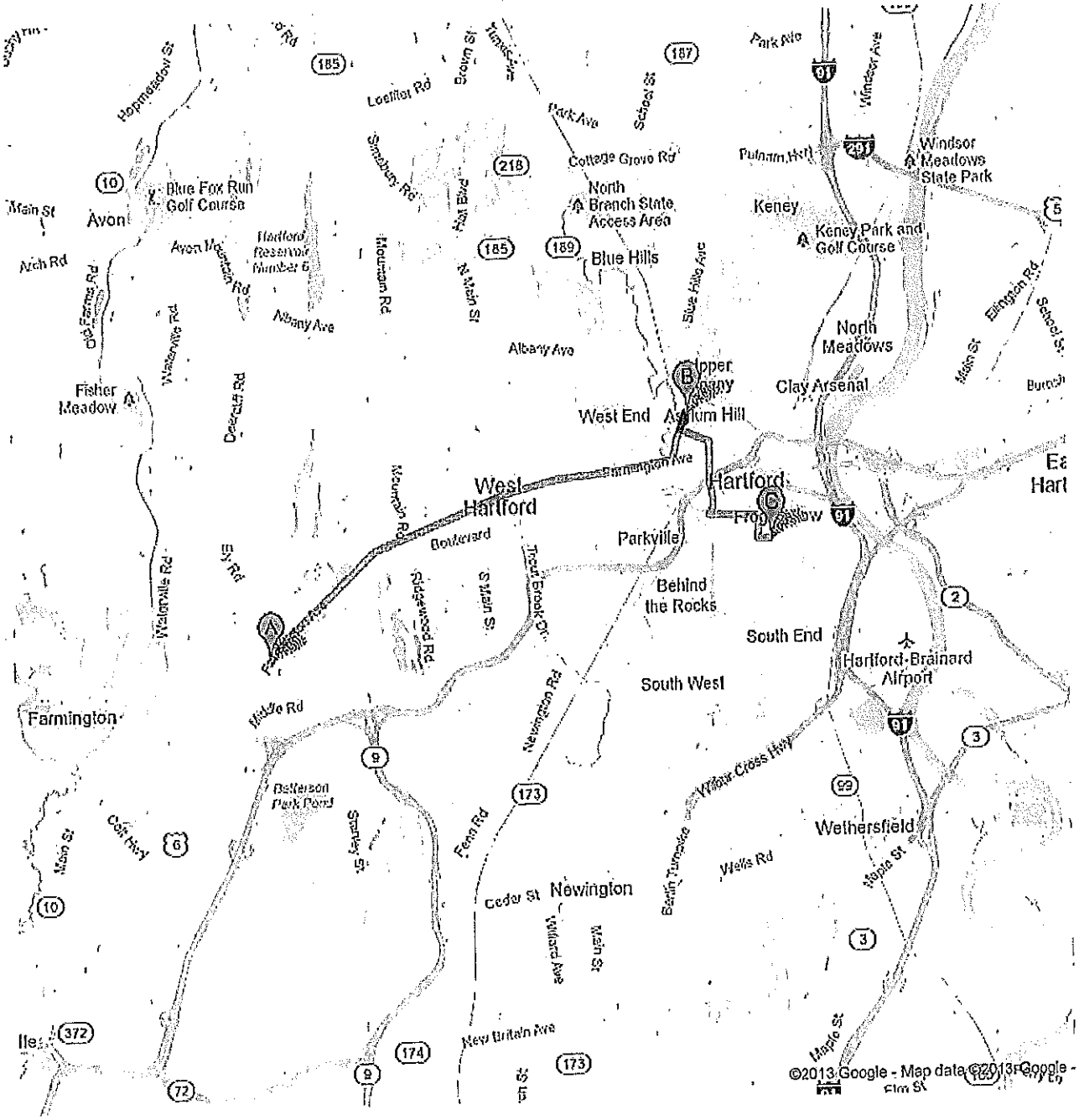
Stephen M. Cowherd
Jeffers Cowherd
5 Walls Drive
Fairfield, CT 06824

Jennifer L. Groves, Esq.
Updike, Kelly & Spellacy, P.C.

EXHIBIT A

Google

Directions to Hartford Hospital
80 Seymour Street, Hartford, Connecticut 06102
8.4 mi – about **23 mins**



John Dempsey Hospital
263 Farmington Avenue, Farmington, CT 06032

	1. Head **northeast** on **CT-4 E/Farmington Ave** toward **Main Rd** Continue to follow Farmington Ave About 13 mins	go 5.4 mi total 5.4 mi
↰	2. Turn left onto **Woodland St** About 2 mins	go 0.6 mi total 6.0 mi
		Total: **6.0 mi** – about **15 mins**

Saint Francis Behavioral Health
114 Woodland St, Hartford, CT 06105

total 0.0 mi

	3. Head **south** on **Woodland St** toward **Collins St**	go 0.2 mi total 0.2 mi
↰	4. Take the 2nd left onto **Asylum Ave** About 1 min	go 0.4 mi total 0.6 mi
↱	5. Turn right onto **Sigourney St** About 2 mins	go 0.7 mi total 1.3 mi
	6. Continue onto **Park Terrace**	go 0.2 mi total 1.4 mi
↰	7. Turn left onto **Park St** About 2 mins	go 0.6 mi total 2.0 mi
↱	8. Turn right onto **Washington St** About 58 secs	go 0.3 mi total 2.3 mi
↰	9. Turn left onto **Zwieback St** Destination will be on the left	go 0.1 mi total 2.4 mi
		Total: **2.4 mi** – about **8 mins**

Hartford Hospital
80 Seymour Street, Hartford, Connecticut 06102

These directions are for planning purposes only. You may find that construction projects, traffic, weather, or other events may cause conditions to differ from the map results, and you should plan your route accordingly. You must obey all signs or notices regarding your route.

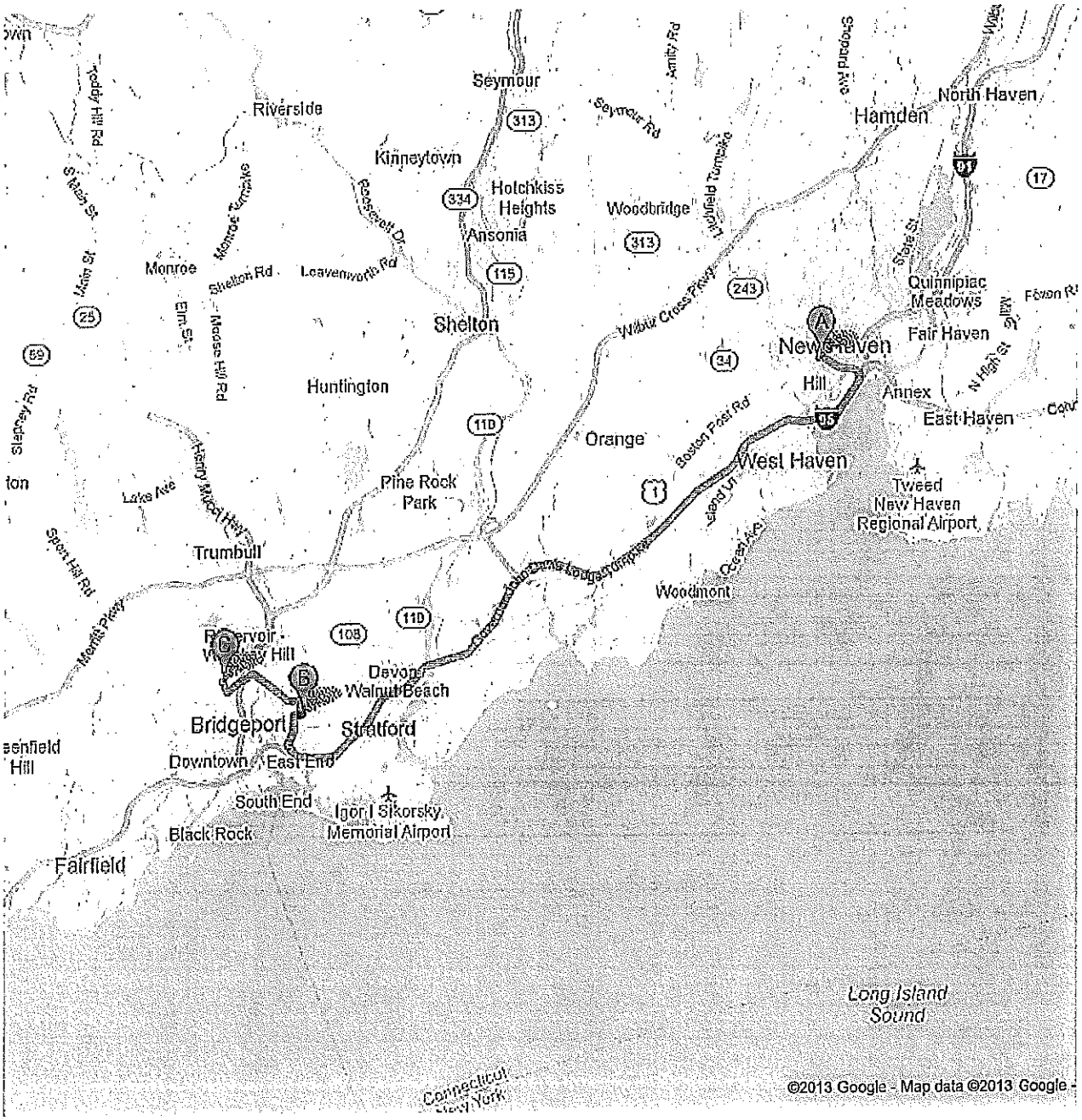
Map data ©2013 Google

Directions weren't right? Please find your route on maps.google.com and click "Report a problem" at the bottom left.

EXHIBIT B

Google

Directions to St. Vincent's Medical Center
2800 Main St, Bridgeport, CT 06606
22.1 mi – about **35 mins**



Yale-New Haven Hospital
20 York Street, New Haven, CT 06510

	1. Head **northeast** toward **York St**	go 148 ft total 148 ft
	2. Turn left onto **York St**	go 249 ft total 397 ft
	3. Take the 1st right onto **S Frontage Rd**	go 341 ft total 0.1 mi
	4. Slight left onto **Oak St Connector** About 1 min	go 0.7 mi total 0.9 mi
	5. Keep right at the fork, follow signs for **Interstate 95 S/N.Y. City** and merge onto **I-95 S** About 18 mins	go 17.2 mi total 18.1 mi
	6. Take exit **29** for **Seaview Avenue** toward **Connecticut 130/Stratford Avenue**	go 0.3 mi total 18.4 mi
	7. Turn right onto **Seaview Ave** About 2 mins	go 0.7 mi total 19.1 mi
	8. Turn right onto **Grant St** Destination will be on the left About 1 min	go 0.2 mi total 19.3 mi
		Total: **19.3 mi** – about **24 mins**

Bridgeport Hospital
267 Grant Street, Bridgeport, CT 06610

total 0.0 mi

	9. Head **west** on **Grant St** toward **Central Ave**	go 266 ft total 266 ft
	10. Turn right onto **Central Ave** About 2 mins	go 0.3 mi total 0.4 mi
	11. Turn left onto **Boston Ave** About 4 mins	go 1.3 mi total 1.7 mi
	12. Turn left onto **North Ave** About 2 mins	go 0.2 mi total 1.9 mi
	13. Turn right onto **Capitol Ave** About 2 mins	go 0.5 mi total 2.5 mi
	14. Turn right onto **Main St** Destination will be on the right About 1 min	go 0.3 mi total 2.8 mi
		Total: **2.8 mi** – about **11 mins**

St. Vincent's Medical Center
2800 Main St, Bridgeport, CT 06606

These directions are for planning purposes only. You may find that construction projects, traffic, weather, or other events may cause conditions to differ from the map results, and you should plan your route accordingly. You must obey all signs or notices regarding your route.

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EXHIBIT C

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

TESTIMONY PRESENTED BEFORE THE COMMITTEE ON PUBLIC HEALTH
March 7, 2012

Kimberly Martone, Director of Operations, Office of Health Care Access, 860-418-7029

House Bill – Bill 5321 - An Act Concerning the Office of Health Care Access and the Certificate of Need Process

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The Department of Public Health would like to provide the following information in favor of House Bill 5321. We thank the Committee for choosing to take up the Department's proposal. Below is information on the provisions contained in the bill.

Section 1

The Department's Office of Health Care Access (OHCA) is proposing to replace the phrase "how the proposal will impact the financial strength of the health care system in the state" within §19a-639(a)(4) of the General Statutes with "that the proposal is financially feasible for the applicant." In evaluating Certificate of Need (CON) applications, OHCA can verify and measure the effect a CON proposal has on the applicant by reviewing the financial status of the applicant; however, OHCA does not have the data to properly evaluate the financial impact of the CON proposal on the state's health care system. Moreover, CON applicants struggle to produce evidence demonstrating the impact of the proposal on the state's health care system. It is also worth noting that the majority of the CON proposals received and reviewed by OHCA over the past year involve the acquisition of imaging equipment, the establishment of substance abuse/mental health services, and transfer of ownership of a health care facility. Such proposals do not lend themselves to an easy demonstration of their impact on the financial strength of the health care system statewide.

Prior to the changes implemented under Public Act 10-179, OHCA evaluated the financial feasibility of the proposal rather than looking at the impact on the entire state. This financial feasibility evaluation is a more realistic guideline and most applicants are able to produce financial documents and analysis demonstrating that a particular proposal is financially feasible.

Section 2

OHCA proposes to amend the proposed language in this section by deleting "after the date the office closes the public hearing" in line 49 and substituting "following the close of the hearing record." This is to clarify the closing of the hearing record as opposed to the actual public hearing. At the public hearing, OHCA often orders additional evidence be provided after the public hearing has ended. Once the information is received by OHCA, it then *closes* the hearing record through a letter. Therefore, the proposed language clarifies when the hearing record is legally closed as well as the day on which the 60 day review period for OHCA to render a decision begins.

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EXHIBIT B

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Office of Health Care Access

February 4, 2013

IN THE MATTER OF:

An Application for a Certificate of Need filed Pursuant to Section 19a-638, C.G.S. by:	Notice of Agreed Settlement Office of Health Care Access Docket Number: 12-31768-CON

Lawrence & Memorial Hospital

To:

Ms. Shraddha Patel
Director of Business Development & Planning
Lawrence & Memorial Hospital
365 Montauk Avenue
New London, CT 06320

Dear Ms. Patel:

This letter will serve as notice of the approved Certificate of Need Application in the above-referenced matter. On February 4, 2013, the Agreed Settlement, attached hereto, was adopted and issued as an Order by the Department of Health, Office of Health Care Access.

Kimberly R. Martone
Director of Operations

Enclosure
KRM:amv

Office of Health Care Access

Certificate of Need Application

Agreed Settlement

Applicant:	**Lawrence & Memorial Hospital** **365 Montauk Avenue, New London, CT 06320**
Docket Number:	**12-31768-CON**
Project Title:	**Establish and Operate an Elective Angioplasty Program at Lawrence & Memorial Hospital**

Project Description: Lawrence & Memorial Hospital proposes to establish and operate an elective angioplasty program without onsite surgical backup at Lawrence & Memorial Hospital, with no associated capital expenditure.

Nature of Proceedings: On August 31, 2012, the Office of Health Care Access ("OHCA") received a completed Certificate of Need ("CON") application from Lawrence & Memorial Hospital to establish an elective angioplasty program without onsite backup at Lawrence & Memorial Hospital, with no associated capital expenditure. Lawrence & Memorial Hospital published notice of its intent to file the CON Application in *The Day,* on April 30, May 1 and 2, 2012. A public hearing regarding the CON application was held on December 13, 2012. On December 4, 2012, the Applicants were notified of the date, time and place of the hearing. On November 26, 2012, a notice to the public announcing the hearing was published in *The Day*.

Attorney Kevin Hansted was the designated hearing officer in this matter. The hearing was conducted as a contested case in accordance with the provisions of the Uniform Administrative Procedure Act (Chapter 54 of the General Statutes) and Conn. Gen. Stat. § 19a-639a. OHCA's authority to review and approve, modify or deny this proposal is established by Conn. Gen. Stat. § 19a-638. These provisions, as well as the principles and guidelines set forth in Conn. Gen. Stat. § 19a-639, were fully considered by OHCA in its review.

Findings of Fact

1. Lawrence & Memorial Hospital is a not-for-profit 280-bed acute care hospital located at 365 Montauk Avenue in New London, Connecticut and a health care facility or institution as defined by Conn. Gen. Stat. §19a-630. Ex. A. 9

2. Lawrence & Memorial Hospital proposes establishing and operating an elective angioplasty[1] program without onsite backup.

3. The proposed elective PCI program will be supported by a collaborative relationship with Yale-New Haven Hospital and Yale School of Medicine. Ex. A, p. 9.

4. Yale-New Haven Hospital is a not-for-profit, 944-bed acute care hospital located in New Haven, Connecticut. Yale-New Haven Hospital is a full service (i.e., cardiac catheterization[2], angioplasty and open-heart surgery) cardiac provider.

5. The proposed elective PCI program would build upon Lawrence & Memorial's primary[3] PCI program (approved by OHCA in Docket Number: 04-30297-CON) and would employ the same cardiac interventionalists, equipment, staff and facilities. Ex. A, p. 9.

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[1]Elective (Scheduled) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure performed in a catheterization laboratory whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a previously diagnosed blockage in the heart. An expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow.
Source: DPH/OHCA Statewide Facility and Services Plan Chapter 3.

[2] Cardiac catheterization is defined as a medical procedure requiring the passage of a catheter into one or more cardiac chambers of the left and right heart, with or without coronary arteriograms, for the purpose of diagnosing congenital or acquired cardiovascular disease, or for determining measurement of blood pressure flow.
Source: DPH/OHCA Statewide Facility and Services Plan Chapter 3

[3] Primary (emergent) Percutaneous Coronary Intervention (PCI) or Coronary Angioplasty (PCA) is an interventional procedure whereby a catheter, usually inserted into an artery in the groin, is threaded through the circulatory system to a previously diagnosed blockage in the heart. An expandable balloon is passed to this spot and inflated several times, thereby flattening the blockage-causing plaque, potentially widening the artery, and thus improving blood flow.
Source: DPH/OHCA Statewide Facility and Services Plan Charter 3.

6. Lawrence & Memorial Hospital has submitted the following agreements, policies and protocols:
   - Patient selection guidelines policies (*Attachment F*)
   - Policies and Procedures for PCI Procedure (*Attachment F*)
   - Joint quality assurance reviews process and training between Lawrence & Memorial Hospital and Yale-New Haven Hospital (*Attachment I*)
   - Transfer Protocol and Agreement between Lawrence & Memorial Hospital and Yale-New Haven Hospital (*Attachment I*)
   - Yale-New Haven Hospital Department of Surgery surgical backup policy for the Lawrence & Memorial Hospital elective PCI program (*Attachment I*)

   Ex. A. p. 37-38

7. Lawrence & Memorial Hospital has a primary tertiary cardiac referral relationship with Yale-New Haven Hospital whereby Yale-New Haven Hospital provides surgical backup to Lawrence & Memorial Hospital. Since the establishment of the primary PCI program in 2009, 98% or 545 out of 555 transfers from Lawrence & Memorial Hospital to other acute care hospitals for advanced cardiac services were to Yale-New Haven Hospital. Ex. A. p. 23

8. The proposed elective PCI program will be developed and managed by Lawrence & Memorial Hospital in collaboration with Lawrence & Memorial Hospital Physician Association, Inc. in order to achieve clinical quality and outcomes that meet or exceed national standards. Ex. A. (*Attachment I*) p. 425

9. The proposed elective PCI service will be performed in Lawrence & Memorial Hospital's two existing and fully functioning diagnostic cardiac catheterization laboratories by interventional cardiologists on staff at Lawrence & Memorial Hospital and Yale-New Haven Hospital/Yale School of Medicine. Ex. A. pp. 26, 531

10. The proposed elective PCI program will augment existing primary PCI services as well as inpatient and outpatient cardiac services at Lawrence & Memorial Hospital which include:
    - Coronary Care and Telemetry Unit (25 beds)
    - Coronary Intensive Care Unit (10 beds)
    - Diagnostic cardiac catheterization (2,400 procedures completed between 2009 and 2011)
    - Interventional Radiology Laboratory
    - Pacemaker Insertions and Evaluation
    - Implantable Cardiac Defibrillator (ICD) Insertions and Evaluation
    - Vascular and Thoracic Surgery
    - Cardiac Rehabilitation
    - Cardiac Imaging Services including CT (64-slice scanner) and MRI (3.0 Tesla) scanner
    - Direct audio/video link between Lawrence & Memorial Hospital and Yale-New Haven Hospital
    - Stress testing (Exercise and Echocardiogram)
    - Nuclear stress testing (Stress, Rest, Pharmacological)
    - Echocardiography

- 24- Hour Holter monitoring and 30-Day Event Monitoring
- Tilt table studies
- Echocardiograms
- Outpatient cardiovascular care
- Community education programs

Ex. A. pp. 26-27, 532

11. Lawrence & Memorial Hospital defined the population to be served through this proposal as being represented by the towns that are part of the primary ("PSA") and secondary ("SSA") service area, which comprise 75% of Lawrence & Memorial Hospital's inpatient volume ("Proposed Service Area"):

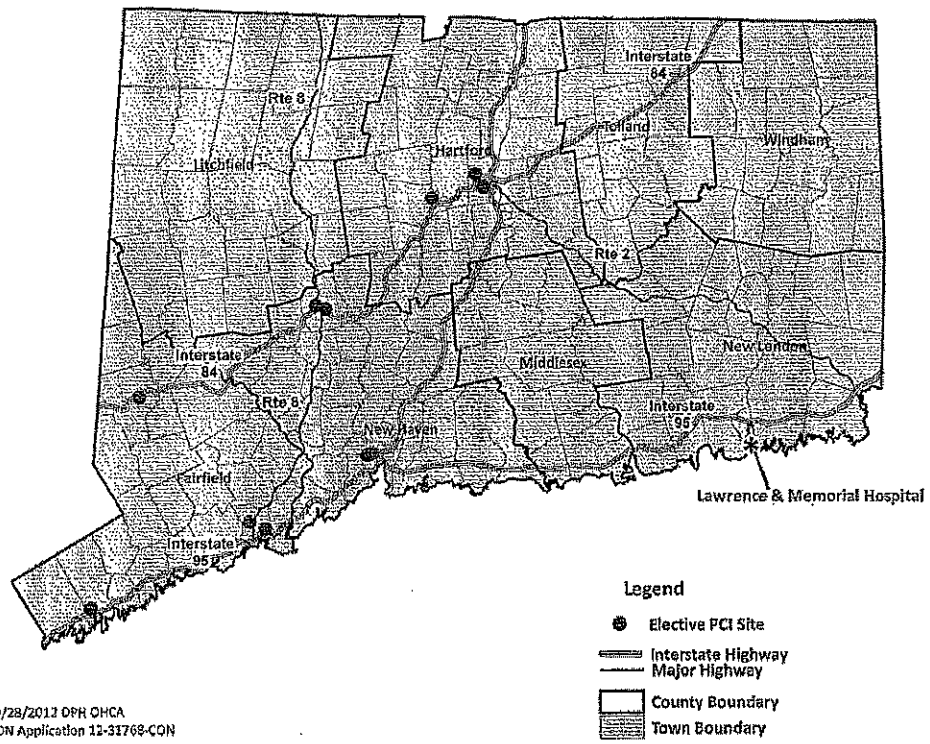
Table 1: Primary and secondary service area

PSA	SSA
East Lyme	Bozrah
Groton	Colchester
Ledyard	Franklin
Lyme	Griswold
Montville	Lisbon
New London	Old Saybrook
Old Lyme	Preston
Stonington	Norwich
North Stonington	Salem
Waterford	Voluntown
	Westerly (RI)

Ex. A. p. 27

12. The map below shows New London County's geographical isolation from facilities that perform elective PCI procedures for patients residing in southeastern Connecticut.

Sites that Offer Elective Percutaneous Coronary Intervention (PCI) in Connecticut



13. Travel distances from Lawrence & Memorial Hospital to the nearest existing full-service cardiac providers are as follows:

Table 2: Mileage from Town of New London to closest facilities

Hospital	City, State	Miles from Town of New London
YNHH	New Haven, CT	49
St. Francis Hospital	Hartford, CT	48
Hartford Hospital	Hartford, CT	49
Miriam Hospital	Providence, RI	61

Ex. A. p. 20

14. A study by the Robert Wood Johnson Foundation in 2012 evaluating the health of Connecticut communities indicated that New London County had higher than state and national rates of adult smoking and obesity and also exceeded state and national benchmarks with respect to the ratio of the population to primary care physicians and preventable hospitalizations. Below are the key statistics from the study that relate to cardiac health.

Table 3: Key statistics

	New London County	Connecticut	United States Benchmark
Health Behaviors			
Adult Smoking	19%	16%	14%
Adult Obesity	24%	23%	21%
Clinical Care			
Primary Care Physicians	1,098:1	729:01:00	631:01:00
Preventable Hospital Stays	70	63	49

Source: Robert Wood Johnson Foundation, County Health Rankings & Roadmaps (http://www.countyhealthrankings.org/#app/).
Ex. A. pp. 538-539

15. Lawrence & Memorial Hospital presented heart disease death rate and hospitalization data provided by the Centers for Disease Control and Prevention. According to these data, New London County has high heart disease death and hospitalization rates. Coupled with the lack of elective PCI services in Lawrence & Memorial's service area and New London County, these data further demonstrate the area's need for elective PCI. Ex. A. pp. 30-31, 539

16. Age is another key risk factor for coronary heart disease. Lawrence & Memorial Hospital states that cardiovascular disease is the leading cause of death in the state for residents aged 85+ and the second leading cause of death for residents ages 65-84. Data presented by Lawrence & Memorial Hospital shows that the overall population within Lawrence & Memorial Hospital's proposed service area is expected to increase by 1.6% in 2015. However, the rate of growth in the age groups (65-74) and (85+) is expected to increase by 18.4% and 14.3%, respectively, in 2015. The table below represents the demographic characteristics within Lawrence & Memorial Hospital's Proposed Service Area.

Table 4: Total Service Area Population Statistics

Age Cohort	2010	2015	% Change
0-44	170,507	165,257	-3.10%
45-54	45,925	45,447	-1%
55-64	33,181	39,230	18.20%
65-74	20,345	24,084	18.40%
75-84	14,473	14,225	-1.70%
85+	6,637	7,587	14.30%
Total	**293,078**	**297,845**	**1.60%**

Ex. A. p. 31-32

17. The physicians who will participate in the proposed elective PCI program currently perform PCI procedures at both Lawrence & Memorial Hospital and Yale-New Haven Hospital and provide on-call coverage for Lawrence & Memorial Hospital's existing primary PCI program. Ex. A. p. 524

18. Lawrence & Memorial Hospital does not anticipate an expansion in the physician referral base either geographically or in terms of quantity of physicians in the service area. Lawrence & Memorial Hospital's volume projections in the initial CON filing were not based on assumptions regarding new physicians in the market or an expansion of Lawrence & Memorial Hospital's geographic reach beyond the existing service area. Rather, Lawrence & Memorial Hospital's volume projections were based on actual data of transfers from Lawrence & Memorial Hospital's catheterization lab to Yale-New Haven Hospital for elective PCI and, in the future, the retention of select patients (i.e., non-high risk patients) that could remain at Lawrence & Memorial Hospital for their elective PCI procedure. Ex. A. p. 524

19. Lawrence & Memorial Hospital's historical volume of diagnostic cardiac catheterizations and volume transferred same day for elective PCI since 2009 is as follows:

Table 5: Lawrence & Memorial Hospital Diagnostic Catheterization Volume and Volume Transferred Same Day for Elective PCI

Fiscal Year	Total Diagnostic Caths	Total Patients Transferred for Elective PCI	Location of Transfer		
			YNHH	St. Francis	Hartford Hospital
2009	810	168	161	7	0
2010	858	200	198	2	0
2011	724	138	137	1	0
2012*	266	49	49	0	0

*Note: Represents actual volumes for FY 2012 (10/1/11 through 03/01/12) Ex. A. p.23

20. Lawrence & Memorial Hospital's historical volume for primary or emergent PCI is shown in the following table:

Table 6: Total Primary PCI Cases at Lawrence & Memorial Hospital

Program	FY 2009	FY 2010	FY 2011	Actual FY 2012*	Annualized FY 2012
Primary PCI	78	81	74	44	88

*Note: Represents actual volumes for FY 2012 (10/1/11 through 03/01/12)
Ex. A. p. 40

21. Projected volume for elective PCI at Lawrence & Memorial Hospital is shown in the table below:

Table 7: Total projected PCI cases at Lawrence & Memorial Hospital

Program	FY 2013	FY 2014	FY 2015
Primary PCI	89	89	89
Elective PCI	73	130	135
Total	162	219	224

Ex. A. p. 40

22. The 2011 ACCF/AHA/SCAI[4] Guidelines for PCI recommend criteria and standards for the performance of angioplasty at hospitals without on-site cardiac surgery. All of these criteria and standards will be utilized by Lawrence & Memorial Hospital. Ex. A. pp. 12-13

23. The CPORT-E[5] (Cardiovascular Patient Outcomes Research Team Elective) study indicates that programs with case totals over 200 have sufficient volume to sustain a quality and safe emergent and elective PCI program. Lawrence & Memorial Hospital is projected to exceed 200 total cases in Year 2 of operation. Ex. A. pp. 40, 44

24. The following data from OHCA's Acute Care Hospital Inpatient Discharge Database ("HIDD") represents OHCA's market share analysis of the Lawrence & Memorial service area for fiscal year 2011.

[4] The American College of Cardiology Foundation (ACCCF) / The American Heart Association Task Force on Practice Guidelines (AHA) / The Society for Cardiovascular Angiography and Intervention (SCAI)

[5] CPORT-E is a randomized trial, concluded on March 31, 2011, comparing medical, economic and quality of life outcomes of non-primary PCI at hospitals with and without on- site cardiac surgery. Source: http://my.americanheart.org/idc/groups/ahamah-public/@wcm/@sop/@scon/documents/downloadable/ucm_433712.pdf

Table 8: Service Area Discharge Data & Market Share

	FY 11			
Town	Total Town Discharges	Total Lawrence & Memorial Discharges	% of Hospital Discharges	Share of Town
Primary Service Area				
New London	4,040	3,390	22%	84%
Groton	5,341	4,266	28%	80%
Waterford	2,665	2,047	13%	77%
East Lyme	1,845	1,332	9%	72%
Stonington	722	475	3%	66%
Ledyard	1,470	835	5%	57%
Montville	2,345	863	6%	37%
Old Lyme and Lyme	912	251	2%	28%
Secondary Service Area				
Norwich	5,667	464	3%	8%

Source: OHCA's Acute Care Hospital Inpatient Discharge Database ("HIDD")

25. Per 2011 ACCF/AHA/SCAI guidelines and recommendations, Lawrence & Memorial Hospital participates in the ACC-NCDR PCI registry for quality assurance and benchmarking for its emergent PCI program. Lawrence & Memorial Hospital will continue to submit data to the ACC registry in order to ensure quality outcomes for its proposed elective PCI program. Ex. A. p. 49

26. Yale-New Haven Hospital, a full cardiac service provider, will be the receiving facility for patients from Lawrence & Memorial Hospital that require surgical intervention. Ex. A. p. 522

27. Lawrence & Memorial Hospital states that since the inception of Lawrence & Memorial Hospital's primary PCI program in 2005 there have been 13 total mortalities including patients who expired due to non-cardiac deaths (e.g., pre-existing conditions such as infections, neurological conditions, etc.). The 13 total deaths translate into a 4.1% mortality rate. This outcome is favorable compared to data from the 2011 ACCF/AHA/SCAI guidelines indicating a national in-hospital mortality rate of 4.81% in ST-segment elevation myocardial infarction (STEMI) patients that required primary PCI intervention. Ex. A. p. 47.

28. Lawrence & Memorial Hospital's proposed elective PCI program would utilize the same Yale-New Haven Hospital/Yale School of Medicine interventionalists and same clinical staff (catheterization laboratory technicians, nurses, etc.) that currently support the emergent PCI program. Lawrence & Memorial Hospital's Medical Director of its Primary Angioplasty Program and of the proposed elective program is five years post-fellowship training and has performed over 500 PCI procedures. Ex. A. p. 527

29. Lawrence & Memorial Hospital has asserted that elective PCI at Lawrence & Memorial Hospital would increase quality of care as patients who are currently transferred from Lawrence & Memorial Hospital to another facility for elective PCI are at enhanced risk of infections, bleeding complications, and other adverse events associated with multiple procedures at two facilities. Ex. A. p. 527

30. Eliminating transfers for elective PCI would reduce costs to the health care system from duplicate testing and redundant costs for dyes, catheters, surgical trays, and other supplies. Ex. A. p. 527

31. The November 2011 ACCF/AHA/SCAI Practice Guidelines note a location for elective PCI without on-site surgery is the one that "will clearly fill a void in the healthcare needs of the community" and "the cardiology community [should] foster "the [elective PCI without on-site surgery] programs…when such programs improve access to a higher level of cardiovascular care than would otherwise be available." Ex. A. Attachment B/ *2011 ACCF/AHA/SCAI Clinical Practice Guidelines*

32. Lawrence & Memorial Hospital has stated that it will adhere to strict patient selection criteria recommended by ACCF/AHA/SCAI in determining which patients are eligible to receive elective PCI at Lawrence & Memorial Hospital. According to SCAI, non-high risk patients are the best candidates for elective PCI without on-site cardiac surgery and, therefore, Lawrence & Memorial Hospital will only perform procedures on these patient types. Ex. A. pp. 36, 526

33. Lawrence & Memorial Hospital currently finances its primary PCI program through an annual fee of $1.45 million paid to Yale-New Haven Hospital. Adding elective PCI would reduce the cost per case while utilizing the same Yale-New Haven Hospital physicians to perform both elective and primary cases. Ex. A. pp. 53, 524

34. This proposal will not incur any additional capital or overhead costs thereby improving the cost effectiveness of the PCI service. Ex. A. p. 52

35. Lawrence & Memorial Hospital's current and three year projected payer mix is below.

Table 9: Patient Population Mix

	Current** FY 2012	Year 1 FY 2013	Year 2 FY 2014	Year 3 FY 2015
Medicare*	46.90%	46.90%	46.90%	46.90%
Medicaid*	10.00%	10.00%	10.00%	10.00%
CHAMPUS & TriCare	0.00%	0.00%	0.00%	0.00%
Total Government	**56.90%**	**56.90%**	**56.90%**	**56.90%**
Commercial Insurers*	41.90%	41.90%	41.90%	41.90%
Uninsured	1.30%	1.30%	1.30%	1.30%
Workers Compensation	0.00%	0.00%	0.00%	0.00%
Total Non-Government	**43.10%**	**43.10%**	**43.10%**	**43.10%**
Total Payer Mix	**100.00%**	**100.00%**	**100.00%**	**100.00%**

Ex. A. p. 51

36. OHCA is currently in the process of establishing its policies and procedures as regulations. Therefore, OHCA has not made any findings as to this proposal's relationship to any regulations adopted by OHCA. (Conn. Gen. Stat. § 19a-639(a)(1))

37. This CON application was deemed complete by OHCA prior to the state-wide health care facilities and services plan being published. Therefore, OHCA has not made any findings as to the relationship between this CON application and the state-wide health care facilities and services plan. (Conn. Gen. Stat.§ 19a-639(a)(2))

38. Lawrence & Memorial Hospital has satisfactorily demonstrated that there is a clear public need for its proposal. (Conn. Gen. Stat. § 19a-639(a)(3))

39. Lawrence & Memorial Hospital has satisfactorily demonstrated that its proposal is financially feasible. (Conn. Gen. Stat. § 19a-639(a)(4))

40. Lawrence & Memorial Hospital has satisfactory demonstrated that its proposal would improve quality, accessibility and cost effectiveness of health care delivery in the region. (Conn. Gen. Stat. § 19a-639(a)(5))

41. Lawrence & Memorial Hospital has shown that there would be improvements to the provision of health care services to the relevant populations and payer mix. (Conn. Gen. Stat. § 19a-639(a)(6))

42. Lawrence & Memorial Hospital has satisfactorily identified the population to be served by their proposal and satisfactorily demonstrated that said population has a need as proposed. (Conn. Gen. Stat. § 19a-639(a)(7))

43. There are no existing elective PCI programs in Lawrence & Memorial Hospital's service area. Therefore, OHCA has not made any findings as to the utilization of existing elective PCI programs in the service area. (Conn. Gen. Stat. § 19a-639(a)(8))

44. Lawrence & Memorial Hospital has satisfactorily demonstrated that the proposal would not result in an unnecessary duplication of existing or approved elective PCI services. (Conn. Gen. Stat. § 19a-639(a)(9))

Discussion

CON applications are decided on a case by case basis and do not lend themselves to general applicability due to the uniqueness of the facts in each case. In rendering its decision, OHCA considers the factors set forth in Conn. Gen. Stat. § 19a-639(a). The Applicant bears the burden of proof in this matter by a preponderance of the evidence. *Goldstar Medical Services, Inc., et al. v. Department of Social Services,* 288 Conn. 790 (2008).

Lawrence & Memorial Hospital is a not-for-profit 280-bed acute care hospital located in New London, Connecticut and a health care facility or institution as defined by Conn. Gen. Stat. § 19a-630. Lawrence & Memorial Hospital proposes to establish and operate an elective PCI program without onsite cardiac surgical backup. *FF.1-2.*

November 2011 ACC/AHA/SCAI PCI practice guidelines state that "it is only appropriate to consider initiation of a PCI program without on-site cardiac surgical backup if this program will clearly fill a void in the healthcare needs of the community." *FF 32.* The guidelines note that competition with another PCI program in the same geographic area, particularly an established program with surgical backup, may not be in the best interests of the community." Lawrence & Memorial Hospital, located in New London County, is geographically isolated in terms of elective PCI accessibility, as there are no facilities that perform elective PCI procedures in Lawrence & Memorial Hospital's service area or within southeastern Connecticut. *FF. 12.* Specifically, the closest facility offering full cardiac services in Connecticut is 48 miles away from New London. *FF.13.* Thus, the proposed elective PCI program will not duplicate or overlap any of the existing programs in the state.

In addition to geographic isolation, there are several New London County and/or Lawrence & Memorial Hospital service area population characteristics which indicate that such a program would be beneficial to residents. First, New London County residents have high heart disease death and hospitalization rates. *FF 15.* Second, age is a key risk factor for heart disease, and the 2015 rate of growth expected for Lawrence & Memorial Hospital service area's aging population is significantly higher than for the area as a whole. *FF16.* Third, New London County residents' smoking, obesity, and preventable hospitalization rates exceed both state and national health rates, according to a 2012 Robert Wood Johnson Foundation study. *FF14.* Furthermore, the ratio of the population to primary care physicians in New London County is high. A high ratio implies reduced ability to meet demand for primary care services, which may negatively affect the health of a community, as treatment for needed services may be delayed or not sought at all. Residents with cardiovascular disease or coronary heart disease may remain undiagnosed without an adequate base of primary care to order diagnostics or refer patients to cardiologists. *FF.14.*

The proposed program would build upon Lawrence & Memorial Hospital's primary PCI program and would utilize the same experienced cardiac interventionalists, equipment, clinical staff and facilities. *FF.5.* The elective PCI program will be supported by a collaborative relationship with Yale-New Haven Hospital, which is the Lawrence & Memorial Hospital's primary tertiary cardiac referral site. *FF.3.* Since the establishment of its primary PCI program in 2009, 98% of transfers from Lawrence & Memorial Hospital to other acute care hospitals for advanced cardiac services were to YNHH. *FF7.* Lawrence & Memorial Hospital's projected

volume is reasonable to sustain a quality and safe elective PCI program which is needed for patients residing in southeastern Connecticut. The above facts, coupled with the observation that Lawrence & Memorial Hospital's mortality rate compares favorably to the mortality rate published in the 2011 ACCF/AHA/SCAI guidelines, further support the establishment of an elective PCI program by Lawrence & Memorial Hospital. *FF28.*

This proposal is cost effective, as it will not incur any capital or overhead costs because it will build upon Lawrence & Memorial Hospital's existing primary PCI program as it will utilize the same cardiac interventionalists, equipment, staff and facilities. *FF.34-35.*

Based on foregoing, OHCA has determined that approval of the proposed elective PCI program will improve the accessibility and quality of care for patients residing in southeastern Connecticut. Lawrence & Memorial Hospital's proposal will bring appropriate access to needed elective PCI services within a reasonable travel time and improve the quality of cardiac services in a region that fares worse than the state as a whole in terms of health outcomes, health factors and limited access to primary care.

There is a substantial question as to L&M's emergency transfer protocol's compliance with the Memorandum of Decision for Declaratory Ruling Proceeding Concerning the Provision of Emergency Medical Services (February 14, 2003). Therefore, OHCA is not making any determination as to L&M's emergency transfer protocol in terms of compliance with existing state and federal laws. OHCA is referring the protocol to the Office of Emergency Medical Services for its review and consideration.

ORDER

NOW, THEREFORE, the Department of Public Health, Office of Health Care Access, and Lawrence & Memorial Hospital hereby stipulate and agree to the terms of settlement with respect to establishment an elective angioplasty program without onsite surgical backup at Lawrence & Memorial Hospital, as follows:

Lawrence & Memorial Hospital is required to fulfill the following conditions for the first seven (7) years from commencement of the Elective Angioplasty program. At the end of the 7 year period, the Office of Health Care Access reserves the right to continue requiring any of the listed conditions if Lawrence & Memorial Hospital is not performing total PCI procedures above the minimum recommended volumes prescribed by the America College of Cardiology/American Heart Association at that time.

1. Lawrence & Memorial Hospital shall submit on a quarterly basis to OHCA the following reports which must be submitted within thirty (30) calendar days of the end of each quarter:
   a. Elective and Emergency PCI performed each quarter by town of patient origin, in a format to be specified.
   b. Elective and Emergency PCI performed each quarter, broken out by inpatient and outpatient, in a format to be specified.
   c. The number of patients transferred to another hospital for cardiac treatment as a direct result of Emergency and/or Elective PCI at Lawrence & Memorial Hospital. Details to include:
      i. The cause/reason for transfer;
      ii. The name of the facility to which the patient was transferred; and
      iii. The actual time-line beginning with the reason for transfer, including the transportation time and the actual procedure administered at the facility to which the patient was transferred.

2. Reports a through c above shall not include patient identifiable data.

3. Based on OHCA's review of this quarterly data, the Office may request a meeting with Lawrence & Memorial Hospital to discuss the data submitted.

4. If Lawrence & Memorial Hospital does not perform the minimum number of elective PCIs within twelve months of the initiation of the elective PCI program, as recommended by America College of Cardiology/American Heart Association, Lawrence &Memorial Hospital shall submit monthly reports of the number of elective PCIs arrayed by physician to OHCA until such time as these volumes are met by Lawrence & Memorial Hospital or until it meets with OHCA to discuss a plan that will adhere to the quality standards recommended by the American College of Cardiology/American Heart Association.

5. Lawrence & Memorial Hospital shall participate in the ACC National Cardiovascular Database Registry (ACC-NCDR) and report all data including the optional follow-up section. Lawrence and Memorial Hospital shall provide OHCA quarterly data reports from ACC-NCDR. Data must be reported to OHCA thirty (30) calendar days subsequent to Lawrence & Memorial Hospital receiving the reports from ACC. Lawrence & Memorial Hospital is required to comply with the ACC/AHA criteria and standards. If Lawrence and Memorial Hospital determines not to participate in the ACC-NCDR, Lawrence & Memorial Hospital shall notify OHCA immediately, and continue to comply with the ACC/AHA criteria and standards. This condition supersedes Condition 3 of Docket Number 04-30297-CON, as modified by Docket Numbers 06-30297-MDF and 08-30297-MDF

6. The Office of Health Care Access and Lawrence & Memorial Hospital agree that this Agreed Settlement represents a final agreement between the Office of Health Care Access and Lawrence & Memorial Hospital with respect to Docket No. 12-31768-CON. The execution of this Agreed Settlement resolves all objections, claims and disputes, which may have been raised by Lawrence & Memorial Hospital with regard to Docket Number 12-31768-CON.

7. This Agreed Settlement is an order of the Office of Health Care Access with all the rights and obligations attendant thereto, and the Office of Health Care Access may enforce this Agreed Settlement under the provisions of Conn. Gen. Stat. §§ 19a-642 and 19a-653 with all fees and costs of such enforcement being the responsibility of Lawrence & Memorial Hospital.

Signed by CRISTA F. DURAND
(Print name)

VICE PRESIDENT STRATEGIC PLANNING
(Title)

1/31/13
Date

Duly Authorized Agent for
Lawrence & Memorial Hospital

The above Agreed Settlement is hereby accepted and so ordered by the Department of Public Health Office of Health Care Access on February 4, 2013.

Date: 2/4/13

Lisa A. Davis, MBA, BSN, RN
Deputy Commissioner